4.576 The EC member State measures do not meet any of the four criteria set out in Article 5.7. First, the scientific evidence with respect to the products subject to the member State measures is not "insufficient". Scientific evidence is "insufficient," according to the Appellate Body, if it "does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*." Here, the evidence is plainly sufficient to perform a risk assessment, because the European Communities itself has conducted positive risk assessments for each product subject to a member State measure.

4.577 Second, the member State bans were not adopted on the basis of "available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members." As the United States noted in its First Written Submission, the relevant Scientific Committee in the European Communities reviewed each of the member State bans and concluded in each case that the information provided by the member State did not warrant any change in the Scientific Committee's earlier favourable risk assessment. Thus, the European Communities' own scientific committees have confirmed that the member State measures are not based on "available pertinent information."

4.578 Third, the member States have not sought "to obtain the additional information necessary for a more objective assessment of risk." In fact, there is no information in the record that the member States have sought to perform any risk assessments that would support their bans. To the contrary, as noted above, the European Communities' additional CD of documents contains no new information that could constitute an assessment of the risks by the member States.

4.579 Fourth and finally, neither the member States nor the European Commission has reviewed the import and marketing bans within a reasonable period of time. When asked by the Panel whether the member State measures were "reviewed within a reasonable period of time," the European Communities answered, without providing any evidence or elaboration, that the "measures are constantly subject to review." The conclusory statement that a measure is "constantly subject to review" does not come close to meeting the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption.

N. SECOND WRITTEN SUBMISSION OF CANADA

1. Introduction

4.580 In defending its measures in these proceedings, the European Communities has resorted to obfuscation or mischaracterization of the salient facts and scientific evidence, and has presented legal arguments regarding obligations under the WTO Agreements that find little, if any, resonance in either logic, accepted principles of treaty interpretation, textual construction or the relevant jurisprudence. In its Second Written Submission, Canada demonstrates, through reference to the European Communities' own documents, relevant documents from international organizations and case law, that the European Communities' defences to Canada's claims are untenable in fact and in law.

4.581 Canada notes that the European Communities has not yet presented any arguments with respect to the consistency of the moratorium with a number of provisions in the *SPS Agreement*. The European Communities, other than to simply assert that the moratorium does not exist, and never did, has not presented any arguments or evidence to refute Canada's *prima facie* case with respect to violations of Articles 2.2, 2.3, 5.1, 5.5, 5.6, 7, 8, paragraph 1 of Annex B and paragraph 1(a) of Annex C. Similarly, the European Communities has failed to present any arguments to counter

Canada's *prima facie* case that the product-specific marketing bans violate Articles 2.2, 2.3, 5.1, 5.5, 5.6, 8, and paragraph 1(a) of Annex C.

2. The moratorium

4.582 The European Communities' sole defence to Canada's claims regarding the moratorium is the astonishing claim that there is not and never was a moratorium. The European Communities admits that there have been delays in the processing of biotech applications over the last 5 years, but asserts that these delays are not a result of a systemic suspension of approvals for biotech products. The European Communities attempts to rationalize the delays on several grounds, including:

- The need for legislative changes to strengthen inadequate risk assessment and risk management provisions;
- The need for legislative changes necessary to comply with the European Communities' other international obligations, such as those under the Biosafety Protocol;
- The distinction between risk assessment and risk management;
- The existence of scientific uncertainty; and/or
- Requests for more information and objections by regulatory authorities.

4.583 These attempts to rationalize the obvious delays in the approval procedures for biotech products are, in effect, veiled attempts to rationalize the moratorium.

(a) The European Communities' assertion that the moratorium does not exist is without merit

4.584 Given the facts in this case and in the light of some of the European Communities' own assertions or explanations presented in these proceedings, that there has been a moratorium on the approval of biotech products since October 1998 is indisputable. The critical factual issue in this case is not whether there has been a moratorium, but whether the various attempts by the Commission to re-start or "relaunch" the authorization process for biotech products, prior to the establishment of this Panel in August 2003, succeeded. Canada asserts, not only that those attempts did not succeed, but that subsequent efforts to relaunch the approvals process have also been unsuccessful, and that the moratorium remains in place.

4.585 Various EC member States have demanded a succession of new conditions on the marketing of biotech products before they would agree to new authorizations. As a result, the European Communities has failed to process pending applications, decision-making on approvals of pending product applications has come to a stand-still, and, despite attempts by the Commission to break this log-jam, it has failed to convince the member States to restart the approval process.

4.586 The Commission's stated reason for proposing its so-called "interim approach" in July 2000 was precisely because the approval process had stalled. The Commission in its press release at the time indicated that "[t]he objective [of the interim approach] is to resume the authorization process for GMOs in the near future…" However, the "interim approach" failed because it did not have the political support of enough EC member States.

4.587 Then, as the European Communities got closer to enacting and implementing the revised approval legislation, additional conditions for restarting the approval process emerged. Just prior to the adoption of Directive 2001/18, Denmark, France, Greece, Italy, Luxembourg and now Austria reaffirmed their commitment to suspend approvals, essentially claiming that the new procedures were not adequate.

4.588 Despite the reassurances of the Commission, the entry into force of Directive 2001/18 did not result in the lifting of the moratorium. EC member States continued to refuse to lift the moratorium until new legislation regarding traceability and labelling was in place. In the context of specific biotech product applications, some EC member States continued to object to the approval of products that had been positively assessed by the lead competent authority under Directive 2001/18, not on the basis of safety concerns, but on the grounds that approval of GMOs should be suspended pending the adoption of new legislation on traceability and labelling.

4.589 Five EC members States – France, Belgium, Denmark, Greece and Italy – also indicated that they would insist on yet other prerequisites for restarting the approval process: the formulation of a special environmental liability scheme and the adoption of EC-wide legislation to regulate the "co-existence" of genetically modified crops with conventionally bred and organic crops – conditions which are not even relevant for pending approvals for food use or import and processing.

4.590 Given the evidence in this case, the European Communities' assertion that "the approval procedures have never been suspended or stalled" is completely baseless. Despite the Commission's numerous attempts to lift the moratorium, the "goalposts" keep shifting as EC member States keep introducing new conditions.

(b) Rationalizations for the moratorium

4.591 The European Communities asserts there was a "pressing need" to revise Directive 90/220 because that Directive did not "address all issues raised by new scientific understandings and the regulatory developments which were taking place at the international level" and did not include "common/harmonised criteria on the risk assessment to be performed and did not provide for any post-market surveillance measures." None of these *ex post facto* rationalizations for the moratorium is supported by the evidence.

4.592 The European Communities' claim that "new scientific understandings" required new legislation is without merit. The opposite is true, as demonstrated by legislative developments that made the European Communities' biotech approval procedures *less onerous* in the light of the advanced state of scientific understanding that had evolved since the adoption of Directive 90/220 in 1990. Commission Directive 94/15/EC, simplifying the information requirements for notifications, and Commission Decision 94/730/EC, simplifying the procedures for approval of field trials for biotech products, are examples of such developments.

4.593 Turning to risk management issues, the European Communities' attempt to portray the revisions to Directive 90/220 as necessary to address risk management needs is equally without merit. Directive 90/220 already provided for "detection and identification techniques", "monitoring plans and techniques" and labelling requirements. Moreover, Directive 90/220 already enabled regulators to impose conditions in relation to these issues as part of the consent to market the biotech product in question.

4.594 The European Communities' rationale for amending Directive 90/220 is contradicted by the Commission's 1996 Report on the Review of Directive 90/220. That report suggests that changes to

Directive 90/220 were required because the approval procedure was "difficult to implement, time-consuming and cumbersome to follow both for users and authorities." One of the principal difficulties underlying the "cumbersome" procedure was the absence of a means to resolve conflicting scientific views by member States. The European Communities later revised Directive 90/220 to make consultation with an independent scientific committee at the Community level mandatory in cases where objections are raised. Contrary to the European Communities' assertion, the role of the scientific committee at the Community level was precisely to act as an "independent system of conflict resolution" to resolve disagreements amongst member States on the basis of science. In short, the rationale the European Communities now puts forward for revising Directive 90/220 is inaccurate and cannot be a legitimate justification for the moratorium.

4.595 Turning to Regulation 258/97, the European Communities argues that the "delays" in processing applications under Regulation 258/97 were not due to an inadequate framework for risk assessment, but rather inadequate risk management provisions. This argument is flawed for several reasons. Regulation 258/97 already requires that GMO novel foods and food ingredients be labelled. More importantly, the European Communities has failed to identify any risks arising from the scientific assessment of pending biotech applications that would justify adopting traceability and detection measures as "risk management measures" in every case, regardless of the risks involved. Consequently, to "delay" the approval of products under Regulation 258/97 on the basis that the existing legislation does not provide for risk management measures, where the risk assessments for those products have not identified any risks that need to be managed, is unjustifiable.

4.596 For the three products that were, in the words of the European Communities, "partially affected by this situation," (maize Bt11, GA21, NK603) the relevant risk assessments conducted by the European Communities' independent scientific committees under Regulation 258/97 did not identify any risks for which risk management measures would be justified. In all three cases, the risk assessments, taking into consideration the objections raised by member States, concluded that the product in question was a safe as conventional maize. Accordingly, based on the outcome of the risk assessments, there was no justification for imposing "risk management" measures. Consequently, the "delays" in approving biotech products under Regulation 258/97 were not a result of the necessity to adopt "risk management" measures; they were a result of the moratorium on the approval of biotech products imposed by the European Communities.

4.597 In an effort to minimize the importance of the conclusions of its own independent scientific committees, the European Communities goes to great pains to stress the distinction between risk assessment *strictu sensu* and risk management and the respective roles of the scientific committees and Regulatory Committee. The European Communities stresses that risk management decisions are made by the Regulatory Committees and risk assessment *strictu sensu* falls to the scientific committees. In other words, the Regulatory Committees are responsible for selecting the appropriate SPS measure. This is not particularly surprising, problematic or relevant to the issues in this case.

4.598 Even if one takes the European Communities' misleading portrayal of its regulatory regime at face value, it follows logically that the Regulatory Committees must have evaluated the various risk management options that might be applied in light of the risks that were identified in the risk assessment. It is telling that the Regulatory Committee has failed to do so in every instance.

4.599 In any event, the issue in this dispute is not the respective roles of the various bodies comprising the European Communities' regulatory process, nor is it whether the European Communities is adhering to its own legal requirements. The issue is the failure of the European Communities to consider and approve biotech products as a result of an across the board moratorium and the European Communities' failure to base its measures – the moratorium, the product-specific

marketing bans, and the safeguard measures – on a risk assessment that meets the requirements of Annex A and Article 5.1 of the *SPS Agreement*.

4.600 The European Communities also attempts to use the Biosafety Protocol to rationalize the moratorium. The European Communities insinuates that measures regulating GMOs should be dealt with "outside" the WTO Agreement because GMOs have their own "special agreement", the Biosafety Protocol. This position is obviously without merit. Nothing in the WTO Agreements suggests that EC measures to regulate biotech products should be exempt from obligations contained in those agreements. Given that the complaining parties to this dispute are not parties to the Protocol, the Protocol is not a "relevant rule[] of international law applicable in the relations between the parties." Consequently, in this case, the Protocol should not be taken into account in the interpretation of the obligations under the WTO Agreement. Moreover, given that the Protocol's own terms emphasize that "this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements," it is difficult to see how the Protocol can be used to override the obligations of the WTO Agreement.

4.601 In any event, there is no inconsistency between the obligations of the Protocol and the WTO obligations relevant to this dispute. The European Communities' measures – its moratorium, its product-specific bans and its member State national bans – are stark refutations of the Protocol's central premise that decisions regarding the importation of LMOs should be made on a case-by-case basis, and be based on a transparent, scientifically-sound risk assessment. Furthermore, the European Communities' assertion that it adopted its new legislation for biotech approvals only after the Protocol was concluded, "in order to be sure that its own legislation was consistent with the international approach" is inconsistent with the facts. The risk assessment provisions of Directive 90/220 were far more detailed and onerous than those of the Protocol. That the European Communities submitted numerous decisions, concerning the approvals of products under Directive 90/220, to the Bio-safety Clearing House implies that the European Communities considered these decisions to be based on risk assessments that were consistent with the requirements of the Protocol. Thus, if the risk assessments conducted under Directive 90/220 met the requirements of the Protocol, amendments to Directive 90/220 could not have been necessary "in order to ensure that its own legislation was consistent with the international approach."

4.602 The European Communities further attempts to rationalize the moratorium on the basis of "scientific uncertainty." However, the European Communities presents an incomplete and misleading portrait of the state of the relevant scientific evidence, exaggerating the risks of biotech products in comparison to their conventional counterparts. It is particularly striking that in presenting this scientific context, the European Communities ignores the conclusions of its own scientific committees reviewing individual product applications and the conclusions of more than 20 years of EC-sponsored research in the field of biotechnology. In essence, the European Communities, without directly saying so, is questioning the validity of the conclusions of its own scientific experts.

4.603 In fact, the European Communities' independent scientific committees, in evaluating specific product applications, addressed the hypothetical risks raised by the European Communities in this proceeding. The European Communities' scientific committees did not identify an absence of sufficient scientific evidence as a justification for being unable to make an objective assessment of the evidence and reach a conclusion as to the risks presented. To the contrary, the European Communities' scientific committees were able to form firm conclusions as to the safety of the products in question.

4.604 In its Written Rebuttal, Canada reviews each of the hypothetical risks raised by the European Communities and highlights how the European Communities' scientific committees have addressed

these issues. Despite the European Communities' attempts to mischaracterize and exaggerate the risks of biotech products and to insinuate that there exists significant and intractable scientific uncertainty, it is abundantly clear that the European Communities' scientific committees have thoroughly and carefully assessed, on a case-by-case basis, each of these risks in the context of specific applications and on the basis of sound and adequate scientific evidence. The unambiguous conclusion of the European Communities' own scientists is that the biotech products with pending applications do not pose any greater risk to human health or the environment than their conventional counterparts.

(c) The European Communities mischaracterizes risks associated with biotech products in comparison to non-biotech products with novel traits in an attempt to justify the moratorium

4.605 The European Communities makes a number of unfounded allegations regarding the comparability of the risks associated with biotech plants and non-biotech plants with novel traits. In doing so, the European Communities ignores the repeated conclusions of its own scientific bodies.

4.606 Many of the scientific issues raised by the European Communities, while true for biotech plants, are, in fact, similar for plants derived using more conventional breeding technologies available to plant developers. International organizations such as the FAO, the WHO and the OECD have concluded that the use of modern biotechnology does not inherently result in foods that are less safe than those produced by conventional techniques. Unexpected effects can occur with any method of breeding. Nevertheless, in comparison to crops developed through traditional breeding or mutagenesis, biotech crops in the European Communities are subjected to a very extensive pre-market evaluation for potential hazards. While new varieties of traditionally bred crops are evaluated for agronomic and morphological traits, most have not been subjected to any kind of food safety evaluation. In fact, the more rigorous assessment of biotech plants has highlighted the need for further evaluation of "traditional" varieties of plants, which have been developed using a trial and error approach. Many of the potential risks associated with conventional crops received very limited attention prior to the evaluation of transgenic crops.

4.607 In terms of genetic stability, the European Communities states that genetic engineering introduces new genes in random locations in the genome of a plant. This is not a phenomenon unique to genetic engineering and can be observed in cases where plant breeders have broken the barriers that prevent species from mating using conventional techniques.

4.608 The European Communities further asserts that there are major differences in the potential allergenicity of GM foods as compared to other novel foods, making numerous vague, and ultimately unmeritorious, allegations to suggest that GM foods hold a much greater potential for containing allergens that have been unintentionally introduced via the insertion of new genetic material. Any novel food, regardless of the method of production, could result in the introduction of proteins to the human diet for which there has been no previous significant exposure and, consequently, for which the allergenic potential is unknown.

4.609 The European Communities also asserts that "[t]here are however significant differences for the issue of potential invasiveness or persistence in the environment between herbicide/pesticide resistance in GM plants and in conventional crops …" There is no legitimate scientific basis to this assertion and it is noteworthy that the European Communities does not reference any scientific authority for the proposition.

4.610 As a general point, the strategies for managing herbicide resistance are the same regardless of whether the herbicide-tolerant crop was produced using rDNA techniques, mutagenesis or conventional selective breeding. As herbicide-tolerant crops do not have a selective advantage unless

the specific herbicide to which the crop is tolerant is applied (*i.e.* the "relevant selection pressure is present"), the invasiveness or persistence of a herbicide-tolerant crop in the natural environment will be no different from its non-herbicide-tolerant counterpart if the herbicide is not applied.

4.611 The European Communities' distinction between non-selective and selective herbicides is misleading. Herbicides fall on a spectrum of selectivity; some herbicides only control a very limited number of plant species, while others control for a wider range of species. The European Communities neglects to mention the several varieties of herbicide-tolerant crops resistant to the broad spectrum herbicide imidazolinone that have been developed through conventional breeding and mutagenesis. Consequently, the use of broad spectrum herbicides is not limited only to herbicide-tolerant biotech crops. Furthermore, the European Communities discounts the fact that many selective herbicides are far more harmful to the environment than the broad spectrum herbicides the European Communities singles out, glyphosate and glufosinate ammonium. Similarly, the European Communities fails to mention any of the environmental benefits associated with the use of herbicide tolerant biotech crops. As the UK Royal Society has documented, herbicide tolerant biotech crops may be used to benefit wildlife and provide biodiversity in the agricultural environment. Lastly, the European Communities fails to point out that the various risks associated with herbicide use are comprehensively reviewed under the generally applicable EC legislation concerning plant protection products, Directive 91/414/EEC. Even more surprisingly, the European Communities fails to mention that the safety of glyphosate has been fully assessed under Directive 91/414/EEC as recently as 2001.

3. Product specific marketing bans

(a) Oilseed Rape Ms1xRF1 and Ms1xRf2

4.612 Whatever the *ex post facto* rationalization offered by the European Communities in relation to these particular products, the fact remains that the European Communities failed to complete the approval procedure under Directive 90/220; the applicant has been unable to market its products in the European Communities as a result of the failure of France to issue the letters of consent and the consequent uncertainty regarding the legal status of the products. Therefore, the European Communities has failed to "complete" the approval procedure without "undue delay" in patent violation of Article 1(a) of Annex C of the *SPS Agreement*. Moreover, by failing to complete the approval procedure, the European Communities has instituted and maintained effective product-specific marketing bans for Ms1xRf1 and M1xRf2. As these product-specific marketing bans are not based on a risk assessment (the risk assessments that were conducted supported the approval of these products rather than the imposition of marketing bans), these measures are inconsistent with Articles 5.1 and 2.2 of the *SPS Agreement*.

(b) Oilseed Rape Ms8xRf3

4.613 Oilseed rape Ms8xRf3 remains subject to a product-specific marketing ban and continues to serve as an example of how the European Communities has given effect to the moratorium. Eight years after an initial submission for approval – to Belgium in 1996 – six years after the SCP issued its opinion in May 1998 – and after years of safe commercial use in other parts of the world, the product remains unapproved either for import and processing or cultivation, despite reasonably available risk management measures. The product-specific marketing ban violates Articles 5.1 and 2.2 of the *SPS Agreement* as it is not "based on" a risk assessment and violates Article 5.6 as being more trade restrictive than necessary to achieve the European Communities' appropriate level of protection. By any reasonable standard, the extraordinary length of time to process this application constitutes "undue delay". Accordingly, the European Communities has acted inconsistently with paragraph 1(a) of Annex C of the *SPS Agreement*, and by extension, has violated Article 8.

4.614 The European Communities' description of the history of this application is both misleading and incomplete. A review of the Chronology and Attachments submitted by the European Communities in Exhibit EC-63 reveals that over the last eight years, the notifier has made sustained and good faith efforts to respond to the ever-shifting and increasingly unreasonable demands of the member States. The processing of this application illustrates how the European Communities has effectively used its approval procedures to thwart the approval of this product, irrespective of the risks to human health and the environment and regardless of attempts by the notifier to address the concerns of member States. The logical conclusion to draw from this documentation is that, regardless of the risks, 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.

(c) Oilseed Rape GT73

4.615 Oilseed rape GT73 remains subject to a product-specific marketing ban and continues to serve as an example of how the European Communities has given effect to the moratorium. Nine years after an initial submission for approval – to France in 1995, and, as a result of France's inaction, to the Netherlands in 1998 – and after years of safe commercial use in other parts of the world, the Commission submitted the file to the Regulatory Committee for Directive 2001/18 for a vote on 16 June 2004. Neither the Commission's proposed decision to approve the product – nor a rejection of this decision – obtained the required qualified majority. Despite entry into force of the new regulatory framework, despite positive review by the member State competent authority, and despite the positive opinion by EFSA issued as recently as February 2004, the member States are still refusing to approve GT73 for import and processing.

4.616 The obvious fact that the moratorium is still in place today cannot be disputed by simply arguing that, after years of delay, there still remain two further procedural steps after which, theoretically, approval for this product could be granted. Even if one were to argue that approval might ultimately be granted – assuming another failure by the European Communities' Council of Ministers to come to any conclusion at a potential Council vote in or around October 2004, and subsequent approval by the Commission – the fact that approval would occur after nine years of mostly stalled procedures, and at the very last possible procedural step, after countless delays beyond legal timelines and beyond scientific justification, would be further proof for the continued *existence* of the moratorium rather than anything else.

4. Mootness is not relevant

4.617 The European Communities' assertions with respect to the relevance of the concept of "mootness" are factually and legally incorrect or misleading. WTO jurisprudence is replete with instances where panels made findings with respect to measures that were either removed or modified by the responding party after the terms of reference had been established. A panel's jurisdiction to consider a measure is first determined by its terms of reference. If the measure falls within its terms of reference, the panel is to exercise its discretion and make findings on those measures necessary to fulfil the dispute settlement objective of "securing a positive resolution of the dispute". In cases where the measure in question existed at the time of the establishment of the terms of reference of the panel, the consistent practice of panels has been to at least make findings on the WTO/GATT consistency of that measure.

4.618 From a factual standpoint, Canada contests vigorously the European Communities' assertion that the measures before this Panel never existed or were withdrawn by the European Communities prior to the establishment of this Panel's terms of reference. Similarly, Canada disputes that the

European Communities' suggestion that "a case on a measure that is not in existence any longer would be devoid of any practical purpose" applies to a situation, like the one at hand, where there is a real possibility of the measure recurring.

5. The European Communities' appropriate level of protection

4.619 As the European Communities appears to admit that its appropriate level of protection in respect of biotech products is a "high level of protection," Canada submits that the Panel should first review the moratorium and the product-specific marketing bans in relation to the obligations under Article 5.6 of the *SPS Agreement*. The evidence demonstrates that the moratorium and product-specific marketing bans are more trade restrictive than required to achieve the European Communities' appropriate level of protection.

6. EC member State national measures ("safeguard measures")

(a) Article 5.7 of the *SPS Agreement* does not apply

4.620 The European Communities argues that the safeguard measures are provisional and are therefore subject only to Article 5.7 of the *SPS Agreement* to the exclusion of the other provisions cited by Canada as having been violated. The European Communities further claims that the burden lies on the complaining party to establish a *prima facie* case that the measures in question are inconsistent with the requirements of Article 5.7, and that Canada has not met this burden. The European Communities' arguments in this regard are completely without merit.

4.621 First, the Appellate Body has not defined the relationship between Article 5.7, and Article 2.2 and 5.1 is "one of exclusion, not exception". Equating the relationship between Articles 2.2 and 5.1, and Article 5.7, with the relationship between Articles 3.1 and 3.3 is inappropriate because the purposes, and therefore the relationships between these Articles, respectively, are different.

4.622 The European Communities' argument with respect to Article 5.7 distorts the basic architecture of the *SPS Agreement*, as reflected in Articles 2, 3 and 5. The European Communities bifurcates the SPS regime on the basis of whether measures are "definitive" (or "permanent") or "provisional". There is no basis for a bifurcation of this nature in either the text of the *SPS Agreement* or the relevant jurisprudence. To the contrary, the basic architecture of the *SPS Agreement* demonstrates that the bifurcation occurs in Article 3, between measures based on international standards, and other SPS measures. Article 3 provides Members with two equally legitimate options. A Member can adopt a measure that is based on a relevant international standard, where such a standard exists. Alternatively, a Member can adopt a measure in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5, where it seeks a level of protection that is higher than the level of protection implied by the international standard.

4.623 In essence, Articles 3.1 and 3.3 represent "separate but equal" tracks to follow in adopting an SPS measure. Article 3.3 is not merely a "qualified exemption" from the basic obligation in Article 3.1 to base such measures on international standards. It is the expression of the "autonomous right" of WTO Members to establish their own appropriate levels of protection, including levels of protection that are higher than those implied by the relevant international standards. However, a Member choosing the second option is obliged to meet the requirements of Article 5.1 and base its measures on a risk assessment consistent with the definition found in Annex A.1 of the *SPS Agreement*.

4.624 Where a measure is not based on a risk assessment, and therefore inconsistent with Article 5.1, it will also, by implication, be inconsistent with the general requirement in Article 2.2 not to maintain SPS measures without sufficient scientific evidence. If it is found that the measure in question is being maintained without sufficient scientific evidence, it is open to the Member defending the measure to argue that sufficient scientific evidence does not exist to enable it to complete a risk assessment. This is where Article 5.7 enters the picture.

4.625 As the Appellate Body has explicitly noted, Article 5.7 "operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence". Article 5.7 enables the WTO Members, in certain, limited circumstances, to adopt and maintain SPS measures despite the fact that they are not supported by sufficient scientific evidence. Article 5.7 does not exist as an option that can be freely chosen by the Member concerned in place of Article 2.2.

4.626 The European Communities' argument that the threshold (or "demarcation line") for the applicability of Article 5.7 lies with the provisional nature of the measure rather than with the "sufficiency or insufficiency of scientific evidence" is also without merit. The European Communities' position is based on a number of dubious textual arguments and the flawed assertion that the four conditions set out in Article 5.7 have "equivalent status". These assertions ignore the fact that the first condition, insufficiency of scientific evidence, is expressed as a threshold.

4.627 While the European Communities' legislation indicates that "safeguard" measures are meant to be temporary, the same legislation requires that a decision on the justifiability of such measures shall be taken in reasonably short order. Of the five safeguard measures being challenged by Canada, none has been in place less than 45 months. If such measures are provisional, they are so in name only.

4.628 In any event, the mere fact that a Member labels a measure as provisional does not permit that Member to escape the other obligations of the *SPS Agreement*. It is not the provisional nature of the measure that matters, but whether the measure is being maintained without sufficient scientific evidence. Only if the measure, whether provisional or otherwise, is found by a panel to be maintained without sufficient scientific evidence do the considerations under Article 5.7 come into play. Obviously, it would be the Member invoking the provision that would have the initial burden of demonstrating a *prima facie* case.

(b) Even if Article 5.7 were to apply to the EC member State national measures, it would not exclude the application of Articles 5.5 and/or 5.6

4.629 The issue in relation to Article 5.5 is consistency in the application of appropriate levels of protection in comparable situations. This is a different matter from the putative inability of the European Communities to complete a risk assessment with respect to a particular product because of the insufficiency of scientific evidence. As the establishment of an appropriate level of protection logically precedes the selection of the risk management tool – that is, the measure in question – the main issue is whether it is possible to determine if comparable situations exist. This is a factual matter that goes to whether the conditions of Article 5.5 have been met and does not have a bearing on the legal interpretation of the relationship between the Articles 5.5 and 5.7.

4.630 Similarly, the European Communities' answer with respect to the relationship between Article 5.7 and 5.6 is based upon a false premise. Nothing in the text of either Articles 5.6, 5.7 or 2.2 supports the European Communities' argument. As a matter of practice, there can be many situations where the risk manager, when faced with insufficient evidence, nevertheless has risk management

options from which to choose. In this light, Article 5.6 still has a valid role to play, even if, in a given situation, a determination that it has been violated is factually more complicated.

(c) The EC member State national measures are not based on a risk assessment, as required by Article 5.1

4.631 The European Communities asserts that the phrase "as appropriate to the circumstances", as used in Article 5.1, means that, in the context of the safeguard measures, the Panel would have to go back to Article 5.7 "because … the circumstances are that the scientific evidence is insufficient for the specific legislator and its specific level of protection". The European Communities' interpretation of "as appropriate to the circumstances" in this regard is completely unsupported by the jurisprudence and any reasonable textual construction of the terms. While these words provide the WTO Member flexibility in conducting the risk assessment, as the panel is *Australia – Salmon* concluded, the words cannot annul or supersede the substantive obligation of Article 5.1 to base the measure on a risk assessment. Moreover, Article 5.7 operates as an exception to Articles 2.2 and 5.1. It is only where a panel has found that a measure is inconsistent with Article 5.1 and/or Article 2.2 that Article 5.7 comes into play, and then only if the Member seeking to uphold the measure invokes it.

4.632 The European Communities' argument that Article 5.1 does not "expressly require a 'risk assessment' – it only requires that the Member take into account risk assessment techniques developed by the relevant international organisations", is a blatant distortion of both the clear text in Article 5.1 and its related jurisprudence.

4.633 In the alternative, the European Communities argues that the member States' safeguard measures are based on risk assessments. In pointing, astoundingly, to the risk assessments that formed the basis for the European Communities' approval of these products, the European Communities claims that these risk assessments can serve as the basis both for the original Community consent and for the member State bans. However, in these circumstances, the risk assessments in question cannot serve this dual function. The publicly available scientific opinions do not equivocate in their conclusions, nor do they present diverging views of the potential risks associated with these products. To the contrary, they clearly and unambiguously find that there is no evidence to indicate that the products in question pose a threat to human health or the environment.

4.634 The European Communities then states that, "[f]urthermore, the member States have made their own assessments and further risk assessments *may be* forthcoming." However, for the most part, the European Communities has failed to submit any documentary evidence of either the member State "assessments" or "further risk assessments" in relation to the five safeguard measures challenged by Canada in this proceeding until requested to do so by the Panel. A review of the additional information submitted by the European Communities in this regard demonstrates that the safeguard measures do not even come close to meeting the standard established by WTO jurisprudence for meeting the requirements of Article 5.1, and, by implication, the requirements in Article 2.2 that SPS measures must be based on scientific principles, and not be maintained without sufficient scientific evidence.

(d) The EC member State national measures violate the *TBT Agreement*

4.635 The European Communities' arguments that the safeguard measures do not violate the *TBT Agreement* are excessively narrow and reflect a jurisprudentially untenable conception of the scope of the definition of a "technical regulation", and the ambit of the obligations set out in Articles 2.1, 2.2 and 2.9. To the extent that the EC member State measures are based on ostensible

risks that are not covered by the *SPS Agreement*, the measures are technical regulations, and are therefore subject to the *TBT Agreement*.

(i) The EC member State national measures are "technical regulations"

4.636 The European Communities' assertion that individual decisions taken pursuant to the European Communities' legislative instruments – referred to by the European Communities as "administrative acts" – "are not themselves technical regulations", is bereft of any textual or jurisprudential support. The only part of the text that the European Communities cites – the phrase "applicable administrative provisions" – is not particularly instructive; the absence of "applicable administrative provisions" does not, by itself, signify that a particular measure is not a technical regulation. The similarities between the measures at issue in this dispute and the measure at issue in *EC – Asbestos* support the conclusion that the safeguard measures are indeed "technical regulations" as interpreted by the Appellate Body in *EC – Asbestos* and *EC – Sardines*.

4.637 The safeguard measures meet all three criteria established by the Appellate Body to determine whether a particular measure falls within the definition of a "technical regulation". First, all of the safeguard measures either identify the specific products subject to the prohibitions, or are expressed in terms that render those products readily identifiable. Second, each safeguard measure proscribes oilseed/rape and corn possessing certain characteristics or genetic materials. This is similar to the proscription in *EC – Asbestos* of products – such as cement – containing the asbestos fibre. For these reasons, the European Communities' assertion that these measures do not prescribe or proscribe product characteristics is untenable. Third, compliance with the product characteristics set out in the safeguard measures is compulsory. The European Communities' argument that "[t]here is no way for the notified product to comply with the member State measure" misses the point. The issue is not whether the notified product can comply, but whether oilseed/rape or corn products can comply, in the same sense that, in *EC – Asbestos*, the issue is not whether asbestos cement can comply with the prohibition, but whether cement can comply.

(ii) The measures violate Article 2.1

4.638 Canada rebutted the arguments made in the European Communities' First Written Submission in Canada's answer to Panel's Question 69.

(iii) The measures violate Article 2.2

4.639 While Canada would agree with the rather obvious statement that whether a particular measure fulfils its objective depends on what that objective is, Canada does not agree with the European Communities' implied argument that the safeguard measures are necessary. Canada notes that the European Communities' argument must be implied because nowhere does the European Communities explicitly argue – nor does it provide any evidence – that the safeguard measures actually fulfil a legitimate objective; the European Communities does not even indicate what level(s) of acceptable risk the "relevant legislators" in the respective EC member States are applying.

4.640 In the light of the objectives of the safeguard measures – in so far as those objectives can reasonably be discerned from the measures themselves and the European Communities' legislation relating to the assessment and approval of biotech products – and in the light of the scientific and other evidence, Canada has demonstrated that the measures in question do not meet the requirements of Article 2.2 of the *TBT Agreement*. The European Communities has not presented any arguments with respect to the specific safeguard measures that counter Canada's *prima facie* case. The additional information relating to the safeguard measures finally provided by the European Communities at the

request of the Panel only strengthens Canada's legal position that those measures are more trade restrictive than necessary.

(iv) The measures violate Article 2.9

4.641 The European Communities does not contest the substance of Canada's arguments with respect to the inconsistency of the safeguard measures with Article 2.9, confining itself to making additional arguments for why the safeguard measures are not technical regulations. To illustrate why these arguments are without merit, the Panel need not look any further than the measure in issue in *EC –Sardines*. The measure in that case, Regulation 2136/89, a measure that the European Communities conceded is a technical regulation, applies to a single product: preserved sardines. Clearly, therefore, whether a measure applies to a single product or a multiplicity of them is not determinative of whether that measure is a technical regulation or not. It also undermines the European Communities' contention that a measure must be of a "general nature" in order to qualify as a technical regulation.

O. SECOND WRITTEN SUBMISSION OF ARGENTINA

1. Arguments

(a) The *de facto* moratorium

(i) Introduction – The existence of a de facto moratorium

4.642 In this stage of the proceedings, Argentina will argue that the European Communities has not refuted any of the arguments that the complaining parties put forward in this dispute. The European Communities' attitude towards our arguments consists, for instance, in dogmatic statements to the effect that there simply is no *de facto* moratorium nor any suspension of the treatment of specific applications for approval. Moreover, the European Communities affirms that, even assuming that there were such a measure, it would not be a challengeable measure under the WTO Agreement. Nonetheless, the European Communities simply declares that there is no measure at all, without refuting any of the arguments concerning its existence and inconsistency developed by the complaining parties.

4.643 The European Communities has indicated that events occurring after the establishment of a panel should be taken into account because the challenged measure may have ceased to exist, thus implicitly admitting the existence of a *de facto* moratorium, at least before the establishment of this Panel.

4.644 The European Communities also asserts that the *SPS Agreement* would not apply to this dispute, because, as the European Communities understands the *SPS Agreement* , the issues relating to agricultural biotech products go beyond the scope of the *SPS Agreement*. Despite this, the European Communities does indeed admit that the agricultural biotech products are partially covered by the *SPS Agreement*. According to Argentina, the *SPS Agreement* **is** the Agreement to be applied, since it refers to protection against certain risks and not against certain products.

4.645 In addition, the European Communities considers that there is legislation relevant to this dispute outside the WTO rules, and that this should be taken into account by the Panel in settling this case. In any event, Argentina considers that the "extra-WTO" legislation invoked by the European Communities does not relieve the European Communities of its obligation to have a scientific backing for its measures.

(ii) The de facto moratorium measure

4.646 The existence of a *de facto* moratorium measure has been amply demonstrated, and the European Communities has not refuted the evidence submitted, but rather tried either to reinterpret or deny it.

4.647 The *de facto* moratorium has the following characteristics: (i) it has never been set forth in the form of positive legislation; (ii) it has prevented the approval of any new agricultural biotech product in the European Communities since 1998, through the systematic suspension of proceedings and the failure to consider individual applications for authorization or approval of agricultural biotech products; (iii) it has led to a systematic and unjustified delay in the time-frames set forth in the European Communities' legislation, so that proceedings are never concluded; and (iv) it entails discrimination against agricultural biotech products.

4.648 The existence of a *de facto* moratorium is obvious because there have been neither approvals nor rejections of applications for agricultural biotech products in the European Communities since 1998, despite the fact that several applications have received a favourable scientific opinion from the European Communities' scientific committees.

4.649 Moreover, it is relevant that the existence of a *de facto* moratorium has been acknowledged by senior EC officials with direct responsibility for the matters considered in this dispute. Furthermore, at the EC member State level the existence of a *de facto* moratorium continued to be acknowledged even as late as June 2004.

4.650 More recently, at the time of the curiously opportune Bt11 maize approval, reference was made in the official document to the existence of a *de facto* moratorium, which states that the Bt11 maize approval "*would* bring to an end the *current* moratorium on genetically modified food and feed in Europe" (italics added). The document not only rejects the European Communities' argument regarding the non-existence of a *de facto* moratorium but also the argument regarding "mootness". The European Communities' statement on "mootness" also contradicts the WTO jurisprudence concerning Article 19.1 of the DSU.

4.651 The European Communities tries to play down the statements of its own senior officials by arguing that they are not binding on the European Communities. In this respect, the European Communities quotes jurisprudence relating to "casual statements". Nevertheless, it does not explain how the statements of senior EC officials with direct competence in the matter can constitute "casual statements".

4.652 Furthermore, with regard to the European Communities' statement that *"it may constitute additional evidence that the Member in question applies that measure in a specific way"*, if the European Communities is referring to the recent decision on Bt11 maize, Argentina would point out that this decision relates to only a single product and does not end the existence of the *de facto* moratorium. This approval may have occurred precisely because of the establishment of the Panel and should not be regarded as the normal way in which the European Communities was conducting its approval procedures.

4.653 The European Communities also states that there have been approvals under Regulation 258/97 after 1998. According to the European Communities, this shows that the proceedings were not suspended. Nevertheless, Argentina would like to make it clear that these "approvals" mentioned by the European Communities are not true approvals but only notifications under the simplified procedure of Regulation 258/97.

4.654 Regarding the argument that the complaining parties have failed to identify any instrument or text on the basis of which the moratorium was established, Argentina has already explained in its first written submission that the moratorium was not set forth in the form of positive legislation. The measures referred to in Annex A:1 to the *SPS Agreement* are not the only sanitary or phytosanitary measures covered by that Agreement. The European Communities also argues that, in any case, a measure not set forth in the form of positive legislation could not be questioned in the WTO. On the contrary, as described in Argentina's submission, GATT/WTO jurisprudence has consistently taken a broad approach to the concept of "measure". In fact, the tendency has always been to extend this concept in such a way that Members' obligations cannot be circumvented.

(iii) Not simply a delay – Disregard of scientific evidence

4.655 In these proceedings, the European Communities is trying to cut short the period which began in 1998, thereby denying the existence of a *de facto* moratorium and turning all into a mere question of delay. Argentina does not agree with the European Communties' claim that any delay would have to end with the application of Directive 2001/18. This Directive entered into force in October 2002, and no approvals were issued afterwards despite the scientific evidence at hand.

4.656 The European Communities keeps trying to make out that the clock should be put back to zero from that moment, regardless of the fact that no approvals were given and it stalled on all applications by claiming that more stringent legislation was necessary, namely, on traceability and labelling. The same applies to the European Communities' response to the Panel's Question 36, in which it states that *"the re-submission represents the starting date for the reasonable period of time needed to examine the new information and to conduct a risk assessment of the newly identified issues"*. Setting the clock back to zero with Directive 2001/18 would imply disregarding the whole period that had elapsed since the initial submissions of the applications, including the moment when the positive scientific opinions were issued.

4.657 In its response to the Panel's Question 37, the European Communities is again trying to reduce the claim to a simple question of delays. Argentina strongly objects to this "reductionist" view. Argentina relies heavily on the scientific evidence on which any SPS measure must be based, and this substantive requirement goes far beyond the simple question of undue delay. Both the *de facto* moratorium and the "suspension and failure to consider" must meet substantive requirements, i.e. the need for scientific evidence, and thus be consistent with Articles 5.1, 2.2, 5.5, 2.3 and 5.6 of the *SPS Agreement*.

(iv) The European Communities implements and maintains a de facto moratorium

4.658 As Argentina has already pointed out, the European Communities has constantly made the adoption of more stringent legislation a precondition for lifting the moratorium. Nevertheless, the European Communities has systematically imposed additional requirements with the result that proceedings could never be completed. As soon as they had met one set of requirements, applicants were being asked to meet another. In fact, the European Communities stopped approving or rejecting applications as from 1998 because it deemed that its legislation – at that time Directive 90/220 and Regulation 258/97 – was inadequate. As an immediate consequence, on 4 September 1998 the European Communities began the so-called "Inter-Service Consultation".

4.659 The European Communities keeps on denying the existence of a *de facto* moratorium or a suspension of proceedings. According to the European Communities, because of the legislative insufficiency, a transitional mechanism – the so-called "interim approach" – was established, to facilitate the move towards a new regime.

4.660 This was the context in which the European Communities began the legislative procedure that ended with the adoption of Directive 2001/18. However, before Directive 2001/18 entered into force in October 2002, the European Communities again argued the need for more appropriate legislation. This prompted the beginning of the discussion on traceability and labelling, so there have been no approvals – or even rejections – of agricultural biotech products under Directive 2001/18 either. In December 2003, a new "Inter-Service Consultation" phase was initiated.

4.661 Argentina will now address these issues and their importance in agricultural biotech product approval proceedings, thereby demonstrating how the lack of approvals since 1998 was deliberately decided upon and maintained by the European Communities.

a.- The "Inter-Service Consultation" phase

4.662 From the information on the CD ROMs provided by the European Communities it is clear that the European Communities and/or its member States tried to refute or ignore the positive scientific opinions of its scientific committees, in order to stall the approval or marketing of agricultural biotech products. Furthermore, the information submitted on the above-mentioned CD ROMs gives us a clear picture of the relevant procedural stages for each agricultural biotech product. There are stages with no legal basis in the approval procedures but with political relevance as a means of stalling the procedure. This shows that the European Communities was treating agricultural biotech products "in baskets".

4.663 The "Inter-Service Consultation phase" effectively prevented all the applications – with positive scientific opinions in 1998 – from moving forward. In short, all the applications with positive scientific opinions from year 1998 were stalled in the "Inter-Service Consultation phase", with no exception. A first group of products (Falcon GS40 Oilseed rape, MS8xRF3 Oilseed rape, and A5/15 Fodder beet) was placed in a common "basket" in September 1998 and prevented from reaching the Regulatory Committee voting stage until June and October 1999, when they were not even voted on. The remaining two products (Bt 531 cotton and RRC 1445 cotton) did go to a vote but due to the lack of the required majority they were put in a second "basket" in May 1999. The two "baskets" were effectively stalled in the proceedings until the applications had to be resubmitted under Directive 2001/18 in January 2003.

4.664 In its response to the Panel's Question 94, the European Communities describes how "Interservice Consultation" might work. Argentina must conclude that this "Interservice Consultation" stage is further evidence of both a *de facto* moratorium and of the "suspension and failure to consider", specifically with respect to Bt-531 cotton and RRC 1445 cotton.

b.- The "Common Position" and the declaration by various member States

4.665 As has been proved, in 1998 the procedures for approvals and rejections of applications were stopped because the European Communities' legislation was considered inappropriate. In this context, in June 1999, the EU Council of Environmental Ministers drew up a document called the "Common Position" for the reform of Directive 90/220. This document stated that there would be no approvals until there was new legislation. The Declaration by Denmark, Greece, France, Italy and Luxembourg stated their intention of not allowing more biotech approvals. This position was reiterated in July 2000 during an informal Environment Council meeting in Paris.

4.666 In Argentina's view, the "Common Position" reveals the European Communities' intention not to approve any more agricultural biotech products. This element of will and intent shows that the *de facto* moratorium is not merely the sum of simple delays in the approval proceedings.

4.667 In September 1998 and May 1999, the European Communities began to stop approving agricultural biotech products by means of the "Inter-Service Consultation" phase. Shortly after that, in June 1999, came the "Common Position" and the Declaration of the five member States, arguing the need for reform of the approval legislation. At that point, the approval procedures were all stopped and the European Communities had entered a "discussion phase". Some member States – France, Belgium, Denmark, Greece and Italy – asked for additional requirements before the approval proceedings were restarted, this time calling for an environmental liability scheme. This regime had also been recognized within the European Communities as capable of continuing the *de facto* moratorium.

c.- Regarding the "Interim approach"

4.668 The European Communities' consideration of a change in the legislation created uncertainty about the approvals. As a consequence, several applicants offered to fulfil the requirements contained in the "Common Position", since they had no other choice. After that, in July 2000, the Commission proposed the so-called "Interim approach". This came after a long period of time without approvals and was the result of the applicants' concerns – not of any initiative by the European Communities, as the European Communities would have the Panel believe.

4.669 During July 2000, the Commission considered several options regarding the approval of agricultural biotech products. The options were: (a) the application of Directive 90/220 as it stood at that date; (b) waiting until the member States internalized Directive 90/200/EEC; and (c) a proactive position to re-launch the approval system. The European Communities chose the option apparently aimed at re-launching the approval procedure – "Interim approach" – which consisted in anticipating the stricter requirements of the future Directive 2001/18, specially those relating to monitoring, labelling and traceability. In this context, the concerns manifested by the European Communities and by the member States referred to labelling and traceability, and these issues were made a *conditio sine qua non* for the approval of agricultural biotech products. Under the "Interim approach" there were neither approvals nor rejections. Moreover, the entry into force of Directive 2001/18 brought the "Interim approach" stage to a close. To sum up, the "Interim approach" became just another manifestation of the *de facto* moratorium.

d.- Further applications receive positive scientific opinions, before the entry into force of Directive 2001/18

4.670 While all the applications with a positive scientific opinion dated 1998 were stalled, new applications were in position to be approved thanks to the positive opinion of the scientific committees. Both Phoe6/Ac Oilseed rape and Bt11 maize received a positive opinion on 30 November 2000 and were to be resubmitted under Directive 2001/18. Thus, both applications were stalled for two years. The same can be argued with reference to the potato, though within a shorter time frame since the positive scientific opinion was issued in July 2002.

4.671 In February 2001, six member States – Denmark, France, Greece, Italy, Luxembourg and Austria – reaffirmed their commitment to suspending approvals, on the grounds that the new procedures were inadequate.

4.672 By the end of October 2001, the majority of member States essentially agreed that the moratorium should not be lifted until the full traceability and labelling provisions had entered into force. At an informal meeting of the Environment Council, eight member States – France, Austria, Finland, Luxembourg, Denmark, Italy, the Netherlands, and Sweden – effectively rejected the Commission's plan to consider new authorizations, by demanding that the new regulations be in force

first. At that time, the Commission estimated that it would be an additional two years before any traceability and labelling requirements could be enacted. In December 2001, Belgium declared once again that the *de facto* moratorium would have to be maintained until there was proper legislation on traceability and labelling.

4.673 Consequently, the European Communities was clearly announcing its intention to maintain the *de facto* moratorium, even if Directive 2001/18 entered into force. This refutes the European Communities' claim that any delays should have ended with the entry into force of Directive 2001/18.

e.- Claims concerning the review of Directive 90/220

4.674 With respect to the European Communities' excuses for repealing Directive 90/220, these have basically consisted in the following: "new scientific understandings", the lack of harmonized criteria on the risk assessment to be performed, and the lack of post-marketing surveillance measures and labelling provisions.

4.675 The lack of harmonized criteria on risk assessment, had already been addressed in the "Report on the Review of Directive 90/220/EEC" in the context of the Commission's Communication on Biotechnology and the White Paper.[82] Notwithstanding what this document states, in its response to the Panel's Question 17 the European Communities asserts that there is currently no pre-eminence of the European Communities' scientific committees over the rest.

4.676 Argentina wishes to point out that in its response to the Panel's Question 17, the European Communities also makes reference to the jurisprudence of the European Court of Justice, which establishes the criteria used to determine whether a scientific opinion of the relevant scientific committee may be disregarded. The European Communities has not observed the rules laid down by its own Court of Justice. In fact, the European Communities has not provided any reason of a scientific nature for disregarding the opinions of its own scientific committees, which favoured the approval of agricultural biotech products.

4.677 Argentina considers this circumstance confirms the lack of scientific support for the application of the *de facto* moratorium and shows that what at a certain point was advanced as an argument for changing the European Communities' approval system has turned into an excuse inconsistent with WTO obligations.

4.678 Another argument used by the European Communities to justify the modification of Directive 90/220 is that relating to "post-market surveillance measures". Directive 90/220 already dealt with "post-marketing monitoring measures" in its Annex II (V), so we are again faced with an argument that is really just another excuse. With respect to the issue of the lack of labelling provisions, Directive 90/220 already had such a provision, which applicants could only evade on good scientific grounds.

f.- Entry into force of Directive 2001/18

4.679 In November 2003, once Directive 2001/18 had entered into in force, NK 603 maize received a positive scientific opinion, while GT73 oilseed rape received one in February 2004. By that time, this WTO Panel had been established.

[82] COM(96) 630 final, Brussels, 10 December 1996, "Report on the Review of Directive 90/220/EEC".

4.680 There were no approvals under Directive 2001/18 either. Moreover, at a meeting of Agriculture Ministers held in January 2003, several EC member States set conditions on the implementation of. Directive 2001/18, this time concerning the adoption of a labelling and traceability regime. Additionally, a co-existence regime was also requested.

4.681 In this connection, the EC authorities have indicated their intention to resort to the European Court of Justice because most member States have failed to internalise Directive 2001/18.

4.682 This is another fact which demonstrates the existence of a *de facto* moratorium.

g.- Regarding the traceability and labelling legislation

4.683 The need for a new traceability and labelling regime was specifically invoked in the case of Regulation 258/97. In this respect, the European Communities pointed out in its response to the Panel's Question 91 that the aforementioned Regulation was appropriate to matters relating to "risk assessment" but that "it became clear in 1999 that there would have to be new legislation addressing some issues such as labelling and traceability, and also the development and validation of detection methods. These issues have been addressed through Regulations 1830/2003 (labelling and traceability) and 1829/2003 (food and feed)".

4.684 In this case, too, the European Communities' argument has become an excuse. In fact, Regulation 258/97 does contain provisions concerning "labelling".

4.685 With respect to "traceability" and "detection methods", the European Communities has failed to identify the existence of a risk as prescribed by the Codex Principles for the Risk Analysis of Food Derived from Modern Biotechnology. Thus, the European Communities' claims regarding traceability and detection methods are in fact excuses to justify the *de facto* moratorium.

h.- Regarding the European Communities' arguments based on the Cartagena Protocol and the so-called "precautionary principle"

4.686 The European Communities argues the relevance of an "extra-WTO" instrument and of the so-called "precautionary principle" for dealing with the issues raised in this case.

4.687 According to Article 3.2 of the DSU, as interpreted by the Appellate Body, any treaty interpreter must resort to the Vienna Convention on the Law of Treaties in order to interpret the covered agreements. In this case, with respect to the "extra-WTO" rules invoked by the European Communities, we need to resort to Article 31 of the Vienna Convention.

4.688 The rules referred to by the European Communities are clearly not an agreement "relating to the treaty which was made between all the parties in connection with the conclusion of the treaty" – Article 31.2 (a). Nor are they an "instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty" – Article 31.2 (b). Clearly, the rules cited by the European Communities are not a "subsequent agreement between the parties regarding the interpretation of the treaty or the applications of its provisions" – Article 31.3(a). Nor can the Cartagena Protocol be regarded as "any relevant rule of international law applicable in the relations between the parties" – Article 31.3(c), since the European Communities is the only party in this WTO dispute bound by the provisions of the Protocol.

4.689 The European Communities also refers to the so-called "precautionary principle". It should be pointed out that the Appellate Body has addressed the status of this so-called "principle" in *EC-Hormones*.

4.690 Finally, the Cartagena Protocol states, in one of its recitals:

> "Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements"

What it is relevant in this case is that the Cartagena Protocol does not allow the European Communities to circumvent its WTO obligations, and that the European Communities' arguments in this respect have been just another excuse to maintain the *de facto* moratorium, because the European Communities has also said that Directive 2001/18 would not be adopted until the conclusion of the Cartagena Protocol, to enable it to adapt its legislation to that Protocol.

4.691 It should be recalled that the Cartagena Protocol establishes the obligation to undertake a risk assessment. Comparing Annexes I and III to the Cartagena Protocol with Directive 90/220, we note a great consistency.

4.692 From the above it is clear that the European Communities' arguments are, once again, mere excuses.

(v) The de facto moratorium is inconsistent with Article 10.1 of the SPS Agreement

4.693 As a developing country, Argentina must again stress the relevance of the SPS Article 10 provisions as they establish special and differential treatment for developing country Members.

4.694 Argentina would like to comment on the European Communities' statement to the effect that "The European Communities does not doubt the importance of these provisions and can assure Argentina that it bears them in mind when developing and applying its legislation, including, where relevant, its GMO legislation". First of all, Argentina welcomes that the European Communities recognizes the importance of these provisions. Nevertheless, we do not agree with the rest of the statement, especially the words "*where relevant*". Argentina must again point out that Article 10 is mandatory for WTO Members.

4.695 Argentina reiterates that the European Communities has failed to present any proof that it took into account the special needs of developing country Members when drafting and applying its legislation relating to agricultural biotech products.

4.696 Furthermore, Argentina disagrees with the European Communities' characterization that "Argentina's argument seem to come to nothing more than saying that since the European Communities has violated other provisions of the agreements and this affects Argentina, a developing country, it has consequently also failed to comply with its obligations of special and differential treatment towards developing countries". The European Communities is wrong in claiming that Argentina's argument is based on an interpretation of a consequential obligation. Argentina has argued that the European Communities' adoption of the *de facto* moratorium omitted all consideration of the obligations of developed countries arising out of Article 10.1 of the *SPS Agreement*, and specifically the obligation to take account of the special needs of developing country Members. Furthermore, even taking into account the EC legislation itself, a reading of the main provisions on the subject – Directives 90/220, 2001/18 and Regulation 257/98 – reveals no reference to developing

country Members' biotech products, still less any reference to those countries' special needs being taken into account.

4.697 Argentina reiterates that the *de facto* moratorium applied by the European Communities since 1998 has had the effect of closing the EC market to agricultural biotech products not approved before that date. The trade flows or imports to which the European Communities appears to refer cannot actually include any new post-1998 agricultural biotech products since no product has been approved – or rejected – because of the way in which the *de facto* moratorium has been operating.

4.698 Neither has the European Communities denied Argentina's claim that the lack of consideration of the special needs of developing countries is aggravated in the case of the European Communities because it is not just a national market but a market that now has 25 member States. In addition, the last ten States to join the European Communities have had to accept the *"acquis communautaire"*, which includes the *de facto* moratorium.

4.699 Argentina thus reiterates its request for the Panel to find that the European Communities is violating Article 10.1 of the *SPS Agreement*.

(b) The "suspension of processing and failure to consider individual applications for specific products of particular interest to Argentina"

(i) General comments

4.700 As previously stated, since the *de facto* moratorium affects all applications, these relevant additional stages also apply to the products of interest of Argentina, namely, Bt-531 cotton, RRC 1445 cotton, NK 603 maize, GA 21 maize and soy lines A2704-12 and A5547-127.

4.701 On the other hand, having examined the information finally submitted by the European Communities in the CD ROMs, Argentina finds that this information does not match the positive scientific opinions from the European Communities' scientific committees. First of all, most of the information provided by the European Communities is political rather than scientific in nature. Secondly, most of the documents listed by the European Communities are dated before the issuance of the positive scientific opinions. Accordingly, Argentina believes that the scientific committees were aware of all these documents and issued a positive opinion anyway. Furthermore, as only observations published in indexed scientific journals with peer review procedures should be considered in the analysis, opinions without this basis are not to be taken into account.

4.702 In any event, as regards specific comments on issues Argentina considers to be relevant from a scientific point of view, we enclose comments confirming that the additional information which the European Communities kept talking about, which the European Communities never submitted until the Panel and the Parties requested it in the First Substantive Meeting, which it provided without proper translations thereby delaying the procedures, and on which the European Communities said it had based its measures on the specific products of interest to Argentina, nevertheless does not refute the positive scientific opinions issued by the European Communities' scientific committees which favour the approval of all these products.

4.703 This having been said, we will now deal with the applications individually.

(ii) Specific products

a.- Bt 531 cotton and RRC 1445 cotton

4.704 The European Communities has acknowledged that the application for approval of both cotton types was stalled in the proceedings: these products obtained a positive opinion from the European Communities' Scientific Committee on 14 July 1998 and were submitted to the Regulatory Committee, where there was no qualified majority, in February 1999. The European Communities admitted this, but it also acknowledged that there were certain stages within the proceedings with no legal basis that were capable of stalling the proceedings: specifically, the European Communities admits that, after the positive scientific opinion of 14 July 1998, on 4 September 1998 the so-called "Inter-Service Consultation" phase began. In February 1999, in the absence of a qualified majority, the Regulatory Committee had to submit, without delay, a draft measure to the Council. Instead of that, the so-called "Inter-Service Consultation" phase took place again – 7 May 1999 – stalling the procedure. The applications had to be resubmitted under Directive 2001/18 in January 2003.

Comments on the information provided in the CD ROMs

4.705 In Argentina's view, the information provided by the European Communities does not refute the decisive, positive scientific opinions dated 14 July 1998.

4.706 Regarding Bt-531 cotton under Directive 90/220, the documentation provided by the European Communities is the following: the objections from Germany (February 1998); the outcome of the written procedure (April 1999); the statement by Austria; Denmark's position; the Opinion of the Commission du Génie Biomoléculaire (January 1999); the letter by the Commissie Genetische Modificatie (December 1998); the statement of the Swedish Board of Agriculture (February 1998); the letter to the Commission from Swedish Board of Agriculture (February 1998); the response to the European Communities by the United Kingdom (February 1998 and February 1999). These documents are either of a non-scientific nature or pre-date the issuance of the positive scientific opinion by the EC Scientific Committee in July 1997 or do favour the approval of Bt-531 cotton or are specifically refuted by the scientific arguments submitted by Argentina.

4.707 Regarding RRC 1445 cotton under Directive 90/220, the documentation provided by the European Communities is the following: the outcome of the written procedure (February 1998); the statement by Austria; Denmark's statement; the objections from France (February 1998); the Opinion of the Commission du Génie Biomoléculaire (January 1999); the letter by the Commissie Genetische Modificatie (December 1998); the excerpt from the minutes of the ScP meeting of COGEM (January 1998); the statement by Swedish Board of Agriculture (February 1998); and the response of the United Kingdom. These documents are either of a non-scientific nature or pre-date the issuance of the positive scientific opinion by the EC Scientific Committee in July 1997 or do favour the approval of RRC 1445 cotton or are specifically refuted by the scientific arguments submitted by Argentina.

Rebuttal of European Communities' responses to the Panel

4.708 The European Communities states in its response to the Panel's questions that "the internal procedures for the preparation of a Commission proposal for decision were ongoing"; referring to paragraphs 225 (Bt-531 cotton) and 232 (RRC 1445 cotton). Argentina considers that: (a) both specific products had obtained a positive scientific opinion in July 1998; (b) the European Communities' comment relates to the period after the positive scientific opinions had been issued; and (c) that period was followed by the "Common Position" when applicants were asked to prepare

for the future legislation – Directive 2001/18. This being the case, Argentina doubts that the internal procedures were ongoing, since so many additional requirements were constantly introduced.

4.709 Furthermore, the entry into force of Directive 2001/18 did not change the fact that the applications were not ongoing, since both Bt-531 cotton and RRC 1445 cotton were stalled in their respective procedures.

4.710 In its response to the questions put by the Panel, the European Communities describes how "Interservice Consultation" might work. Argentina considers that this "Interservice Consultation" stage – dealing with informal steps, seeking opinions from other areas on a text to be proposed, and capable of being repeated for a second time if needed – is proof of "suspension", specifically with respect to Bt-531 cotton and RRC 1445 cotton.

b.- NK 603 maize

4.711 This procedure was started in the year 2000 and received a positive scientific opinion from the scientific committee in November 2003. Despite this, shortly afterwards, on 8 December 2003, the European Communities once again started an "Inter-Service Consultation".

4.712 Argentina recalls that the "Inter-Service Consultation" phase was used to stall the procedures for Bt-531 cotton and RRC 1445 cotton under Directive 90/220, until the applications had to be resubmitted under Directive 2001/18. In the case of NK-603 maize, with a positive scientific opinion "already" issued under Directive 2001/18, the European Communities recommenced this procedural stage, thereby declaring once again its political intention of not allowing the approval proceeding to be completed: in fact, on 18 February 2004, there was no qualified majority within the Regulatory Committee.

Comments on the information provided on the CD ROMs

4.713 Regarding NK 603 maize under Directive 2001/18, with reference to the information provided by the European Communities on the CD ROMs, Argentina considers that none of these documents match the positive scientific opinion of the scientific committees dated November 2003. Although the European Communities submits information of a scientific nature, almost all of it pre-dates the positive scientific opinion: the response by Austria to the European Communities (August 2003); the additional comments of the SBB (April 2003); the SBB evaluation (no date); the SBB evaluation of the additional information (August 2003); the Opinion of AFSSA; the Opinion of the Commission du Génie Biomoléculaire; and the letters by AFSSA (March 2003, March 2003 and July 2003, respectively); the statement by the Swedish Board of Agriculture (February 2003); the ACRE advice (March 2003 and August 2003); the Annex B of ACRE advice (March 2003). The Scientific Committee must have taken all this information into account when it issued its positive opinion.

4.714 Regarding NK 603 maize under Regulation 258/97, though some of the information provided may be of a scientific nature, it pre-dates the positive scientific opinion of November 2003: the objection by Austria (no date); the SBB letter (February 2003); the SBB evaluation (no date); the Opinion by AFSSA (February 2003). The Scientific Committee must have taken all this information into account when it issued its positive opinion. The only remaining document – dated April 2004 – explains the minutes of the meeting within the Regulatory Committee and does not refute the positive scientific opinion.

c.- GA 21 maize

4.715 Although the application for GA 21 maize was withdrawn in September 2003, Argentina regards its withdrawal as a perfect illustration of the effect of the *de facto* moratorium and the "suspension or failure to consider". As already stated, GA 21 maize received a positive scientific assessment both under Directive 90/220– September 2000 – and under Regulation 258/97 – February 2002. Five years and two months had elapsed under Directive 90/220 and Directive 2001/18, and three years and eight months had elapsed under Regulation 258/97, before the applications were withdrawn.

Comments on the information provided on the CD ROMs

4.716 The European Communities only submits information regarding the procedure under Regulation 258/97. None of this information refutes the positive scientific opinion by the Scientific Committee of February 2002, since it is all dated earlier: the position of Austria (no date); the SBB report (September 1998); the letter and paper from the Danish Ministry for AGRI (April 2000); the letter from the National Food Administration (April 2000); the letter from the United Kingdom to the Commission (April 2000). The scientific committee must have taken all this information into account when it issued its positive opinion.

(c) "Undue delay"

4.717 Argentina reiterates that the European Communities has infringed its obligations under Article 8 and Annex C of the *SPS Agreement* in applying its control, inspection and approval procedures to the treatment of the various agricultural biotech product applications filed since 1998. Argentina will not repeat arguments already submitted, but feels it necessary to clarify and answer some of arguments contained in the European Communities' first written submission and oral statement.

4.718 Argentina completely agrees with the statement that: "The European Communities does not exclude that an omission or failure to act could be subject to the *SPS Agreement* (...)", and certainly Argentina also agrees that: "Whether a specific omission or failure to act constitutes a violation of the *SPS Agreement* depends on the nature of the obligation in question which is alleged to have been violated".

4.719 The European Communities argues that two conditions must be met for a determination of undue delay: firstly, the approval system must be a sanitary or phytosanitary measure within the meaning of Article 1 of the *SPS Agreement* and, secondly, the delay must be inconsistent with the corresponding obligations set out in the *SPS Agreement*. Argentina agrees with this EC explanation, and believes that both conditions are met. The European Communities itself, as well as the complaining parties, have accepted that the approval system set up under the relevant EC GMO legislation is "a procedure to check and ensure the fulfilment of sanitary or phytosanitary measures".

4.720 The EC legislation specifically contemplates time-frames for the different institutions involved in the complex and detailed procedure. The European Communities has not even tried to specify the reasons for its failure to consider, approve or reject products within the time-frames provided by its own legislation.

4.721 The Article 8 also requires all Members, "in the operation of control, inspection and approval procedures", to "ensure" the consistency of their procedures with the provisions of the *SPS Agreement*. Argentina reiterates its contention that the European Communities has not followed

the procedures envisaged in its legislation, and this has led to infringements of Article 8 and Annex C of the *SPS Agreement*.

4.722 Argentina stresses that the European Communities has not refuted the evidence with regard to undue delay, either generally or in particular, for each product of particular interest to Argentina.

4.723 Among the arguments put forward by the European Communities, one relates to force majeure, and this obviously cannot be applied to the present case; another expresses the idea "that delays are due to scientific considerations". Nevertheless, the basis of the scientific considerations is not identified in the European Communities' submissions with respect to any of the products of special interest to Argentina. The opinions of the scientific committees demonstrate precisely the opposite, since the majority of these committees issued their scientific opinions within the time limits foreseen by the legislation. Despite that, there was a lack of consideration or approval by the "non-scientific" institutions.

4.724 With respect to Annex C, paragraph 1(a), in order to verify and ensure how sanitary and phytosanitary measures are implemented, Argentina has compared the different treatments given to agricultural biotech products before and after 1998. The European Communities has failed to demonstrate that from 1998 onwards the proceedings to verify and ensure the implementation of sanitary and phytosanitary measures were begun and completed without delay, and, at the same time, in such a way as to result in a situation not less favourable for the imported agricultural biotech products.

4.725 With respect to Annex C, paragraph 1(b), Argentina rejects the European Communities' claim that "Argentina and the United States offer nothing beyond mere assertion that the European Communities has not done what it is required to do under the different obligations". In its First Written Submission, Argentina analyses Annex C, paragraph 1(b). Argentina rejects the European Communities' interpretation and reiterates the arguments proposed in its First Written Submission with reference to Annex C, paragraph 1(c). The procedures and information requirements are established within this legislative framework. A close scrutiny of the chronologies reveals the numerous occasions on which additional information was required from the applicant in connection with the products of special interest to Argentina. With regard to Annex C 1(e), Argentina again points out that paragraph 1(e) applies the term "reasonable and necessary" to the requirements for the control, inspection and approval of individual specimens of a product.

4.726 In this case, as previously explained, there is no basis for the European Communities' claims about the need to introduce changes in the control, inspection and approval procedures for agricultural biotech products. Argentina does not find it reasonable to ask for "additional" requirements, since these supposedly "additional" requirements were already envisaged in the former legislation and/or in the scientific committee opinions.

4.727 In conclusion, Argentina respectfully requests the Panel to find the European Communities' "undue delay" in each of the respective approval proceedings for agricultural biotech products of particular interest to Argentina to be inconsistent with Article 8 and with Annex C, paragraphs 1(a), 1(b), 1(c) and 1(e) of the *SPS Agreement.*

(d) Bans by various member States

4.728 Finally, with reference to the measures imposed by Germany, Austria, Italy and Luxembourg, Argentina first reaffirms what it stated in its First Written Submission. Moreover, since in its First

Oral Statement Argentina reserved the right to develop arguments relating to Article 5.7 of the *SPS Agreement*, we would also like to make the following observations.

(i) Article 5.7 as a defence for measures that would otherwise infringe Articles 2.2 and 5.1

4.729 Argentina does not accept the role that the European Communities proposes to attribute to Article 5.7, when it states that the complaining parties should have begun with an infringement of that Article before considering an infringement of Articles 5.1 and 2.2. Article 5.7 is a defence against the alleged infringement of, in this case, Articles 5.1 and 2.2, and is not to be invoked otherwise. The Appellate Body in *Japan – Agricultural Products II* has explicitly confirmed the character of Article 5.7 as an exception. It is up to the European Communities to invoke this defence, not up to the complaining parties to raise any infringement of Article 5.7.

4.730 With respect to the application of Articles 5.7 and 5.1, Argentina takes the following view of the European Communities' statement that Article 5.7 applies to "provisional measures": Article 5.7 is not applicable to any measure merely called or deemed to be "provisional" but rather establishes a first and fundamental requirement for any measure to be adopted provisionally; there has to be insufficient relevant scientific evidence.

4.731 This being said, Argentina maintains that as far as the member State measures are concerned the relevant scientific evidence was not insufficient, since there were specific scientific opinions by the EC committees first favouring the approval of these products and later rejecting the member State measures. Secondly, Argentina does not agree with the European Communities' affirmation that the phrase "as appropriate to the circumstances" in Article 5.1 would send the Panel back to Article 5.7. Therefore, we believe that Article 5.1 does apply in this case. Furthermore, we do not agree with the European Communities' statement that the risk assessment "carried out at the time when the original Community consent was given" can "serve, at least temporarily, as a basis both for the original Community consent, and for the member State provisional measures".

4.732 With regard to the relationship between Articles 5.7 and 2.2, Argentina would like to comment on the European Communities' assertion concerning the "demarcation line" between provisional measures under Article 5.7 and definitive measures under Article 2.2, which emphasizes the words "maintained" and "provisionally adopt" . We do not agree with this. The "demarcation line" should rather be based on whether there is or is not sufficient scientific evidence for the intended measure – Article 2.2 establishes basic rights and obligations, and in particular that "any" sanitary or phytosanitary measure must be based on scientific principles, and not on whether the measure is intended to be "definitive" or "provisional".

4.733 When a Member meets the four conditions of Article 5.7, this Member is entitled to adopt a measure under Article 5.7, but a failure to meet the first of these conditions will not cause an infringement of Article 5.7, but rather prevent the Member from "flipping out" of the general conditions of Article 2.2.

4.734 As indicated above, it is up to the European Communities to invoke Article 5.7 as a defence, and hence to bear the burden of proof. Argentina therefore considers that the member State bans infringe Article 5.1 and Article 2.2 and are not covered by the exception of Article 5.7 of the *SPS Agreement*.

4.735 Thus, there was a positive scientific opinion in favour of approving these products. Nevertheless, the member States may have considered this not to be sufficient and therefore adopted their own measures. Two of the four measures were not even meant to be provisional, although the

European Communities claims that they were meant to be: the Austrian and Luxembourg measures explicitly refer to "prohibitions". And the other two, despite referring to "suspensions" had not even been lifted as of June 2004.

4.736 We rebut the European Communities' claim that "the issue of fact is whether or not the member States are or are not provisional measures". Argentina considers that the issue of fact is whether the scientific evidence was or was not sufficient. We also strongly reject the European Communities' suggestion that "On the contrary, the complaining parties have actually asserted that the member State measures are provisional measures". Argentina has never asserted this.

(ii) Article 5.7, Article 5.5 and Article 5.6

4.737 Referring to the European Communities' response to the Panel's Question 19, Argentina once again points out that, Article 5.7 does not preclude the application of Article 5.5 of the *SPS Agreement*. Argentina considers that these articles relate to different obligations: whereas Article 5.7 relates to the amount of information needed to apply a measure and to the provisional character of that measure, Article 5.5 refers to distinctions in levels of protection which entail discrimination or disguised trade restrictions, and Article 5.6 concerns the degree of trade restriction resulting from the measure. On the same grounds, Argentina rebuts the European Communities' attempt to represent Article 5.7 as an article capable of excluding Articles 5.1, 5.5 and 5.6. We consider that Article 5.7 is not the pivotal article.

(iii) Article 5.7

4.738 With regard to the requirements of Article 5.7, we recall the WTO jurisprudence, according to which (1) the four requirements of Article 5.7 must be fulfilled in order to establish a valid provisional measure, and (2) should the first two requirements not be fulfilled, there is no need to analyse the other two, since resort to Article 5.7 cannot be justified if two of the requirements are not met. Indeed, the nonfulfilment of just one of the requirements precludes the invocation of Article 5.7 of the *SPS Agreement*.

4.739 With respect to the first requirement, the scientific evidence was not insufficient, since each product had received at least two positive scientific opinions, firstly in favour of approval and finally specifically rejecting the member States' attempt to introduce a "special safeguard". With respect to the second requirement, the member States did not base their measures on the "available pertinent information", since they disregarded the positive scientific opinions of the scientific committees. The evidence submitted by the European Communities in this case does not reflect these positive opinions, either because it is non-scientific or because it pre-dates the respective scientific opinion – which rejected it. With regard to the third requirement, the member States did not seek to obtain the further information necessary for a more objective risk assessment, because the evidence provided in this case does not reflect the positive scientific opinions given by the scientific committees. With the fourth requirement, as already mentioned, the member States did not review their measures: on the one hand, Austria and Luxembourg established prohibitions which they did not even envisage lifting. On the other, Germany and Italy formally established "suspensions" but never lifted or reviewed them.

(iv) No invocation regarding the de facto moratorium or the "suspension of processing and failure to consider specific applications of products of interest of Argentina"

4.740 Argentina recalls that the European Communities has invoked Article 5.7 only in relation to the member State measures. Were the Panel to find that the *de facto* moratorium and the suspension

and failure to consider are inconsistent with Article 5.1 or Article 2.2, Article 5.7 would not apply as a defence.

P. SECOND WRITTEN SUBMISSION OF THE EUROPEAN COMMUNITIES

1. Horizontal issues

(a) Burden of proof

4.741 A correct allocation of the burden of proof is fundamental for this dispute. The parties disagree on a number of factual and legal issues which are at the core of this dispute, but complaining parties seek to ignore. They seek a Panel finding based on the assumption that the risks posed by all the relevant GMOs are clear, and that the only reason why they have not all been approved is the "moratorium." Complaining parties do not engage in any meaningful product-by-product discussion. That does not mean that the European Communities has the burden of proof. Complaining parties must prove for each application that the absence of risk has been established and that no useful further investigation into the risks is underway. The case-law on burden of proof is consistent: the party invoking the existence of a certain situation bears the burden of proving it; to shift the burden, a *prima facie* case must be established. The establishment of the *prima facie* case cannot be reduced to mere assertion, without supporting evidence. The Panel must first verify if complaining parties have established a *prima facie* case in relation to each of their claims, before ascertaining whether the European Communities has refuted it.

(b) Risk assessment and the role of scientific opinions

(i) The meaning of "risk assessment" in the SPS Agreement

4.742 The term "risk assessment" in the *SPS Agreement* has to be understood in the broad sense of "risk analysis" as defined by the Codex Alimentarius and other international instruments. Risk assessment therefore encompasses three different aspects: (1) risk assessment in the narrow sense, i.e. as a "scientifically based process"; (2) risk management; and (3) risk communication. This conclusion follows from the definition of risk assessment given in paragraph 4 of Annex A. It also follows from paragraphs 2 and 3 of Article 5, which make it clear that in making an assessment of the risks, Members must take into account not only scientific but also economic and regulatory considerations. The list of factors to be taken into account is not exhaustive.

4.743 The United States and Canada seem to agree that at least some risk management considerations must be taken into consideration in an approval procedure. In particular, Canada takes the position that management considerations may only apply with regard to risks that are identified based on relevant scientific evidence. The European Communities disagrees. Particular risks can only be assessed and potentially identified in the risk assessment process on the basis of the available scientific information *at the time of the assessment*. Scientific knowledge may not be sufficient to clearly identify the risk. Moreover, risks may become known or relevant at a later stage. In this way the precautionary approach (or principle) becomes highly relevant. Prudent governments as risk managers and regulators are entitled to develop and apply appropriate safeguards to protect citizens and the environment. They are entitled to adopt risk management options, such as an appropriate general surveillance scheme, which are able to detect and identify any negative impact that was unforeseen or unidentified in the initial process of risk assessment. This approach is entirely consistent with international developments.

(ii) Risk assessment and the role of scientific opinions

4.744 Complaining parties generally seek to rely on the theory that the European Communities is bound to authorize GMOs for which European Communities' scientific committees have issued "favourable" scientific opinions. This position is flawed in a number of respects.

4.745 First, scientific opinions are only part of the risk assessment in a narrow sense, i.e. the scientifically based process of (a) hazard identification (b) hazard characterisation (c) exposure assessment and (d) risk characterisation. On the other hand, risk management and risk communication considerations are assessed by the regulator itself and not by those who deliver a scientific opinion (in contrast with the usual practices in North America). A complete risk assessment, within the meaning of the *SPS Agreement*, includes also these latter aspects.

4.746 Second, the scientific opinions by "EC committees" are not binding. There are several scientific committees with different mandates and at different levels in the European Communities. In case of scientific disagreement, the opinions of the European Communities' scientific committees do not overrule other scientific opinions, such as those issued by member States' scientific bodies. There is no obligation in SPS law – or indeed in any WTO law – for a regulatory power to effectively delegate to a single scientific committee only. This conclusion becomes particularly relevant in a federal or quasi-federal regulatory context.

4.747 Third, scientific opinions are limited in scope and, therefore, often do not conclude the risk assessment process, even in a narrow sense. The science on GMOs being in constant evolution, new risk considerations sometimes arise spontaneously and change the scope of the risk assessment, as in this case. The process of addressing risk/scientific issues, which are unresolved or new, may require the authorities to go back for a further assessment by an independent scientific body that had issued an earlier positive opinion, much later in the process of analysing a particular application.

(c) The *SPS Agreement*

(i) The scope of the SPS Agreement

4.748 The scope of the *SPS Agreement* is determined by Annex A.1, first paragraph. The list of risks or matters subject to the *SPS Agreement* is exhaustive, as it is clear from the text of Annex A.1, contrary to the more flexible approach taken with regard to the form of the measures subject to the agreement (Annex A.1, second paragraph, contains the word "includes", which is absent from the first paragraph).In determining the material scope of the *SPS Agreement*, it is necessary to rely on internationally accepted definitions of the terms in Annex A.1. On this issue, complaining parties are inconsistent among themselves, and individual complaining parties are internally inconsistent, as they rely on the definitions in other international instruments only when it suits their case. In any event, it is clear that the "common and ordinary" meaning approach advocated, in some instances, by complaining parties, to the exclusion of the international definitions, would not be sufficient. The common language definitions of SPS terms are often so vague and broad as to deprive of any meaning the categories and distinctions set out in Annex A.1. For instance, the definition proposed by the United States of the term "toxin" ("any substance which, when introduced into or absorbed by a living organism, destroys life or injures health") is capable of encompassing anything, from a chemical residue to a lead bullet.

4.749 There is a strong relationship between the *SPS Agreement* and the texts of specialised international organisations and bodies. Article 3 contains obligations on Members with regard to international standards, guidelines or recommendations. Some of the key terms in Annex A.1 are

themselves international standards (the Codex definition of contaminant is a "standard": Codex Standard 193, rev 1, 1995). Furthermore, Article 12(3) refers to the objective of securing from the relevant international organisations the best available scientific and technical advice for the administration of the *SPS Agreement*. This must include advice on the technical concepts that those organisations have developed and that were adopted by the drafters of the *SPS Agreement*.

4.750 In their attempt to stretch the scope of the *SPS Agreement*, complaining parties pay also little attention to the literal wording of Annex A.1, which carefully defines the specific circumstances in which the Agreement is to be applied. For instance, complaining parties continue with the careless assumption that it would be sufficient for them to establish that a measure concerns a "toxin" (or an "additive", or a "contaminant") for that measure to fall within the scope of the *SPS Agreement*. That is wrong as a matter of law. Annex A.1(b) refers to toxins "in foods, beverages and feedstuffs". Toxic characteristics of seeds or crops, or effects on non-target organisms, do not therefore fall within that provision, when the GMO does not fall within the concept of "food, beverage or feedstuff." Similarly, as regards the issue of antibiotic resistance, complaining parties disregard the fact that antibiotic resistance may be developed through ways other than the uptake of food or feed by humans or animals, so this issue could in any event not be apprehended solely under sub-paragraph (b) in so far as human health is concerned. Furthermore, complaining parties do not attempt to attribute a proper meaning to the terms "disease-causing" or "disease-carrying", ignoring the plain fact that the development of antibiotic resistance cannot be said to be a "disease" "caused" or "carried" by a GMO.

4.751 A measure can only fall within Annex A.1 if it is applied to protect human, animal or plant life or health. Therefore, the effects of the relevant GMO on non-living components in the environment, such as biogeochemistry, particularly carbon and nitrogen recycling through changes in soil decomposition of organic material, clearly fall outside the scope of the *SPS Agreement*. The same comment may be made with respect to micro-organisms or micro-flora which do not affect human, animal or plant life or health, but which are nevertheless part of the ecological equilibrium.

4.752 The negotiating history confirms that it was intended to have a precisely limited scope. Of particular note are the discussions that took place on whether environmental risks should be covered. Those that opposed this stressed that environmental risks were of a different nature and that rules designed for SPS measures would not necessarily be appropriate for environmental risks. This view ultimately prevailed, and consequently the *SPS Agreement* does not cover measures for the protection of the environment *as such* (or based on consumer concerns, moral grounds etc.)

(ii) Mixed acts

4.753 How to deal with measures that protect against the risks defined in the *SPS Agreement*, but that pursue also other legitimate objectives not covered by the *SPS Agreement*, is an important threshold issue. Nothing obliges Members to refrain from adopting single acts, incorporating two or more measures regulated by more than one WTO Agreement or provision. When a WTO Member adopts a single, indivisible act that pursues multiple legitimate objectives, some falling under the *SPS Agreement* and some falling under other WTO Agreements, that Member cannot be directed to withdraw or revise its measure unless it is found to be inconsistent with *all* relevant agreements.

4.754 In the case of a mixed act, the challenged act is not itself an SPS measure. It contains or includes an SPS measure. But it also contains or includes a TBT measure. To find that the TBT measure, because it is in the same act as an SPS measure, is itself transformed into an SPS measure, would be an error of reasoning and of law. Article 1.5 of the *TBT Agreement* does not change this conclusion. It is a jurisdictional conflict rule. The methods used to delimit the scopes of the Agreements are different. So a "technical regulation" could fall within the *SPS Agreement*. In that

case, Article 1.5 means that such a measure falls to be considered only under the *SPS Agreement*. This situation is different from the case in which a "technical regulation" pursues *not only* SPS objectives, but also *other* types of legitimate objectives.

(iii) Article 2 and Article 5.7 of the SPS Agreement

4.755 Article 2.2 contains an express cross-reference to Article 5.7. Article 5.7 is thereby incorporated by reference into the text of Article 2.2, which is entitled "Basic Rights and Obligations.". Thus, read in the context of Article 2, the text in Article 5.7 sets out basic rights and obligations, of equivalent status to the other basic rights and obligations set out in Article 2. The text of Article 2.2 shows that the drafters saw Article 5.7 as excluding the application of the substantive obligations in Article 2.2. The comma after the word "evidence" means that the words that follow exclude all the words up to the word "evidence." This is entirely logical. A concept of "necessity" is already referred to in Article 2.1 and is in any event built into the text of Article 5.7, because a Member may only act on the basis of available pertinent information, and only provisionally, in order to allow sufficient time for sufficient scientific evidence to be collected.

4.756 The relationship between the text of Article 2.2 and the text of Article 5.7 is therefore one of exclusion, not exception. Complaining parties disagree among themselves on this point, and their arguments are confused and unclear. *If it were true* that there is sufficient scientific evidence, the provisional measure would be inconsistent with Article 5.7, not fall to be assessed under Article 2.2. The exclusionary demarcation line between Articles 2.2 and 5.7 is based on whether or not the measure is provisional. The provisional nature of the measures must be motivated by the insufficiency of the scientific evidence, but an Article 5.7 measure is still provisional.

4.757 Provisional measures continue to be subject to the requirements of Article 2.3. They may not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members; and measures may not be applied in a manner that would constitute a disguised restriction on international trade.

(iv) Article 5.7 and the rest of Article 5 of the SPS Agreement

4.758 Once the text of Article 5.7 is considered in the appropriate context, its relationship with the other provisions of Article 5 becomes clearer. The fact that Article 5.7 is positioned after Articles 5.1 to 5.6 (and not after Article 5.1) also confirms its nature as a special regime applying specifically to provisional measures. Articles 5.5 and 5.6 would be difficult to apply if an acceptable level of risk still has to be established on the basis of a more objective assessment of risks.

4.759 Provisional measures are still subject to a full set of controls under the *SPS Agreement*. They must comply with the requirements of Article 5.7, as well as with Articles 2.1, 2.3 and 2.4. These provisions contain rules and obligations that are analogous to those set out in Articles 5.1 to 5.6, adapted appropriately to the provisional measures scenario. Thus, Articles 5.1 to 5.6 are irrelevant: provisional or temporary measures (whether the member State measures or the alleged temporary "standstill or moratoria") fall to be considered under Article 5.7; and delays are to be considered in accordance with Annex C. Even if Article 5.1 would be considered relevant, the words "as appropriate to the circumstances" enshrine an important degree of flexibility, whether in relation to the member State measures, or in relation to the alleged product specific delays. The obligation under Article 5.1 is only that measures be "based on" an assessment. This does not mean that the assessment itself necessarily automatically dictates the terms of the legislative measure to be adopted.

4.760 Complaining parties accept that under the *SPS Agreement* it is permissible for an EC member State to have a different level of protection compared to that applying elsewhere in the European Communities. Complaining parties are wrong to assert that, in the context of the safeguard measures, the member States are applying the same level of protection as at Community level. They are applying a level of protection that reflects their own particular circumstances. In the context of Articles 5.5 and 5.6, Members enjoy more flexibility in cases where they lack the elements to assess the nature or the extent of a risk. A comparison with other situations is difficult if each situation cannot be precisely defined or evaluated. In the context of Article 5.6, it is difficult to calibrate a measure if the extent of the risks or the availability or effectiveness of protection measures is unclear. In these circumstances, consistency with Articles 5.5 and 5.6 can only be considered taking into account the degree of flexibility present in those provisions.

(v) Article 5.7 of the SPS Agreement

4.761 Complaining parties assert that there is no relationship between the acceptable level of risk – or the analogous concept in the context of provisional measures – on the one hand, and the question of whether or not relevant scientific evidence is insufficient on the other hand. The European Communities does not agree. In the context of provisional measures, a full risk assessment has yet to be completed and the level of acceptable risk may yet to be finally determined by the legislator. However, the concept of sufficiency in Article 5.7 is relational, and must therefore refer to the matters of concern to the legislator. Members may not necessarily react identically with regard to potential risks and uncertainty. Depending on the specific circumstances prevailing in each country, scientific information may or may not be deemed sufficient to decide appropriate measures. A matter of concern for one legislator may not be of equal concern to other legislators because of climatic factors, eating habits, social (environmental) values, etc. There is no magic moment at which the available science become sufficient for *all purposes*. Rather, the actions of a legislator, whether definitive or provisional, in response to the available science, are a function of what that legislator is concerned about.

(vi) Article 2.3 of the SPS Agreement

4.762 Article 2.3 applies to measures, and is therefore irrelevant to any consideration of alleged delay. It refers to a situation in which identical or similar conditions prevail between Members, or between the territory of the importing Member and that of other Members. Complaining parties have not even alleged that identical or similar conditions prevail between their own territories and the territory of some other Member. Nor have they alleged that the European Communities discriminates between Members, including its own territory, in respect of its treatment of GMOs. The European Communities deals with GMOs in an even-handed way, without discrimination. Article 2.3 also states that measures should not be applied in a manner which would constitute a disguised restriction on international trade. The present case concerns the ongoing discussions within the European Communities about how to respond to the risks posed by GMOs, whatever their origin, any trade effects being entirely incidental. This is a basic right of the European Communities under the *SPS Agreement*.

(d) The *TBT Agreement*

4.763 Complaining parties assert that the Panel can resolve all the issues before it by reference only to the *SPS Agreement*. Only Canada and Argentina have invoked, in the alternative, several provisions of the *TBT Agreement*, but only in connection with the alleged product specific marketing delays and the member State measures. There is no inconsistency with the *TBT Agreement*.

(i) The meaning of the term "technical regulation"

4.764 The member State measures are not "technical regulations". The same applies to the alleged product specific delays. It is impossible to understand how an alleged delay – that is, silence or inaction – could lay down mandatory product characteristics. The observations of the European Communities in respect of Articles 2.1, 2.2, 2.9.1, 2.9.2 and 2.9.4 of the *TBT Agreement*, as regards the member State measures, apply *mutatis mutandis* as regards the alleged product specific delays.

(ii) Article 2.1 of the TBT Agreement – the issue of likeness

4.765 Neither the member State measures nor the alleged product specific delays are technical regulations. The Panel should reject the assertions made by Canada and by Argentina as regards the issue of "likeness". Under Article 2.1 of the *TBT Agreement*, "likeness" is properly understood as relating to products within the field of application of the technical regulation. Furthermore, GMOs are not like products to conventional products.

(iii) Article 2.2 of the TBT Agreement

4.766 The general EC GMO legislation might be a technical regulation but is not before this Panel. Complaining parties have not established that any actual *application* of the EC legislation – any delays or member State safeguard measures – is more trade restrictive than necessary. Complaining parties refer to the prohibition on marketing, pending authorization, but that is the very essence of the GMO legislation – not an application of it. The provisional absence of a final decision cannot be turned into an alleged measure.

4.767 There is no obligation to conduct a risk assessment under Article 2.2 of the *TBT Agreement*. In any event, the European Communities is currently in the process of assessing the risks in order to decide whether to authorize these products. The European Communities also contests the suggestion that Article 2.2 includes an obligation according to which the legitimate objective must actually be fulfilled. Whether or not the objective is actually fulfilled in fact is irrelevant, provided that the measure is capable of contributing to that objective. Opinions issued by the European Communities' scientific committees reflect questions posed at the time, and are themselves qualified. They may or may not be sufficient for the Commission or the Council, and may at the same time be insufficient for the member States.

(iv) Article 5 of the TBT Agreement – The meaning of "conformity assessment procedure"

4.768 The European Communities does not agree with the assumption that the EC GMO legislation constitutes a conformity assessment procedure within the meaning of Article 5 of the *TBT Agreement*. A conformity assessment procedure does not exist where there is room for the exercise of discretion, or the weighing of complex and to some extent conflicting considerations. It rather relates to the situation in which precise criteria have already been laid down, and it is simply a question of verifying whether or not a specific product meets those objective and precise criteria (such as weight, dimension, material composition, strength, electrical resistance, and so on).

4.769 In the light of the preceding observations, the European Communities does not agree that Canada and Argentina have demonstrated the relevance of Articles 5.1.1, 5.1.2, 5.2.1 and 5.2.2 of the *TBT Agreement*. Furthermore, there has been no "less favourable treatment" of GMO products, within the meaning of Article 5.1.1. Nor there has been any unnecessary obstacle to trade, within the meaning of Article 5.1.2, as the risks to the environment have a character of irreversibility that makes a stricter approach necessary than would be the case for reversible risks. Neither Canada nor

Argentina have discharged their burden of proving, with regard to the specific facts of each specific product application, any moment at which the European Communities has not acted "as expeditiously as possible", as required by Article 5.2.1. Argentina has made assertions concerning Article 5.2.2 which it has failed to substantiate with specific evidence.

(e) GATT 1994

4.770 If the *SPS Agreement* and the *TBT Agreement* are not applicable to the risks or "measures" contested by complaining parties, their claims will fall to be considered under the GATT 1994. The European Communities considers that Article XX of the GATT 1994 may in any event be relevant.

(f) WTO and other international agreements

4.771 The Panel must interpret the relevant rules of WTO law consistently with other rules of international law relevant to these proceedings, in accordanve with *US – Shrimp*. The 1992 Convention on Biological Diversity and its 2000 Biosafety Protocol "are relevant to this case", and that the provisions of *inter alia* the Codex Alimentarius Commission and other equivalent standards are relevant to these proceedings as *inter alia* "international standards, guidelines and recommendations" within the meaning of both the *SPS Agreement* and the *TBT Agreement*. None of complaining parties disavow the approach taken in *US – Shrimp*. However, they are inconsistent as to the consequences. On the relevance of international instruments, they provide inconsistent answers amongst themselves. Having proposed that no international instruments are relevant, they rely on the relevance of international conventions and texts if it suits them.

(g) Mootness

4.772 The alleged "general moratorium" has never existed. The present dispute has not become moot: rather, it lacked material object *ab initio*. The same applies to product applications that were no longer pending at the time of the establishment of the Panel. There can be no Community decisions on those products, and this was true at the time of Panel establishment, consultations, and before.

4.773 Mootness is relevant for the product specific claims where product applications have been withdrawn or decided *after* establishment of the Panel. Complaining parties urge that the Panel to rule on measures that no longer exist, but do not explain why the Panel should not apply a legal principle – mootness – that is recognized in jurisdictions around the world and commonly applied by international tribunals, including the ICJ. The WTO is *not* an exceptional case impermeable to the application of such a basic principle. The GATT/WTO case-law invoked by complaining parties does not support their claims. If the Panel decides to make findings on measures that no longer exist, the European Communities submits in the alternative that the Panel should not make any recommendations in respect of those measures.

2. Complaining parties' claims

(a) Product-specific delays

4.774 Complaining parties claim that there is a suspension of the approval system in respect of a number of specific applications. These acts are said to constitute at the same time a violation of certain provisions of the *SPS Agreement* and of its Article 8 and Annex C, as well as of provisions of the *TBT Agreement* and the GATT. They merely repeat their assertion that the alleged "general moratorium" has impeded the operation of the European Communities' approval process. They make generalised contentions, claiming that "x" number of years are "excessive" or "patently excessive".

They have failed to identify for each and every product-specific application the instances in which this "failure to apply or suspension" has materialised. They ignore the facts.

(i) Factual issues

The individual product-specific applications/notifications

4.775 There is no specific analysis of each application – only a few specific arguments in relation to a limited number of applications. Of these, several concern applications that have been withdrawn or, as in the case of Bt11 and NK603, brought to a conclusion by way of approval. Claims concerning those applications are not properly before the Panel: if the withdrawals or approvals took place before the Panel was established, the Panel has no jurisdiction; if they took place subsequently they have become moot. The European Communities therefore limits its second written submission to the small number of individual applications which remain outstanding. For all those products in respect of which no specific comments have been made, complaining parties must consider that all time spans in the chronologies submitted by the European Communities do not constitute delay or, if they do, that they are justified.

4.776 An analysis of the procedural steps taken in relation to the pending product applications shows that the few arguments put forward by complaining parties are either plainly mistaken or a misrepresentation of the facts. Some of the issues complaining parties typically ignore include the development of Stewardship programmes for post marketing guidance and monitoring (as recommended by European Communities' scientific committees themselves), the development and validation of detection methods, the update of applications *in agreement* with the applicant companies (the so-called 'interim approach'), and even the applicant companies' delays in providing necessary information. Complaining parties have therefore deliberately chosen not to discuss any of the scientific and technical issues that were raised and discussed during the approval procedures, and which explain the alleged "delays". The European Communities has provided full details about the pending product applications.

The time element

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

(a) To allow review by an organ of the European Communities on the basis of the requirements established by the EC legislation;

(b) To allow debate between the applicant, the member States (both as Competent Authorities and in the Regulatory Committee), and the Commission on scientific and/or technical issues;

(c) To address efforts to deal with risk management concerns (elaboration of monitoring requirements, adequate agricultural practices, etc.) as well as risk communication (labelling, etc.);

(d) To respond to delays voluntarily caused by the applicant and not attributable to the European Communities (multiple notification; insufficient data; bad quality of the data (e.g. molecular data); time to compile requested information or data etc.).

The scientific and technical nature of the reasons for the delays

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

(ii) Legal issues

Burden of proof

4.779 Complaining parties have not discharged their burden of proof. Their factual arguments are generic (general suspension, general failure, overall time elapsed, stalled/delayed at member State level, etc.), or just wrong (Commission's failure to submit proposal to Regulatory Committee, imposition of interim approach, indefinitely suspended, etc.). Assertion is no substitute for rigorous presentation of facts. They also tend to standardise their arguments and repeat them for several product-specific applications. Whenever complaining parties attempt to look at individual facts, they fail to indicate which period of time should be considered a delay and, in all cases, why the delay would be considered unjustified in the specifics of each application.

4.780 In all cases, all three complaining parties fail to address and comment on the numerous risk assessment and risk management issues that were discussed and advanced in the specific proceedings. All those issues should have been known to complaining parties before the initiation of these proceedings, through their contacts with applicant companies. Complaining parties do not appear to have available to them the information that would have enabled them to "exercise their judgement as to whether action under these procedures would be fruitful" in accordance with Article 3.7 of the DSU. The European Communities regrets the unwillingness of complaining parties to engage in meaningful consultations prior to requesting the establishment of this Panel.

Applicable law

4.781 Events in each specific application procedure may originate with considerations within the scope of different WTO agreements. The analysis to be applied to "mixed delays" is the same as that to be applied to mixed acts. Action and inaction are two different sides of the same coin. The European Communities therefore submits that the Panel cannot lawfully reach a final conclusion on the European Communities' behaviour, and make recommendations accordingly, on the basis of Annex C only.

4.782 The European Communities has set out the concerns that have arisen in respect of various product-specific applications together with the relevant WTO Agreement or Agreements that cover them. In almost all cases, the GATT, the *TBT Agreement* and the *SPS Agreement* are all potentially applicable by virtue of the regulatory concerns that underlie the European Communities' procedures. The superficially neat approach of complaining parties is inconsistent with the WTO Agreements. First, and as explained above, the approval procedure itself – which is not contested by complaining parties – does not only address SPS concerns. Second, disregarding the concerns actually addressed in the specific application procedures in effect ignores the provisions of Annex A.1. Complaining parties' approach must therefore be dismissed.

The *SPS Agreement*

4.783 The *SPS Agreement* contains two types of provisions, those disciplining the development of the sanitary or phytosanitary measures and those dealing with their application. Challenging the way in which applications for authorization are dealt with is a challenge against the application of a sanitary or phytosanitary measure. Thus, among the various provisions which complaining parties allege to have been violated, only Article 8 together with Annex C can be applied to the facts of this case. Articles 2.2, 2.3, 5.1, 5.5 and 5.6, on the contrary, all contain obligations concerning the development of a sanitary or phytosanitary measure (i.e. the SPS measure itself).

4.784 The distinction between provisions on development and on application of measures addresses two different regulatory needs arising at two different points in time: the need to ensure the creation of procedures which respect certain parameters and the need to ensure the management of these procedures according to other parameters. This is confirmed by Article 8, which contains two distinct legal provisions. In its first part, it submits "the operation of control, inspection and approval procedures" to the provisions of Annex C. In the second part, it provides that the procedures themselves must be in conformity with all other provisions of the *SPS Agreement*.

4.785 All parties agree that not every delay triggers a violation, and that both the "justification for" and the "duration of" the delay are relevant to determine whether the delay is "undue". That requires a case-by-case assessment. In the case of approval procedures for novel products, each product presents characteristics and specificities peculiar to it. These also vary according to the specific habitat/environment in which the product is going to be produced and marketed, and according to the level of protection that is sought. That a product may have been previously approved in other jurisdictions is not necessarily relevant.

4.786 The time limits in the legislation setting up the approval procedure cannot be but "standard", i.e. average, indicative. Members may not always abide by the standard processing periods, depending on the specific circumstances of each case. That is why paragraph 1(b) of Annex C only requires Members to publish the *standard* processing period or to communicate to the applicant the *anticipated* processing period. The purpose of this provision is one of transparency and is not linked in any way to the concept of "undue" in paragraph 1(a). The European Communities' legislation contains an indication of standard processing times but, at the same time, it has a built-in flexibility. Thus, any period of time during which further information is awaited from the applicant, or during which the scientific committee is analysing the dossier, is not taken into account.

4.787 In the absence of any serious analysis by complaining parties, who simply try to reverse the burden of proof, the European Communities would suggest a possible classification of delays and their justification, as follows:

(a) *The delay is caused by risk considerations which do not fall within the scope of Annex A*

(b) *The delay has been voluntarily accepted by the applicant*

(c) *The delay is caused by the entry into force of new legislation with stricter requirements*

(d) *The delay is not attributable to a Member (e.g. caused by the applicant)*

(e) *The delay is necessary to ensure compliance with existing legislation and relevant international standards*

(f) *The delay is caused by efforts to elaborate monitoring requirements, adequate agricultural practices and similar efforts to manage SPS risks*

4.788 In addition to these justifications, the European Communities submits that delays in approval procedures can also be justified by (g) the analysis of scientific and technical issues, and (h) risk communication matters such as labelling. In none of these cases is delay to be considered "undue".

The *TBT Agreement*

4.789 For a rebuttal of the claims related to the *TBT Agreement*, the European Communities refers the Panel to the horizontal section above.

GATT 1994 – Articles III:4 and XX

4.790 If the Panel finds that any delay in a product-specific application is inconsistent with any of the provisions invoked by complaining parties, the European Communities' actions are nevertheless justified under Article XX of the GATT 1994.

(b) The alleged "general suspension" or "general moratorium"

(i) Measures at issue

4.791 This Panel is being invited by complaining parties to identify the existence of a measure which is alleged to be a "moratorium", and to decide the entire case on that basis. This is notwithstanding complaining parties' evident inability to identify a single decision on the part of the European Communities which reflects such a "moratorium". If the Panel is to assess the consistency with WTO rules of this so-called "moratorium" – and if the European Communities is to bring its actions into compliance with its WTO obligations – the Panel must first define with absolute precision what the "moratorium" consists of and what the measure at issue is. A measure that is a "moratorium" must therefore be shown to be a "plan or course of action" to suspend a procedure, or "a decision not to decide." On the other hand, the "absence of a decision" is not the same thing as a "decision not to decide." The facts which the European Communities has put before the Panel show that there has been no such decision. There may be expressions of individual opinion associated with specific persons, or views of individual member States. But the European Communities itself has not taken any such decision.

4.792 First, even though the European Communities' legislation was being revised in the period 1998 to 2001, the authorization procedures were never suspended to await it's entry into force. The existing applications continued to be assessed on the basis of an "interim approach" which sought to anticipate the new Community legislation, in particular as regards certain risk management requirements. Second, during the period in question the new legislation entered into force and the above period of transition ended (i.e. in the case of Directive 2001/18 well before the establishment of this Panel). While the application procedures, in some cases, may have suffered delays during the transition period, they are now proceeding normally.

4.793 Complaining parties attempt to obtain a factual and legal ruling against the European Communities based on their description of a factual situation that allegedly is the effect, result or consequence of a *presumed* moratorium. That attempt seeks to replace legal and factual analysis with

mere assertion. Panels do not rule on "effects" without establishing the existence of a measure for which the WTO member is responsible. The question of what measure caused an observed effect cannot be left open. Moreover, complaining parties reinvent the definitions and meaning of the terms "moratorium" and "measure." The issue now is no longer that of a suspension of the approval process, but that of a "blockage at key stages in the process", regardless of whether the product applications have moved from one stage to the next. Complaining parties present as a measure, i.e. as a plan or course of action, the most diverse reactions of different players in relation to different applications, and they conveniently leave out everything that does not fit that picture. Such reactions are part of an internal decision-making process and as such do not have external legal effect. In so far as there is no act or final outcome of the decision-making procedure, what could be attacked is a failure to act but, in so far as the *SPS Agreement* is concerned, the only obligation in that respect is to act without undue delay.

(ii) The issues the Panel would have to address if there were a measure

4.794 If the Panel takes the view that there is a measure, it would have to consider the following issues: (1) whether the measure existed when the Panel was established and if so, whether it still exists; (2) to what extent that measure comes within the scope of the *SPS Agreement*; (3) whether the measure is inconsistent with Article 5.7, as the measure would have to be considered to be of a provisional nature applied for reasons of insufficiency of scientific evidence; (4) to the extent that the measure does not fall under the *SPS Agreement*, whether it is a technical regulation falling under the *TBT Agreement* or whether Article III:4 of the GATT 1994 would be applicable; and (5) possible justification under Article XX of the GATT 1994.

(c) The EC member State safeguard measures

(i) Facts and legal argument before the Panel

4.795 To assist the United States, the European Communities gives the example of Bt-176. One of the reasons for the Austrian measure is the issue of antibiotic resistance. Austria's concern is that the antibiotic resistance marker gene might be transferred to bacteria in the human gut, and that this might reduce the effectiveness of antibiotics used in medicine. This issue falls, at least in part, outside the *SPS Agreement*. Therefore, some of the reasons for the Austrian safeguard measure fall outside the *SPS Agreement* and, in relation to these reasons, the Austrian safeguard measure cannot be considered inconsistent with the *SPS Agreement*. The same analysis applies in relation to the other measures.

(ii) The concerns of the member States

4.796 The Panel asked the United States to explain its position in relation to the concerns cited by the member States. The United States answered that question by reference to what it alleges "the member State measures cite" – which is different. The United States thereby changed the terms of reference of the Panel's question, and thus failed to respond to the question actually posed. What is or is not expressly referred to in the member State measures themselves is not the point. Those measures are in some cases relatively succinct, as is often the case with provisional measures. The United States deliberately selects what it knows to be a narrow presentation of the issues, as part of its general strategy to force as much as it possibly can into the scope of the *SPS Agreement*. A true appreciation of the member State concerns emerges from a fair and complete consideration of the histories of each of these measures, and the procedural steps leading up to, and following, their adoption. The European Communities has explained in detail to the Panel and complaining parties the true scope of the concerns that resulted in these measures being adopted and maintained. The European Communities has also explained in detail which of these concerns fall within the

SPS Agreement, and which do not, and why. The United States has not responded to these explanations, but attempts to change the underlying terms of reference. The assertions that the complaining parties do make in respect of specific issues are manifestly erroneous.

Q. THIRD WRITTEN SUBMISSION OF THE UNITED STATES

1. Introduction

4.797 The European Communities has not even attempted to explain how the moratorium is consistent with its SPS obligations. Rather, the European Communities' core defence remains that despite the fact that the moratorium was widely and openly acknowledged by EC member States and EC officials, no moratorium in fact ever existed. The European Communities attempts to support this position through the submission of CDs containing documents related to the processing of applications, and through brief narratives describing the processing of pending applications.

4.798 However, the mere fact that certain applications made some progress through the approval process, or that some of the delays may not have been unjustified, most certainly does not disprove the existence of the moratorium. The moratorium was a political-level decision not to allow any product to reach the final stage of approval; it was entirely consistent with that decision for EC regulators to allow certain applications to make some progress – short of final approval – through the approval process.

4.799 Nonetheless, the United States notes that the application histories submitted by the European Communities do not support the European Communities' view that the moratorium never existed. Rather, the chronologies provide numerous examples of how the moratorium operated to prevent decisions being reached on the different product applications and in different stages in the approval process. In several cases, applications were completely ignored either at the member State or the Commission level for years. In others, member States lodged baseless objections and requests for information that unduly delayed various applications. The EC documents further show that the only risk assessments for the products at issue were those conducted by the lead competent authority and the European Communities' scientific committee, and that the results from those risk assessments neither conflicted with each other nor otherwise justified failing to reach a decision on the products.

2. The second written submission of the European Communities fails to raise any meritorious arguments

(a) The European Communities' concept of "mootness" is not relevant to this dispute

4.800 The concept of "mootness" that the European Communities has articulated is not of relevance to this dispute. The Panel's terms of reference under the DSU are "[t]o examine ... the matter referred to the DSB" in the request for the establishment of the Panel. In this case, those matters are the general and product specific moratoria and the member State safeguard measures as they existed in August 2003. The United States is not aware of, and the European Communities has not identified, any panel that, absent an agreement of the parties, has declined to examine a measure that was in force when its terms of reference were set. To the contrary, past GATT and WTO panels have examined and made findings on measures even if they were discontinued during the panel's work. As the panel wrote in the *India – Autos* dispute: "A WTO panel is generally competent to consider measures in existence at the time of its establishment. ... Panels in the past have examined discontinued measures where there was no agreement of the parties to discontinue the proceedings."

4.801 The European Communities in its second written submission has two responses, both of which are entirely without merit. First, the European Communities argues that "Remarkably, the complaining parties have made no attempt to explain why WTO Panels are prevented from applying a legal principle that is recognized in jurisdictions around the world and commonly applied by international tribunals ... ." The European Communities makes no attempt at defining precisely what "legal principle" of mootness the European Communities claims that the WTO should adopt; the European Communities fails to explain why the GATT and WTO panels cited above have in fact considered terminated measures, and the European Communities makes no attempt to explain how such a principle would be consistent with the text of the DSU. In short, what is "remarkable" is that the European Communities criticizes the complainants for relying on the text of the DSU and on past GATT and WTO practice.

4.802 Second, the European Communities tries to confuse the issue by addressing yet another question: namely, whether a Panel issuing findings on a terminated measure should also recommend that the DSB request the defending Member bring its measure into conformity with WTO rules. Plainly, under that same consistent GATT and WTO practice, panels do issue such recommendations. Furthermore, Article 19.1 of the DSU specifically provides 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." While the European Communities cites the *US – Certain EC Products* dispute as an example to the contrary, that dispute in fact involved an entirely different situation: the measure at issue in that dispute had ceased to exist *before the date of the request for establishment of the panel*.

4.803 Moreover, this is not a case in which the measure at issue has terminated. The United States certainly does not agree that two token product approvals – made only after substantial delays and pursuant to Commission decisions after failures by both the Regulatory Committee and Council to take decisions – suffice to signal that the European Communities has begun to process other outstanding applications without undue delay, as required by the European Communities' obligations under the *SPS Agreement*.

4.804 It is particularly important for the United States, and for the WTO rules-based system as a whole, that the Panel in this dispute comply with past practice and issue findings on the European Communities' moratorium as of August 2003. All but two of the products caught up in the moratorium remain unapproved. 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 EC member States believe that yet additional legislation must be adopted before the granting of new biotech product approvals. And, although the European Communities has now approved two corn varieties for import and consumption, *the European Communities has yet to approve under 2001/18 a single biotech product for planting in the European Communities.* Accordingly, if the Panel were to depart from the DSU and past practice and apply the European Communities' concept of mootness, the possibility is substantial that the European Communities – once freed from the pressure of this ongoing proceeding – would halt all further approvals.

(b) The European Communities again fails to provide any argument rebutting the widely known fact that the European Communities has adopted a general moratorium

4.805 In its second written submission, the European Communities presents a number of arguments why – despite the widespread acknowledgment by EC officials of the imposition of a general moratorium – the Panel should nonetheless find that no moratorium ever existed. The European Communities' arguments in fact lend further support to the existence of the moratorium.

4.806 First, the European Communities defines a moratorium as existing where "the process of decision-making is temporarily stopped." The European Communities then argues that no moratorium existed, because some applications continued to make some progress through the European Communities' elaborate approval procedures. This is a straw-man argument, and simply dispensed with. The United States has never claimed that *all* processing stopped; rather that the European Communities adopted a decision to ensure that no product ever proceeded to the stage of final approval.

4.807 Second, the European Communities relies on its adoption of a so-called "interim approach," under which the Commission "sought to anticipate the new Community legislation." Upon examination, however, the European Communities' reliance on the "interim approach" in fact supports the existence of the moratorium.

4.808 On the one hand, the European Communities explains that: "The 'interim approach,' thus, is not an act that was 'adopted' in any form, it is merely a practice that was followed on the basis of a political intent to try and achieve results in the approval procedures despite the transitional period of legislative changes." On the other hand, the European Communities describes the interim approach as follows: "On [12 July 2000], the Commission agreed on an 'interim approach' for relaunching the authorizations of GMOs, entailing the anticipation of the key provisions (labelling, traceability, monitoring etc) of the forthcoming new environmental legislation. The new requirements would be incorporated into the individual authorizations of GMOs granted under existing legislation." Taken together, the European Communities is representing that under the interim approach, "new requirements" would be incorporated into individual applications; but that this decision was not "adopted in any form" and was "merely a practice that was followed on the basis of a political intent."

4.809 The European Communities' own description of the "interim approach" confirms a fundamental position of the United States: that the European Communities, "on the basis of political intent," made a decision to apply its biotech legislation in a manner that differed substantially from the text of the legislation. And, once it is understood, as the European Communities acknowledges, that the European Communities would feel free to depart from its legislation by changing the approval requirements, it is not at all hard to understand that the European Communities might also decide to delay its final decisions based on the same political considerations.

4.810 In addition, the European Communities states that the "interim approach" would involve applying requirements of unenacted legislation. Those requirements, however, would not be finalized for at least three years after the European Communities' purported adoption of an interim approach in 2000. Particularly in light of the European Communities' admittedly politically-based approval system, it is not credible to believe that the European Communities would decide to depart from the face of its approval legislation by adopting new requirements on an extra-legal basis, while at the same time allowing products to move to final approval when the contents of those new requirements were not yet decided upon. It is no mere coincidence that the European Communities' first biotech approval in over five years occurred in May 2004 – less than one month after entry into force of the European Communities' new legislation.

4.811 Third, the European Communities now tries to explain away the numerous official acknowledgments of the moratorium by claiming that "all these statements" refer simply to the fact that no biotech products reached final decision. To the contrary, the statements uniformly refer to the "moratorium." And, as the European Communities itself informs the panel, a "moratorium" "may be defined as 'a postponement or deliberate temporary suspension of some activity.'" The United States submits that EC officials used the term "moratorium" because it precisely fits the situation: namely,

that the European Communities had decided not to allow any biotech product application to move to final approval.

(c) The European Communities' theory of "mixed delays" is meritless

4.812 The European Communities' novel theory of "mixed delays" is illogical and not supported by the text of the *SPS Agreement*. The *SPS Agreement* provides that Members "shall ensure [that] procedures to check and ensure the fulfilment of [SPS] measures ... are undertaken and completed without undue delay." Nothing in the text of the *SPS Agreement* suggests, as the European Communities contends, that a Member is excused from this obligation if the delay stems from a consideration outside the scope of the SPS Agreement.

4.813 The European Communities has instead invented an entirely new approach to applying the obligations of the WTO agreements. According to the European Communities' approach, as long as a Member can show that its measure is not inconsistent with a different obligation (in this case obligations under the *TBT Agreement*), then that lack of inconsistency with one provision can excuse the inconsistency with another provision. Apparently the European Communities would reverse the usual rule of treaty interpretation that there is no conflict between two obligations if satisfying one of them (for example the stricter one) would also satisfy the other. Instead, for the European Communities, where two obligations apply, only the lesser of the obligations matters. Furthermore, in this dispute the European Communities has not answered the question of how both the *SPS* and *TBT Agreements* could apply to the same measure given the texts of Article 1.5 of the *TBT Agreement* ("The provisions of this Agreement do not apply to [SPS] measures as defined in Annex A of the [*SPS Agreement*]") and Article 1.4 of the *SPS Agreement* ("Nothing in this Agreement shall affect the rights of Members under the [*TBT Agreement*] with respect to measures not within the scope of this Agreement").

4.814 Moreover, the European Communities' argument, if taken to its logical conclusion, would severely undermine the "undue delay" obligation in Annex C. For example, take a case in which a WTO Member delayed an SPS approval procedure for years – for arbitrary reasons, or to protect a domestic producer. Under the European Communities' suggested interpretation, the Member would not be in violation of the *SPS Agreement*, because the delay did not arise from the evaluation of a risk enumerated in the *SPS Agreement*. Surely, in such circumstances, the drafters of the *SPS Agreement* did not intend to excuse a Member from its obligation under Annex C to undertake and complete approval procedures without undue delay.

(d) The European Communities has no basis for its argument that the Panel should depart from the definition of "risk assessment" set out in the Agreement

4.815 The European Communities spends considerable time addressing the definition of "risk assessment" for purposes of analysis under the *SPS Agreement*. As an initial matter, the United States notes that no issue in this dispute would appear to turn on the definition of "risk assessment." In particular, the European Communities has not even attempted to identify any risk assessments that might support the general moratorium, the product-specific moratoria, or the member States safeguard measures. In any event, the definition of "risk assessment" is clearly set out in Annex A.4 of the *SPS Agreement*, and that definition is dispositive. The European Communities' discussion of alternative definitions of "risk assessment" is without merit, and should be disregarded.

(e) The European Communities continues not to present a serious defence of its member State measures

4.816 In its second written submission, the European Communities again fails to point to any contrary risk assessments, nor does it attempt to explain how Article 5.7 applies in light of the full scientific evaluations of these products by the European Communities' own scientific committees. The only new material in the EC's second written submission addressed to the member State measures is an exhibit titled "Table summarising the position in relation to the member State measures, as set out in the first written submission of the European Communities." The table, which purports to show the various reasons why the member States adopted each safeguard measure, should be given no weight by the Panel. It is not supported by any footnotes or any other references, and it appears to be nothing more than an *ex post facto* attempt to justify those measures. Moreover, even if the new table could be considered to have some evidentiary value, it does not begin to show how the safeguard measures might be consistent with the *SPS Agreement*. For example, the table provides no citations to any "available pertinent information" that might be used as part of an argument under Article 5.7, nor does the table explain how scientific evidence might be sufficient when the European Communities has issued affirmative risk assessments for each product.

3. The European Communities cannot explain away the gaps in its product chronologies

4.817 In its second written submission, the European Communities provides brief and conclusory narratives concerning some, but not all, relevant biotech product applications. Those narratives were submitted prior to the European Communities' submission, at the Panel's request, of a more complete set of product application documents, and thus do not refer to the more complete record currently before the Panel. Moreover, the European Communities' narratives are in many cases misleading. An examination of the actual documents in the application histories confirm that many products were subjected to undue delays in the form of lengthy periods of inactivity.

(a) EC Exhibit 69: Glufosinate tolerant and insect resistant (Bt-11) corn

4.818 The Scientific Committee on Plants (SCP) issued a favourable opinion on the application for Bt-11 corn under Directive 90/220 on November 30, 2000. In the narrative in its second written submission, the European Communities attempts to explain away a 2-year gap following the SCP opinion by asserting that "the Scientific Committee recommended a monitoring plan, and the proposal by the applicant remains unsettled." The actual documents, however, reveal that this assertion is untrue. The opinion did not identify any missing information or other deficiency in the application.

(b) EC Exhibit 65: Bt cotton (531)

4.819 The application for Bt cotton (531) under Directive 90/220 suffered a 3-year period of inactivity by EC regulators. The European Communities' justification of this gap is baseless. That certain member States objected at the Regulatory Committee does not justify the European Communities' refusal to act on the application. Indeed, the European Communities' legislative framework provides a specific avenue for further action where the Regulatory Committee is unable to come to a decision: the Commission is to forward the application to the Council "without delay" for a decision. Moreover, nothing in the record indicates that the applicant was ever requested to submit additional information to address the member State objections, nor that the basis of these objections was ever even notified to the applicant. Furthermore, nothing in the record indicates why the member States objected despite the SCP opinion that addressed the very issues covered in the objections. In sum, nothing in the record indicates that the European Communities undertook any process whatsoever to resolve the member State concerns.

4.820 The EC's second written submission also incorrectly states that the applicant "finally provided ... required additional information," which incorrectly implies that delays were due to outstanding data requests. The applicant, however, was not responding to any request from the European Communities, but, on its own initiative, provided additional information to the lead CA as, not surprisingly, the state of scientific knowledge had advanced since the first written submission of the application more than four years before.

(c) EC Exhibit 91: Roundup Ready corn (GA21)

4.821 The novel foods application for Roundup Ready corn (GA21) under Regulation was delayed at the member State level for 10 months while the lead CA completed its risk assessment, and then delayed for 17 months at the Community level before the SCF rendered its positive opinion in February 2002. The European Communities charges that the 17 months it took for the SCF to render its opinion was caused by the applicant. The truth is reflected in the European Communities' own chronology: The Commission asked the SCF for an opinion on 18 May 2000. Eleven months later, the SCF contacted the applicant for the first time, asking for additional information. Within less than one month, the applicant provided an answer to all questions. The European Communities' chronology provides no explanation, other than a cryptic notation about "lack of time," for the further 11 months it took for the SCF to issue an opinion on 27 February 2002.

4.822 After the SCF issued its positive opinion on 27 February 2002, 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 GM Food and Feed regulation was passed in September 2003. Almost two months passed after the positive SCF opinion in February 2002 with no activity at all on this application. The applicant then sent a letter on April 23, 2002 offering to narrow the scope of the application in order to facilitate the European Communities' evaluation. Despite the efforts of the applicant to remove any possible impediments, the Commission still failed to forward the application to the Regulatory Committee. Instead, 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." In other words, the European Communities simply halted the processing of this application in anticipation of possible upcoming changes to its regulations.

(d) EC Exhibits 78 and 85: Roundup Ready corn (GA21)

4.823 The European Communities did not discuss the deliberate release applications for Roundup Ready corn (GA21) under Directive 90/220 in its second written submission, based on the European Communities' unilateral determination that the issues regarding these applications were moot. In response to the Panel's request for more complete information, the European Communities subsequently produced a chronology and supporting documentation for this and other withdrawn applications. These documents confirm that these applications in fact suffered extensive, undue delays. The European Communities delaying tactics also significantly delayed the parallel novel foods application for Roundup Ready corn (GA21) under Regulation 257/98.

4.824 The first application for GA21 under Directive 90/220, submitted in the UK in 1997, was delayed at the member State level for 7 months – from March to November 1999. The European Communities' chronology gives the false impression that activity actually occurred on this application after April 1999 by referencing an ACRE meeting on September 16, 1999. As the minutes to that meeting show, however, GA21 was not on the agenda and was not discussed.

4.825 The second application for GA 21 under Directive 90/220 abruptly halted when it reached the Commission level. The SCP rendered a favourable opinion on 22 September 2000. At this point, however, all activity unexpectedly ceased at the Commission level. The Commission did not submit the application to the Regulatory Committee for a decision, and 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.

(e) EC Exhibits 82 and 94: MaisGuard x Roundup Ready (MON810 x GA21) corn

4.826 MaisGuard x Roundup Ready maize is produced by conventionally hybridizing two "parental" biotech products, MON810 and GA21. Progress on GA21 maize was a limiting step on MON810 x GA21's progress in the regulatory process.

4.827 The deliberate release application for MON810 x GA21 corn under Directive 90/220 was submitted in August 1999, but never reached the Commission level stage of review. The lead CA requested further information on 30 November 1999, and 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. The applicant provided translated documents 5 months later in January 2002. Thereafter, for over 1½ years, until the application was withdrawn, the only activity by the lead CA was a meeting held in April 2002.

4.828 The novel foods application for MON810 x GA21 under Regulation 258/97 shares a similar history. The application was submitted to the lead CA in February 2000. As noted above, the novel foods application for the single trait parent GA21 under Regulation 258/97 stalled at the Commission level. In its comments on the application for MON810 x GA21, Italy stated that "examination of the documentation relating to authorization should only be carried out after the marketing of GA21 has been authorized." To date, the application for MON810 x GA21 is still pending.

(f) EC Exhibit 66: Roundup Ready cotton (RRC1445)

4.829 The European Communities suspended the deliberate release application for Roundup Ready cotton (RRC1445) under Directive 90/220 for nearly four years – from February 1999 until the new legislation, 2001/18, took effect in January 2003. The European Communities' only defence of this 4-year gap is its statement that "the Regulatory Committee failed to reach a qualified majority because a number of member States maintained objections." This observation fails to recognize that following the Regulatory Committee vote, Directive 90/220 obliged the Commission to refer the application to the Council for a decision "without delay," a step the Commission failed to take in this case. The EC's second written submission also incorrectly implies that the objections raised by member States had not been adequately addressed in the SCP. In fact, the SCP assessed the safety of the product at issue based on detailed scientific considerations. Moreover, none of the member States objecting at the Regulatory Committee offered any competing risk assessments or scientific evidence for such objections. Neither did the Commission nor the member States identify any specific inadequacies in the SCP review. Finally, nothing in the record indicates that the Commission communicated any scientific concerns to the applicant, or that the Commission identified to the applicant any shortcomings in the application.

(g) EC Exhibit 64: Roundup Ready fodder beet (A5/15)

4.830 The deliberate release application for Roundup Ready fodder beet (A5/15) has been in the EU approval process for over 7 ½ years, having been submitted to the lead CA in February 1997. The SCP issued a positive opinion on June 23, 1998. The Regulatory Committee, however, did not meet

on this application for over a year and a half and, even then, did not take a vote. Four months later, the Regulatory Committee met once again, on 9 March 2000, and once again, did not vote. After that, the application remained in limbo and was never submitted to either the Regulatory Committee or to the Council. Over 4½ years after the SCP positive opinion and deadlock at the Commission level, the applicant was forced to re-submit its application under the new Directive 2001/18 on 16 January 2003.

4.831 The European Communities attempts in its second written submission to defend the Commission's inaction by pointing to objections raised by member States. However, the SCP considered the existing scientific evidence and the information provided by the applicant to be sufficient to address the objections voiced by the member States. In addition, the European Communities' assertion that there were outstanding requests for information is not true. The applicant had voluntarily provided additional information in an attempt to remove any possible remaining obstacle to a Regulatory Committee vote. The actual reasons for the delay were stated in a January 2001 meeting with the applicant: "[h]aving the revised directive fully adopted will not be sufficient. The 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 vote meeting, if there are no indications that the member-states are supporting the process and/or expected to vote positively. ..."

(h) EC Exhibit 76 and 96: Roundup Ready corn (NK603)

4.832 The NK603 deliberate release application was submitted in January 2000, and finally approved – although provisionally to a GM food and feed approval – in July 2004. The Commission approved the GM food and feed application for NK603 in October 2004. The processing of this application was delayed by the moratorium, and its ultimate approval does not signal the end of the moratorium.

4.833 The approval procedure did not progress "smoothly," as the European Communities contends. For both the GM food and feed and the deliberate release applications, the Regulatory Committee was unable to obtain a qualified majority vote. None of the documents provided by the European Communities support the European Communities' claim that those member States who abstained or voted against the approval of the product in the Regulatory Committee did so on the basis of "their own risk assessments." Member States' objections and the applicant's answers to these were taken into consideration by EFSA in delivering its positive opinions on NK603, and none of the member States questioned the validity of EFSA's favourable opinions. The Council similarly failed to reach qualified majority vote on the proposals. The fact that certain member States failed to cast their votes in accordance with the European Communities' own scientific committee's conclusions shows that member States continue to act based on political considerations.

(i) EC Exhibit 62: Oilseed rape (FALCON GS40/90)

4.834 The deliberate release application for oilseed rape (FALCON GS40/90) has been pending for over 8½ years. It was first submitted on April 1, 1996, and the lead CA forwarded it to the Commission on 25 October 1996. After member States objected during the review period, the SCP formally expressed a positive opinion on July 14, 1998. The Regulatory Committee did not meet until over a year later, on 29 October 1999, and, despite the positive opinion, failed to vote on the application. Four months later, on 9 March 2000, the Regulatory Committee met again, and again failed to vote on the application. Although the European Communities' chronology states that the failure to reach a vote was "due to further requests for information," the European Communities has failed to provide any document that confirms that statement. Instead, the record shows that the only request for information that could possibly have been made at that meeting was a request from Italy,

and the applicant responded to Italy's questions by 30 November 2000. The Commission never submitted a draft measure on the application to the Regulatory Committee again, and the application remained in this indeterminate state at the Commission for almost 3 years. The applicant finally had to submit an updated application under Directive 2001/18 on 16 January 2003.

(j) EC Exhibit 92: Bt-11 Sweet Corn

4.835 The novel food application for BT-11 Sweet corn was finally approved, under the GM Food and Feed directive that entered into force in April 2004, in May 2004. In its responses to the Panel's questions posed on 3 June 2004, the European Communities attempts to justify delays in the processing of the BT-11 application by claiming that "[b]etween October and early December 2003 [after the SCF positive opinion], three new risks assessment were issued by the member States, all of which conflicted with the SCF opinion." The European Communities' contention is unsupported by the record. No risk assessments were submitted during that time period.

4.836 The European Communities' incorrect assertion that competing risk assessments existed should not divert attention away from the real cause of the delays. When the BT-11 application was first evaluated at the Commission level in 2000, member States objected on the basis of the general moratorium. For example, as recalled by Denmark's Agriculture and Fisheries Council, "[i]n August 2000, Denmark submitted an objection to the approval of Bt11 maize in respect of the novel food regulation with reference to the declaration approved by Denmark, France, Italy, Greece and Luxembourg on the suspension of new GMO licences (the moratorium declaration), which was made at the Council meeting (environment) on 24-25 June 1999. The objection included a reference to the fact that, pending the approval of a regulation that would guarantee the labelling and effective tracing of GMOs and products derived from them, the moratorium countries would block any new licences for the cultivation and marketing of GMOs."

4. Many member State requests for information were not based on legitimate scientific concerns

4.837 The chronologies do not show – as the European Communities claims – legitimate scientific grounds for each request for information, and for the resulting delays, in the application histories. Rather, many supposedly scientific questions are requests that seek to force applicants prove the complete absence of hypothetical risks, in disregard of the safety data provided in the application. A pattern of deliberate delaying tactics is also illustrated by other types of scientifically baseless objections or requests for information that would have no relevance to an evaluation of the product's safety.

(a) Member State objections do not illustrate scientific disagreement or uncertainty

4.838 The record shows that none of the various member States' objections and requests for information qualify as competing risk assessments, "scientific disagreement" or "other scientific opinions" that would call into question the positive risk assessments conducted by the European Communities' own scientific committees. None of the objections made by the member States met the SPS definition of risk assessments. The objections were vague and general; did not identify and evaluate any specific risks posed; and were not supported by any scientific evidence that provided a basis for presuming a potential risk existed. Nor could the generic, vague statements in the member State objections and requests for information be considered "conflicting scientific opinion" of any weight that might counter the evidence presented in the product applications or in the risk assessments conducted by the lead Competent Authority or EC-wide scientific committees that demonstrated the safety of the products.

(b) Various member State objections relate solely to inappropriate "theoretical risks"

4.839 As the Appellate Body stated in *EC – Hormones*, "[T]heoretical uncertainty is not the kind of risk, which under Article 5.1, is to be assessed" under the Agreements. Yet the objections and related requests for additional information raised by member States were often based on just such theoretical risks, and this fixation on theoretical risks and their refutation is yet another manifestation of the general moratorium. For example, France objected to the approval of Bt Cry 1F corn, stating numerous times that additional animal studies were necessary "to prove the absence of risk," even though the existing data [*e.g.*, acute protein toxicity studies; compositional analyses] showed that no food safety risks could reasonably be anticipated. Yet, such proof is unattainable. As the Appellate Body explained, "[U]ncertainty [] always remains since science can never provide absolute certainty that a substance will not ever have adverse health effects." It is not possible for a risk assessment to evaluate every risk that a product might theoretically pose. It can, however, provide information that allows decision makers to make reasoned judgments about the risks it is reasonable to assume a product may present, based on the product's characteristics. Accordingly, these member State objections and requests for additional data are not the kind that could be used to justify a delay in an approval procedure under Annex C of the *SPS Agreement*.

(i) Requests for chronic toxicity tests, when acute studies show no effects

4.840 For all of the products at issue in this dispute, the results of the acute toxicity tests and the homology comparisons provide no indication for any concern and do not indicate the need for chronic toxicity tests. For the most part, proteins that would be expected to be toxic to mammals should express toxicity when tested at the high doses required in the acute oral test. None of the proteins at issue in these applications are similar to proteins known to have longer-term effects in mammalian species. In addition, the data submitted on all of the products at issue in this dispute indicate that the inserted proteins are rapidly degraded in mammalian gastric juices. These degradation products become nutrients, and there is no evidence that they specifically bind to or accumulate in mammalian tissues. Consequently, in the absence of any indication of concern in the acute toxicity tests, and in the absence of a structural relationship between the protein and any toxins, allergens or other proteins established to have longer-term toxicity, no further testing would normally be considered scientifically necessary to characterize any potential risks from the protein. Thus, requests for chronic toxicity tests can only be interpreted as a demand to disprove a theoretical risk – that, for some unknown reason, and contrary to all available data, the protein will behave differently than all other proteins.

4.841 Unwarranted requests for chronic toxicity studies contributed to delays in the consideration of the following applications: Roundup Ready Corn (Exhibits 76 and 96) and Roundup Ready (GA21) Corn (Exhibit 91).

(ii) Request for multiple whole food studies

4.842 Another example of requests to disprove hypothetical risks involves whole food studies. As a general matter, international consensus documents do not recommend the routine use of whole food studies. Rather, these documents indicate that such studies are not generally necessary in the absence of some indication for concern in the other data. Nonetheless, for all of the products at issue in this dispute, at least one whole food study was submitted as part of the application. In every case, the initial whole food study indicated no adverse effects. Based on the submitted safety data, as well as the scientific knowledge accumulated from experience with these products, there is no reason to believe that the results of the second – or in some cases third or fourth – whole food would differ in any way relevant to the safety of the product.

4.843 Unwarranted requests for additional whole food studies contributed to delays in the consideration of the following applications: Bt Cry 1F corn (1507) (Exhibits 74 and 75), Roundup Ready Corn (GA21) (Exhibits 78 and 85); MaisGuard (MON810) x RoundupReady (GA21) (Exhibits 82 and 94), Roundup Ready corn (GA21) (Exhibit 91), Bt-11 x Glufosinate Tolerant Sweet Corn (Exhibit 92), and Roundup Ready Corn (Exhibit 96).

(iii) Insistence that safety of hybrid products be proven independent of the data on the parent

4.844 Another example of demands by the European Communities that applicants disprove merely theoretical risks are repeated demands that separate assessments be conducted for each hybrid plant produced through conventional breeding from a previously evaluated biotech product. In these cases, member States requested additional evaluations without having a plausible scientific reason that the risk profile of the hybrid plant would be altered by breeding such that the existing safety data on the parents should be discounted. The products at issue were created by crossing (breeding) varieties of the same species. Both varieties are themselves used in food, and therefore are extremely unlikely to introduce traits that have not been in food before. In addition, plant lines used for such crosses generally have been subject to extensive backcrossing and field testing to ensure genetic stability. Finally, because the plant lines are closely related to each other, crosses between them are no more likely to be subject to unintended changes than conventional breeding between non-biotech plants.

4.845 A further consideration is that modern crop breeding relies on a knowledge base that has been developed over the last 50 years through breeding programs. Hybrid seed typically goes through at least 10 generations of breeding effort prior to the release of seed suitable for farmer cultivation. As a result, modern cultivars of major commercial crops are predictable in almost all aspects of performance (yield, disease resistance, maturity, etc.). The products at issue in this dispute use these hybrids and also employ the same methods of seed production. Consequently, any significant discrepancy that might theoretically arise from this cross would be expected to be detected in the field tests. The request for data on each hybrid corn developed also ignores all of the information about the safety of these plants that has been derived from the established processes in hybrid development, and their history of use. Thus, the mere fact that a product is the result of cross-breeding is insufficient to justify the need for additional studies to confirm the results of the existing data on the parents.

4.846 Unwarranted requests for additional studies of hybrid products contributed to delays in the consideration of the following applications: Bt-11 Corn (Exhibits 69 and 92), Bt Cry 1F corn (Exhibits 74 and 75), and Bt Cry 1ab x Roundup Ready Corn (Exhibits 82 and 94).

(iv) Vague requests for data on environmental effects

4.847 Another category of unwarranted information requests relate to the concerns expressed regarding various vague, potential environmental effects, which, upon examination, amount to yet additional requests to disprove wholly speculative risks. One primary example of these are concerns about potential changes to biogeochemical processes. For a number of reasons, these are risks that, based on what is generally known about the issue and the products, are so unlikely as to be purely theoretical. The available information does not indicate that any of these bioengineered plants present any potential for disrupting these cycles. The attributes of these products are such that there is no general scientific reason to expect that they would cause such effects; for example, the modification is not intended to function in a manner that affects these cycles. In addition, there is generally a duplication of function between many microbial groups, such that even in the unlikely event that there was a measurable effect on a particular group, it would have no effect on any global biogeochemical process. Moreover, given the immense variation in levels of biogeochemical processes due to such agricultural practices as cultivation, fertilization and no-till, it is difficult to envision that, absent a

truly massive change, any variation in biogeochemical processes that could be linked to the biotech plant could be determined to be significant. Any change of such a magnitude should have been discerned as part of the field trials. Absent any indication of unusual activity in the field trials, there is no reason to believe that positing such risks is anything more than mere speculation.

4.848 These types of vague and unwarranted requests for additional studies of environmental effects contributed to delays in the consideration of the following applications: Bt–11 corn (Exhibit 69), Bt Cry 1F corn (Exhibits 74 and 75), and Roundup Ready Corn (GA21) (Exhibits 78 and 85).

(v) Requests for studies on the composition of the food derived from the animal

4.849 A further example of requests related to unfounded and theoretical risk are requests for additional studies to provide confirmation that biotech animal feeds do not alter the composition of the food derived from animals consuming the feed. Where the compositional analyses demonstrate that the nutritional makeup of the feed falls within the normal biological range of variation that has been established for non-engineered, commercially available feeds, there is no general scientific reason to expect that any effects on milk or meat would occur. In addition, where it has been shown that the introduced protein is rapidly degraded or excreted, like any other dietary proteins, there is no scientific basis on which to speculate that these proteins would accumulate in meat or milk. Where a whole food study has been performed to confirm the results of the compositional analysis, and the study provides no indication of adverse effects or unexpected results, such concerns are wholly speculative.

4.850 Unwarranted requests for studies of the products of animals that consumed biotech feed contributed to delays in the consideration of the following applications: Bt (Mon810) x Roundup Ready Corn (Exhibit 82) and Roundup Ready Corn (GA21) (Exhibit 91).

(vi) Objections wholly without scientific merit

4.851 In several instances, member States asked for other types of additional studies that would yield information that would have no relevance in assessing the safety of the product at issue. These include: Bt-11 Corn (Exhibit 69) – information on potential weediness of maize; Bt Cry 1F (Exhibits 74 and 75) – Northern blot data on mature kernels and proteomic analysis; Roundup Ready Corn (Exhibit 76) – PCR analysis, additional allergenicity testing, protein conformation, and proteomic analysis; Bt Corn-Cry 1F (Exhibits 74 and 75) – additional field trials.

R. THIRD WRITTEN SUBMISSION OF CANADA

1. Introduction

4.852 In this submission, Canada responds to arguments and evidence advanced by the European Communities in its Second Written Submission, as well as arguments and evidence put forward by the European Communities in its earlier submissions to which Canada has not yet responded. Canada also addresses specific elements of the documentation made available by the European Communities that has not been specifically referenced or discussed in the European Communities' submissions. In doing so, Canada stands by its original claims and arguments, and this submission should be understood as an elaboration or clarification of those claims and arguments.

4.853 In what follows, Canada first addresses the issues characterized by the European Communities as "horizontal", systematically refuting the European Communities' arguments relating to risk assessment and the role or status of Community-level scientific opinions, as well as the

European Communities' interpretation of the relevant provisions of the *SPS Agreement*, the *TBT Agreement* and the GATT 1994. Canada then turns to the European Communities' arguments relating to Canada's claims and demonstrates, using the European Communities' own documents, why Canada's claims are well founded in fact and law.

2. Horizontal issues

(a) Burden of proof

4.854 Canada largely agrees with the summary of the case law set out in paragraphs 12-17 of the EC's Second Written Submission. Contrary to the European Communities' assertions, however, Canada has met its initial burden in respect of all its claims. The European Communities also misapplies the jurisprudence to the case at hand. Specifically, the European Communities' assertions regarding the need for the complaining party to demonstrate an absence of risk finds no basis in either the text of the WTO Agreements or the related jurisprudence. Finally, the European Communities claims that it has provided most of the evidence in this case. If the European Communities is suggesting that Canada has failed to produce adequate factual evidence to support its legal arguments, the suggestion is utterly without merit.

(b) The European Communities' mischaracterization of Canada's arguments

4.855 In its Second Written Submission the European Communities repeatedly mischaracterizes Canada's arguments. While Canada does its best to identify and correct all such mischaracterizations, it encourages the Panel to verify for itself the accuracy of the European Communities' "restatements" of Canada's arguments.

(c) Risk assessments and Community-level Scientific Committees

4.856 In what appears to be an effort to circumvent its obligations under the *SPS Agreement*, the European Communities claims that the risk assessments for the biotech products subject to the *moratorium* have not been completed yet. To support its argument, it: distorts the meaning of "risk assessment" as used in the *SPS Agreement*; downplays the role of the opinions of Community-level scientific committees; and, argues that the activities of the relevant regulatory committees should also be considered a part of "risk assessment".

4.857 The European Communities' attempt to equate the term "risk assessment" as defined in the *SPS Agreement* with "risk analysis" as defined by Codex Alimentarius relies on specious reasoning. First, the European Communities fails to advance a cogent rationale under the principles of treaty interpretation for relying on the Codex definition of "risk analysis". Second, the European Communities' suggestion that only part of "risk assessment" as used in the *SPS Agreement* must be a "scientifically based process" is at odds with the definition of "risk assessment" in Annex A and the requirements of Article 2.2 of the *SPS Agreement*. Third, the Codex definition of "risk analysis" is only relevant – if at all – to risk assessments in relation to food safety. Fourth, the European Communities' claim that, because the *SPS Agreement* includes labelling for food safety as an SPS measure, "risk communication" is a part of "risk assessment", is as incoherent as it is illogical.

4.858 The European Communities seeks to downplay the opinions of its own Community-level scientific committees by asserting that such opinions do not "over-rule" other scientific opinions. However, the European Communities fails to point out that the role of the Community-level scientific committees is precisely to address scientific disagreement amongst EC member States and to review the validity of objections raised by them. The Commission has consistently treated Community-level

scientific committee opinions as decisive and not as one opinion amongst many. Moreover, the European Communities fails to point to or provide any other "scientific opinion", by an objecting EC member State, that even approximates the rigour and thoroughness of the risk assessments conducted by the Community-level scientific committees or, in many cases, the original competent authority.

4.859 Although Canada agrees that, in principle, the concept of "risk assessment" provided for in the *SPS Agreement* involves both the identification and evaluation of risks and the evaluation of options to manage risks so identified and evaluated, by no stretch of the imagination can the activities of the European Communities' regulatory committees, or the EC member States, be considered as "risk management" activities. There is simply no evidence that the activities of the regulatory committees or the individual EC member States meet the standard set out in the *SPS Agreement*. The only examples of such activities that could conceivably meet that standard are to be found in the work of the Community-level scientific committees, including EFSA.

(d) Interpretive issues relating to the *SPS Agreement*

4.860 The European Communities' interpretive approach to the *SPS Agreement* is a sweeping assault on the obligations of that *Agreement*. The European Communities advances interpretations of the scope and obligations of the *SPS Agreement* that are inconsistent with the ordinary meaning of the text and undermine the *Agreement*'s object and purpose.

(i) The definition of sanitary and phytosanitary measures

4.861 The European Communities distorts Canada's arguments in relation to the meaning of "contaminants". In fact, Canada's arguments are consistent with Codex Standard 193. The European Communities' arguments about Stan 193 are also wrong in principle. The European Communities' assertion that "if the GMO is deliberately re-produced…in the full knowledge of the side effect, that side effect can no longer be described as 'unintentional'" is also flawed. Moreover, the European Communities' assertion that "'crop husbandry' does not cover laboratory work is at odds with the ordinary meaning of the term "husbandry".

4.862 To the extent that the European Communities' approval procedures are applied to protect against risks to human and animal health arising from toxins in food and feedstuffs, such procedures are SPS measures as defined in Annex A(1)(b) of the *SPS Agreement*. The European Communities suggests that the assessment of toxicity of seeds and crops could be undertaken for reasons unrelated to consumption by humans and animals, and that, by extension, such assessments of toxicity fall outside the scope of the *SPS Agreement*. However, apart from effects on non-target organisms, assessing for toxicity only makes sense if these products are used for human or animal consumption. This is reflected in the European Communities' legislation. The assessment of effects on non-target organisms, which typically involves the issue of toxicity, falls under either Annex A(1)(a) or (d).

4.863 The European Communities argues that that because allergens are neither "toxins" nor "diseases", they do not fall within one of the risks identified in Annex A(1)(b). However, the European Communities' own food safety legislation requires an assessment of potential allergenicity. Moreover, international standards, guidelines and recommendations for the safety assessment of biotech foods uniformly recognize the assessment of allergenicity as an integral component of food safety. In this light, it could not have been the intention of the drafters of the *SPS Agreement* to exclude from the scope of the *SPS Agreement* such an important aspect of food safety as the assessment of risks arising from allergens in food. Hence, for the purposes of the *SPS Agreement*, allergens in food and feedstuffs can and should be considered "toxins".

4.864 The European Communities advances interpretations of animal and plant life and health that are inconsistent with the ordinary meaning of these terms in their context and in the light of the object and purpose of the *SPS Agreement*. In particular, the European Communities claims that its legislation constitutes measures to protect the "environment" and "biodiversity" and that because these terms do not appear in the *SPS Agreement*, the approval regime, to the extent that it assesses risks to the "environment" and "biodiversity", is not an SPS measure. However, the types of risks relating to the "biodiversity" and "environment" that are addressed under the legislation are those that ultimately pertain to "animal or plant life or health." Moreover, the text of the *SPS Agreement* supports the conclusion that SPS measures include measures applied to protect the environment. In addition, any harm to biodiversity arising from the biotech products in issue amounts to harm to plant and animals, as defined in the *SPS Agreement*. The European Communities' argument that risks to "biodiversity" are not risks that fall within the scope of the *SPS Agreement* is at odds with the description of the scope of the Pest Risk Analysis (PRA) set out in International Standard for Phytosanitary Measures (ISPM) No. 11.

4.865 The European Communities argues for a narrow interpretation of the term "pests". Both premises of the European Communities' argument are without merit. First, the European Communities suggests that a "pest" must be a living organism and cannot be simply modified DNA. This is a straw-man argument. The focus of inquiry in terms of pest characteristics is the plant containing the transgene, not the modified DNA itself. Second, the European Communities' suggestion that "pest" under the *SPS Agreement* is limited only to organisms that cause injury to plants or plant products is inconsistent with the ordinary meaning of the term in its context.

4.866 The European Communities conflates concerns about the safety of biotech products with concerns about the use of herbicides in order to claim that the approval procedures for biotech products fall, at least in part, outside the *SPS Agreement*. This argument is without merit. The approval procedure for one type of product (crop) cannot be transformed into a non-SPS measure by linking the procedure to concerns related to the use of another type of product (herbicide).

(ii) Article 2 and Article 5.7 of the SPS Agreement

4.867 The European Communities' arguments relating to Articles 2 and 5.7 of the *SPS Agreement* are without merit. The European Communities seeks to juxtapose Articles 2.2 and 5.7 as separate but equal provisions, both representing basic rights and obligations. To lend credence to its arguments, the European Communities tries to establish a parallelism with Articles 3.1 and 3.3 and the Appellate Body's remarks in *EC – Hormones*. The European Communities' interpretive approach is bereft of logic, has no textual foundation and is untenable as a matter of treaty interpretation.

4.868 First, the European Communities tries to demonstrate that Article 5.7, through incorporation by cross-reference, is transformed into one of the "basic rights and obligations" of the *SPS Agreement*. This argument is completely at odds with any reasonable approach to treaty interpretation. Second, the European Communities seeks to rely on a comma to assert that the "necessity" and "scientific principles" elements of Article 2.2 are excluded from applying to an Article 5.7 measure. However, this argument would lead to the conclusion that Article 5.7 measures are not subject to any proportionality requirements, a proposition that is at odds with the jurisprudence, the structure of the *SPS Agreement*, and even the European Communities' own policy on the precautionary principle. Third, despite the European Communities' efforts to demonstrate that the relationship between Articles 2.2 and 5.7 parallels that between Articles 3.1 and 3.3, the reasoning finds no support in the text of the *SPS Agreement* or the existing jurisprudence. Fourth, the European Communities' proposition that provisionality is the "demarcation line" for the applicability of Article 5.7 is destined to fail for several reasons. The jurisprudence cited by the European Communities does not support its

proposition. Contrary to the European Communities' assertions, the complaining parties have never conceded that the measures in question are, in fact, provisional. The European Communities' observation that Article 2.3 continues to apply adds nothing to its arguments about the "demarcation line". The European Communities' attempted bifurcation between "provisional" and "definitive" measures is nowhere reflected in the text of the *SPS Agreement*. The cumulative nature of the four conditions set out in Article 5.7 does not support the European Communities' argument. To the contrary, the opening phrase of Article 5.7 supports Canada's argument that insufficiency of scientific evidence is the threshold. Finally, the European Communities contradicts its earlier statements when it claims it does not have the burden to demonstrate that the *EC member State national measures* are provisional.

(iii) Article 5.7 and the rest of Article 5

4.869 In trying to demonstrate that Article 5.7 excludes the application of the rest of Article 5, the European Communities mischaracterizes Canada's arguments. The European Communities also fails to explain convincingly why Articles 5.5 and 5.6 cannot apply to measures subject to Article 5.7. The European Communities demonstrates a complete misunderstanding of the structure of Article 5, misinterprets Articles 5.2 and 5.3, and misconstrues the role of the concept of "appropriate level of protection". Finally, the European Communities' arguments with respect to the relevance of Articles 5.5 and 5.6 contradict the European Communities' own policy statement on the application of the precautionary principle.

(iv) Article 5.1

4.870 The European Communities asserts that Article 5.1 of the *SPS Agreement* does not apply to the *EC member State national measures*, the *moratorium*, or the *product-specific marketing bans.* This is not supported by either the facts or the jurisprudence. The European Communities fails to cite any authority for the interpretive gloss that it seeks to impose on the phrase "as appropriate to the circumstances". Furthermore, the European Communities' assertion that, "in relation to the alleged product specific delays, there is no 'measure' within the meaning of Article 5.1" rings hollow in the face of the indisputable existence of a measure, namely, the *moratorium.* Thus, the European Communities' contention that the *product-specific marketing bans* are to be considered solely in relation to the requirements of Annex C of the *SPS Agreement* is incorrect. Finally, the European Communities relies on semantics in an effort to avoid the clear obligation set out in Article 5.1, but the fact remains that a rational relationship must exist between the selected measure and a risk assessment. In the case of the *moratorium*, there is no risk assessment at all, and in the case of individual product applications, no rational relationship exists between the *product-specific marketing bans* and repeated risk assessments of the products in question.

(v) Article 5.5

4.871 The European Communities misrepresents Canada's position in stating that the "Complaining parties accept that under the *SPS Agreement* it is permissible for a member State of the European Communities to have a different level of protection compared to that applying elsewhere in the European Communities". Canada has never stated this anywhere in its submissions. In any event, the European Communities' argument is purely theoretical. The European Communities has asserted, but not actually demonstrated, that the EC member States are imposing levels of protection that are different from that of the EC legislation. It has also failed to indicate in any way what these allegedly different levels of protection are and why they can be considered to be different from that reflected in the EC legislation. To the contrary the evidence supports the conclusion that the member States believe themselves to be applying the level of protection reflected in the EC legislation. More

generally, the European Communities' arguments with respect to the applicability of Article 5.5 are simply not relevant in this particular situation.

(vi) Article 5.6

4.872 Nothing in the European Communities' arguments in its Second Written Submission counters the *prima facie* case that Canada has already established.

(vii) Article 5.7

4.873 Canada has already demonstrated why Article 5.7 is not available to exempt the *EC member State national measures* from the requirements of Article 2.2, and why, in any event, those measures do not meet the requirements of Article 5.7. In contrast, the European Communities has not presented any detailed, measure-by-measure facts or arguments to demonstrate either that Article 5.7 applies so as to exempt the measures from Article 2.2, or that the measures in question meet the requirements of Article 5.7. The European Communities' efforts to convince the Panel that the measures in question were taken in the face of great scientific uncertainty collapse in the face of the fact that the European Communities is not faced with competing risk assessments of the stark contrast implied by the European Communities – in fact, as the evidence demonstrates, the European Communities is not faced with competing risk assessments at all – regardless of whether we are talking about pending applications or the member State national measures.

(viii) Article 2.3

4.874 The application of the approval procedure is subject to Articles 2, 5 and Annex C of the *SPS Agreement*. The European Communities' arguments ignore the case law on the relationship between Articles 5.5 and 2.3.

(ix) Annex C(1)(a)

4.875 In essence, the European Communities denies the existence of a *moratorium* and argues that it is justified in refraining from making a decision because scientific understanding may evolve and unforeseen risks may arise in the future. To accept this argument would render illusory the protection accorded by Annex C(1)(a). As a factual matter, apart from the fact that the *moratorium* is the primary cause of the delays, there is no insufficiency of scientific evidence so as to justify the delay in completing the approval procedures in question. While there may be circumstances in which a precautionary approach in selection of the risk management measure is warranted, such circumstances do not exist in this case and, in any event, a precautionary approach cannot override the requirements of Annex C.

4.876 The European Communities is really arguing that the *product-specific marketing bans* are justified under Article 5.7. However, the European Communities has not claimed the protection of Article 5.7, let alone demonstrated that its requirements have been satisfied. The European Communities appears to assume that Article 5.7 does not apply to the operation of inspection, control and approval procedures. This assumption is invalid. As Canada has already demonstrated, the European Communities' measures are subject, not only to Annex C, but also the requirements of Articles 2 and 5. If, as it now appears, the European Communities is attempting to justify the *product-specific marketing bans* on the basis of insufficiency of scientific evidence, the European Communities must claim the protection of Article 5.7 and demonstrate that the *product-specific marketing bans* meet the requirements of that provision. The European Communities has failed to do so.

(e) The *TBT Agreement*

4.877 The European Communities concedes that the relevant EC legislation contains technical regulations. The *product-specific marketing bans* arising from the *moratorium* are mis-applications of that legislation. The "application" of technical regulations is subject to both Article 2.1 and 2.2 of the *TBT Agreement*.

4.878 The European Communities' argument that the phrase "in respect of technical regulations" limits the scope of Article 2.1 of the *TBT Agreement* to situations where the products in question are both subject to technical regulations is untenable. There is nothing in those words to support the narrow scope proposed by the European Communities. Nor is the Biosafety Protocol relevant to a determination of "likeness". The test of "likeness" is fundamentally an examination of the competitive relationships between the products in the market place. Even if it is possible, in principle, for international legal instruments to constitute evidence for or against "likeness", the Biosafety Protocol does not provide any guidance in this respect.

4.879 The European Communities' assertion that only the European Communities' approvals legislation for biotech products is capable of being a technical regulation is not correct. Canada has showed that the *member State national measures* are also technical regulations. Furthermore, the European Communities' contention that the "Complainants have not established that any *application* of the EC legislation … is more trade restrictive than necessary" is without merit.

4.880 Canada is not contesting the European Communities' legislation as such. Rather, it is the *moratorium*, which converts the legislation's conditional marketing ban into a permanent and unconditional marketing ban, and the resulting misapplication of the technical regulation, that Canada is challenging. It is this misapplication of the technical regulation that Canada is challenging as being more trade-restrictive than necessary, contrary to Article 2.2 of the *TBT Agreement*. Thus, the central issue before the Panel is not whether the delays in the approval of specific applications are more trade-restrictive than necessary, but whether denying the approval of specific product applications on a systemic basis – essentially the misapplication of the EC legislation – is more trade-restrictive than necessary.

4.881 The European Communities also claims that Article 2.2 does not require the measure in question to "fulfil a legitimate objective". This argument finds no textual support in Article 2.2. On the contrary, the language of Article 2.2 requires a direct causal relationship between the measure and the achievement of the objective. The European Communities' interpretive approach would make it virtually impossible to gauge the necessity of a given measure.

4.882 It is simply astounding that the European Communities, at this late stage in the proceedings, still cannot inform the Panel what the EC member States' respective appropriate levels of protection were, or how those levels of protection differ from that found in the European Communities' legislation.

4.883 The European Communities asserts that "a conformity assessment procedure does not exist where there is room for the exercise of discretion, or the weighing of complex and to some extent conflicting considerations." This argument is without merit. There is no language in the definition of "conformity assessment procedure" to support the European Communities' characterization. The definition includes a broad, and non-exhaustive, list of activities, many of which include the exercise of discretion. It seems plain that if, as the European Communities concedes, these instruments are technical regulations, then the approval procedures laid down to ensure that the substantive requirements set out therein are met must be conformity assessment procedures.

4.884 The European Communities argues that, because "release into the environment" has a character of irreversibility, the delays in approvals do not violate Article 5.1.2 of the *TBT Agreement*. However, the irreversibility of the negative impact of a given product is only one consideration to take into account when determining whether the application of the conformity assessment procedure is more strict than necessary.

4.885 Although the phrases "as expeditiously as possible" and "without undue delay" use different words, their import is the same. Control, inspection and approval procedures under Annex C of the *SPS Agreement* and conformity assessment procedures under the *TBT Agreement* are intended to achieve basically the same object. In terms of their ordinary meaning, the phrases mean essentially the same thing. The European Communities has not advanced a different or competing interpretation of these phrases. Canada has demonstrated that the *product-specific marketing bans* amount to violations of Article 5.2.1 of the *TBT Agreement*. It is now for the European Communities to rebut Canada's *prima facie* case. To date, it has failed to do so.

(f) Interpretive issues relating to GATT 1994

4.886 The European Communities makes several claims relating to Article XX of the GATT 1994. None of these claims are supported by the facts, the text of the WTO Agreements, the jurisprudence or logic. The European Communities claims that Article XX of the GATT 1994 would be available to justify a violation of one of the provisions of the *TBT Agreement* or the *SPS Agreement*. This claim is completely untenable as a matter of treaty interpretation, and the European Communities offers no cogent argument in support. In regard to GATT 1994, the European Communities has not made out a *prima facie* case for justifying any of the violations of Article III:4 and Article XI:1 (in the case of Greece) of the GATT 1994 arising from the *product-specific marketing bans* or the member State national bans. Clearly, it is the European Communities, as the party invoking Article XX, who bears the initial burden of demonstrating that the requirements of Article XX have been met. Just as clearly, the European Communities has failed to discharge this burden.

(g) "Mixed" acts

4.887 The European Communities has argued that determining which agreement applies to the measures in question is an important threshold issue. However, the European Communities' bifurcation of the measures in dispute into SPS and non-SPS components is merely an attempt to distract the Panel from focusing on the underlying issues in this case, that is whether the *moratorium*, the *product-specific marketing bans*, the delay in processing biotech products, or the *EC member State national measures* are justified in the circumstances. The European Communities' efforts to characterize these measures as falling, in part, outside the scope of the *SPS Agreement* should be rejected. However, even if one were to accept for the purposes of argument that the measures in question involve the assessment of non-SPS risks, the measures are not justifiable under either the *SPS Agreement* or the *TBT Agreement*. Regardless of whether the measures in dispute are applied to protect against exclusively SPS risks or a mix of SPS and non-SPS risks, the conclusion is the same – the European Communities' own risk assessments have concluded that there is no justification for these measures or the delay in processing biotech applications.

(h) "Mixed" delay

4.888 The European Communities argues that the reasons for the delay arise from the assessment of risks that fall within the *SPS Agreement* and risks that fall outside of the *SPS Agreement*. Assuming that the approval procedures can be split into different components, the fact that the entirety of these procedures may not be covered by the *SPS Agreement* does not mean that the entire measure falls out

of the scope of that *Agreement*. Measures taken for SPS reasons are subject to the *SPS Agreement* regardless of whether or not the measures are also be subject to the *TBT Agreement* or GATT 1994. Otherwise a WTO Member would be able to avoid its obligation under Annex C(1)(a) by claiming that the delay arose for non-SPS reasons. Where a procedure falls both under the *SPS Agreement* and the *TBT Agreement* and a Member challenges delay in that administrative procedure under both *Agreements*, the assessment of whether Annex C(1)(a) of the *SPS Agreement* and Article 5.1.2 of the *TBT Agreement* have been violated should be done in parallel. In this case, the measures in question have given rise to violations under both Annex C(1)(a) and Article 5.1.2.

(i) Mootness

4.889 Whether a claim is moot depends on the particular circumstances of the discontinuation or modification of the measure, viewed in light of the resolution of the overall dispute. The jurisprudence of both the International Court of Justice (ICJ) and the WTO confirm this view. On numerous occasions, *GATT* and WTO panels have exercised their discretion and have delivered rulings on measures that had ceased to exist or had been modified after the establishment of a panel. Canada submits that the question of mootness is not relevant to Canada's claims related to the *moratorium* because the *moratorium* has not ceased to exist and the product applications listed in Canada's panel request remain unresolved. In addition, none of the EC member State national measures listed in Canada's panel request have been withdrawn.

3. Canada's claims

(a) Moratorium

4.890 The European Communities denies the existence of the *moratorium*, asserts that it is not a measure, argues, in the alternative, that it no longer exists, that it is of a "mixed" nature and, that it is justified as a provisional measure under Article 5.7 of the *SPS Agreement*.

4.891 Essentially, the European Communities argues that no *moratorium* exists, and that the complaints arise from a series of coincidental delays. According to the European Communities, this case should be viewed exclusively through the lens of Annex C of the *SPS Agreement*, and the sole legal question is whether the delays in this procedure are "undue". While the complaining parties have advanced claims under Annex C of the *SPS Agreement*, to characterize this dispute as merely concerning procedural delays is to demonstrate a misunderstanding of its essence.

4.892 First, the evidence shows that the *moratorium* is more than a series of isolated procedural delays. Second, the European Communities' arguments rest on the faulty premise that the operation of the approval procedures for biotech products is insulated from "political" decision-making. Third, the European Communities attempts to deflect analysis of the hard questions about the necessity of effectively suspending an approval system for six years in order to adopt legislative amendments and whether this effective suspension is consistent with the European Communities' WTO obligations. In this case, the suspension of the approval regime for biotech products, and the resulting delay in the completion of those approval procedures, is not justified. Finally, the European Communities seeks to blame the victim.

4.893 The European Communities argues that, because it is not "possible to identify with any precision the precise acts and omissions" that constitute the *moratorium*, the *moratorium* cannot be a measure for the purposes of the *SPS Agreement*. Evidently, the European Communities has not asked its own officials what they meant when they used the term "*moratorium*". In any event, the meaning is abundantly clear from the context in which it was used.

4.894 The European Communities argues that the limited processing of some product applications necessarily implies that there is no *moratorium*. This self-serving interpretation of "*moratorium*" should be rejected. Canada has never argued that the *moratorium* has resulted in the complete shutdown of all aspects of the approval procedures for biotech products. It is at critical junctures in the approval procedure that the relevant EC body effectively has decided not to decide, thereby putting off making decisions on product applications. It is the effective "decision not to decide" that is the source of the *moratorium*.

4.895 The European Communities argues that if the Panel were to conclude that the *moratorium* is a measure, it would have to determine to what extent the *moratorium* comes within the scope of the *SPS Agreement*. The European Communities largely shifts the onus onto the Panel to develop the European Communities' arguments in this regard. However, the European Communities has admitted that the approval procedures for biotech products are, at least in part, SPS measures. Given that the approval procedures are – at least in part – SPS measures, the suspension of the completion of these procedures on the purported basis that the procedures were not adequate to protect against the risks assessed and managed under these procedures, should be considered an SPS measure. Consequently, even on the European Communities' terms, the *moratorium* is, at least in part, an SPS measure.

4.896 The European Communities has failed to advance any detailed argument in response to Canada's claims that the moratorium violates Articles 2.2, 2.3, 5.1, 5.5 and 5.6. Instead, the European Communities asserts that only Article 8 and Annex C apply. This argument ignores the text of Article 2.2 and the fact that SPS measures can be both procedural and substantive in nature. In relation to the *moratorium*, the European Communities asserts vaguely that "the measure would have to be considered to be of a provisional nature applied for reasons of insufficiency of scientific evidence." In this regard, the European Communities appears to rely on the Panel to divine the European Communities' arguments.

(b) The product-specific marketing bans

(i) Oilseed Rape Ms1xRf1 and MsxRf2

4.897 As Canada explained in its Second Written Submission, the European Communities' assertion that for all intents and purposes these products are approved is disingenuous. This is demonstrated by the European Communities' own official documents. In its Second Written Submission, the European Communities fails to advance any argument to refute Canada's claims regarding the *product-specific marketing bans* in relation to these two products.

(ii) Oilseed Rape Ms8/Rf3

4.898 In paragraph 168 of its Second Written Submission, the European Communities fails to mention a number of significant facts, and actually provides evidence that supports Canada's original contention that the product application was not put to a vote. Despite the existence of a positive SCP opinion, despite a delay of 15 months between that opinion and the submission by the Commission of a proposal for approving the product, and despite the readiness of the applicant to meet the extralegal requirements set out in the so-called "Common Position" on revisions to Directive 90/220 and to submit additional information that met those requirements, the Regulatory Committee never actually voted on the product application.

4.899 In relation to paragraph 169, the European Communities fails to point out that the notifier's attempts to comply with the "interim approach" were actually rebuffed by Belgium because of concerns that accepting the applicant's efforts would lead to the lifting of the *moratorium*. Even after

the Belgian scientific experts recommended approval of the revised post-marketing monitoring plan and proposed agricultural guidelines for Ms8xRf3, the Belgian government reiterated its position that this was not to be interpreted as favouring the lifting of the *moratorium.* In short, there is no question that the *moratorium* was being maintained and was having a direct and observable effect on the processing of the application for Ms8xRf3.

4.900 The European Communities also fails to say that the submission of further information by the notifier was necessary, not because of inadequacies relating to the existing legal requirements, but because the application did not meet requirements that had yet to be defined, clarified or given legal effect. Even Belgium recognized that it would be "improper government practice" to require applicants to meet ever-changing requirements.

4.901 In paragraph 172, the European Communities' assertions concerning "significant new risk information", specifically the UK Farm Scale Evaluation ("FSE") and the impact of the herbicide regime associated with the Ms8xRf3 on farmland biodiversity, are specious for several reasons. First, seed approval legislation is distinct from the pesticide approval legislation. In no other instance are the potential impacts on farmland biodiversity by the associated herbicide regime used as a rationalization for not approving a seed. Second, the European Communities has selectively used concerns about farmland biodiversity to block biotech crops while ignoring other issues that may have an impact on farmland biodiversity. Third, and most startling, EC member States have actually authorized the use of the herbicide formulation in question for general use as well as for specific use on genetically modified herbicide-tolerant crops.

4.902 By conditioning biotech product approval on an assessment of risks arising from associated pesticide use, Belgium side-steps the European Communities' own existing pesticide legislation and imposes new barriers to the approval of herbicide-tolerant biotech products, barriers that are not imposed in comparable situations involving herbicide-tolerant non-biotech crops. This demonstrates that Belgium's attempt to use concerns about herbicide use as a rationale for blocking the approval of Ms8xRf3 is arbitrary and unjustified.

4.903 Regarding the FSE, it is important to be clear about its conclusions. The FSE clearly stated that the potential impact on farmland biodiversity was not caused by the biotech product, *per* se, but by the weed management regime used by the farmer. Belgium's refusal to recommend the approval of Ms8xRf3 due to of the FSE is really because the herbicide associated with the crop is <u>too effective</u> in controlling weeds!

4.904 In addition, the UK authorities recognized that many other factors contribute to changes in farmland biodiversity, from the presence of uncropped fields, margins or strips to the type of crop cultivated. The Belgian Competent Authority appears to ignore these conclusions and similar ones of its own scientific experts and seizes upon only one factor that could impact on farmland biodiversity, the use of the herbicide, to the exclusion of all other factors. This is all the more surprising given that one principal criterion for approval of plant protection products is their efficacy. The failure to place the concerns about farmland biodiversity into a broader context demonstrates that Belgium's actions are arbitrary and unjustified.

4.905 The European Communities' assertion that the use of non-selective herbicides, including glufosinate-ammonium, creates unique or unacceptable environmental risks is without merit. Several EC member States have authorized the use of glufosinate-ammonium in accordance with the requirements for plant protection products set out in Directive 91/414/EEC. Incredibly, the Belgian pesticide regulatory authorities have already authorized glufosinate-ammonium for use with genetically modified herbicide tolerant oilseed rape, including Ms8xRf3. Thus, in an act of

extraordinary inconsistency, the Belgium competent authority under Directive 2001/18 refuses to recommend the approval for cultivation of oilseed rape Ms8xRf3 on the basis of concerns relating to the use of a herbicide that its own government agencies have already approved!

(iii) Oilseed Rape GT73

4.906 Now that the European Communities has provided what appears to be complete documentation, any remaining uncertainty about time line calculations can be removed. That documentation shows that the Dutch Competent Authority required at least forty-two months to conduct the initial assessment, instead of the ninety days set out in the legislation. The European Communities' assertion that "this period of time was entirely dedicated to resolving scientific and technical issues" disguises the fact that it took the Competent Authority over three and one half years to issue the initial assessment. It is not reasonable simply to attribute this to "resolving scientific and technical issues". The "slippage in the timetable" caused by the issue of confidentiality should not be attributed to the applicant where the "slippage" arises from an applicant seeking to ensure the fulfilment of the European Communities' obligations, both under the *SPS Agreement* and domestic law, relating to the protection of legitimate commercial interests.

4.907 The movement of the application from the Netherlands to the Community-level in January 2003 does not negate the existence of the *moratorium*. To the contrary, the continued excessive delays arising with each procedural step support a finding that the *moratorium* continues to be maintained. As to the objections lodged by EC member States, Annex II to this submission demonstrates that the objections were without scientific merit. The European Communities' assertions misrepresent or gloss over a number of salient facts, including the failure by the European Communities to respect its own time limits, the apparent disregard by the EC member States for EFSA's opinion at the Regulatory Committee stage, and the failure of Germany to act in a manner consistent with its own previous statements with respect to the conditions necessary to lift the *moratorium*. In short, the repeated, unjustified delays created by the EC member States demonstrate beyond question that the European Communities has violated its obligations under Annex C of the *SPS Agreement* or, alternatively, Article 5 of the *TBT Agreement*, as well as providing clear and compelling evidence that a *moratorium* on the approval of biotech products has been put in place and continues to exist.

(c) The EC member State national measures

4.908 The European Communities' asserts that the complaining parties have not engaged on the facts; in fact, it is the European Communities that has been remarkably reticent in examining the facts and scientific evidence relating to the *EC member State national measures*. This is reflected in the limited space allotted in the European Communities' submissions to an examination of the facts and science surrounding these measures. The table appended to the European Communities' second written submission is completely unsupported by any arguments or references to specific exhibits. Most of the facts and science relating to these measures comes from the complaining parties.

4.909 Nowhere in its submissions does the European Communities disclose that it has already requested the EC member States to lift their bans, nor does it put into evidence any of its correspondence with those member States in this regard, even though new evidence shows that the Commission favours a repeal of the bans.

4.910 The European Communities also repeats its assertion that "[a]ll the Complainants originally stated that member State measures are provisional measures". This assertion is as incorrect now as it was when it was first made. To the contrary, Canada has noted that, despite the requirements of the

European Communities' own legislation, and despite the numerous and uncontradicted risk assessments declaring these products to be safe, the bans have been maintained, thus belying the notion that these measures are of a temporary nature.

4.911 *France's* decision to extend its bans until October 2006 was not taken in an informational vacuum. On 13 February 2004, the French government received expert scientific advice from its own scientists that importing and marketing oilseed rape seeds derived from Topas 19/2 for processing and animal feed purposes hold no greater risks than importing and marketing conventionally bred oilseed rape seeds. Despite this advice, France extended its ban on oilseed rape seeds derived from Topas 19/2 until October 2006, when the original authorization for this product expires.

4.912 In regard to the cultivation of oilseed rape that has been genetically modified for herbicide tolerance, the French scientific experts found no direct risks to the environment. Any concerns were limited to potential indirect environmental and agronomic management issues arising from the use of the herbicide. As Canada has already demonstrated, however, any concerns held by France with respect to oilseed rape seeds derived from Ms1xRf1 because of the indirect impacts associated with the herbicide glufosinate-ammonium are belied by the fact that France has already authorized the herbicide in question for uses relevant to biotech oilseed rape cultivation, including total weed elimination.

4.913 Regarding the European Communities reference to "different levels of protection sought by different legislators", Canada notes that the European Communities has yet to actually identify these allegedly different levels of protection or the specific products to which they apply, and has yet to identify the specific "legislators" to which it is referring. To assert, as the European Communities does, the national bans are justified on the simple grounds that some mysterious legislator somewhere has in mind an unspecified level of protection, one that is allegedly higher than that intended to be achieved by the Community legislation, is to make a mockery of the rigorous requirements found in the *SPS Agreement* with respect to basing SPS measures on scientific evidence and a risk assessment.

S. THIRD WRITTEN SUBMISSION OF ARGENTINA

1. Introduction

4.914 Argentina's further comments concern, in particular, the information submitted by the European Communities on 30 September 2004 (last set of 5 CD ROMs). In addition, having reserved its rights to develop arguments related to the *TBT Agreement*, Argentina would like to put forward certain comments in this regard as well.

4.915 Argentina wishes to reaffirm that the information provided by the European Communities did not match the positive scientific opinions already issued by the European Communities' scientific committees, which favoured approval of the stalled agricultural biotech products. Moreover, this additional information tends to confirm the information submitted by the European Communities at an earlier stage of this process, in the sense that the European Communities has prevented the applications for agricultural biotech products from reaching final approval, despite the positive scientific opinions. As if this were not enough, the European Communities has itself explicitly acknowledged that this additional information is not relevant to the case. In this respect, Argentina would like to focus on the European Communities' acknowledgement that the relevant information has already been provided. However, taking into consideration the relevant information submitted by the European Communities, Argentina would reply to the additional documentation submitted by the European Communities as follows.

2. Arguments

(a) The *de facto* moratorium

(i) The existence of a de facto moratorium

4.916 Although the European Communities has repeatedly acknowledged the existence of a *de facto* moratorium, it also insists on distorting this fact by referring to issues such as the alleged need for a precise definition of a *de facto* moratorium or the alleged need for specific identification of acts or omissions within the European Communities or the need for a "plan or course of action" or a "decision not to decide".

The "Inter-Service Consultation" phase

4.917 Argentina affirms again that the European Communities has admitted the existence of a *de facto* moratorium. Apart from the declarations and statements made by EC officials, we have demonstrated that the scientific evidence supporting approval of the agricultural biotech products has not been deferred or postponed for mere procedural reasons. From the information on the CD ROMs, it is evident that the European Communities and/or its member States tried to refute or ignore the positive scientific opinions of its Scientific Committees, in order to stall the approval or marketing of agricultural biotech products.

4.918 As we have shown, there are relevant stages within the proceedings, with no legal basis in the approval procedures but with political relevance for stalling the procedure and demonstrate that the European Communities was treating agricultural biotech products "in baskets".

4.919 The "Inter-Service Consultation phase" effectively prevented all the applications – with positive scientific opinions in 1998 – from moving forward: within the Regulatory Committee draft stage, and beginning on 4 September 1998 for all these products, the applications for Falcon GS40 Oilseed rape, MS8xRF3 Oilseed rape, and A5/15 Fodder beet were stalled. Only Bt 531 cotton and RRC 1445 cotton (of particular interest to Argentina) were able to reach the Regulatory Committee voting stage in that year. In respect of these two products, this phase took place twice in September 1998 and May 1999 after there was a lack of a qualified majority vote in February 1999.

4.920 In conclusion, these applications for approval of agricultural biotech products had the following in common: all of them were submitted under Directive 90/220, all of them received a positive scientific opinion within the European Communities before 2000, and all of them underwent an additional stage that was not included in the European Communities' approval legislation, namely, the "Inter-Service Consultation" phase, which is capable of stalling the procedure and reveals the *de facto* moratorium.

4.921 These applications were put to the vote in the Regulatory Committee, where the positive scientific opinions were ignored by those EC member States who voted negatively without any scientific evidence that could override the positive opinions. It is evident that in 1998-1999 the European Communities was revealing its intention not to have any further agricultural biotech products approved. This was confirmed by the "Common Position" and the declarations of several member States, which revealed the position towards agricultural biotech products within the European Communities.

The "Common Position" and the declaration by various member States

4.922 In 1998 the approvals and rejections of applications stopped because the EC legislation was considered inappropriate. In June 1999 the EU Council of Environmental Ministers drew up a document called the "Common Position" for the reform of Directive 90/220. This document stated there would be no approvals until there was new legislation. The Declaration by Denmark, Greece, France, Italy and Luxembourg stated their intention of not allowing more biotech approvals. This position was reiterated in July 2000 during an informal Environment Council meeting in Paris. In Argentina's view, the "Common Position" reveals the European Communities' intention not to approve any more agricultural biotech products.

Regarding the "Interim approach"

4.923 The European Communities' consideration of a change in the legislation created uncertainty about the approvals. As a consequence, several applicants offered to fulfil the requirements contained in the "Common Position", since they had no other choice. Afterwards, in July 2000, the Commission proposed the so-called "Interim approach". This came after a long period of time without approvals and was the result of the applicants' concerns – not of any initiative by the European Communities, as the European Communities asserts.

4.924 Under the "Interim approach" there were neither approvals nor rejections. Moreover, the entry into force of Directive 2001/18 brought the "Interim approach" stage to a close.

4.925 Argentina recalls again what it has previously asserted with regard to what the European Communities calls "progress" in the approval proceedings. This has actually entailed neither approvals nor rejections of applications. The "Interim approach" became just another expression of the *de facto* moratorium.

Further applications receive positive scientific opinions before the entry into force of Directive 2001/18

4.926 While all the applications with a positive scientific opinion dated 1998 were stalled, new applications were in position to be approved thanks to the positive opinion of the Scientific Committees: both Phoe6/Ac Oilseed rape and Bt11 maize received a positive opinion on 30 November 2000 and were to be resubmitted under Directive 2001/18. Both applications were stalled for two years. The same can be argued with reference to the potato, though within a shorter time-frame, since the positive scientific opinion was issued in July 2002.

4.927 In February 2001, six member States reaffirmed their commitment to suspending approvals, on the grounds that the new procedures were inadequate.

4.928 By the end of October 2001, the majority of member States essentially agreed that the moratorium should not be lifted until the full traceability and labelling provisions had entered into force. At an informal meeting of the Environment Council, eight member States effectively rejected the Commission's plan to consider new authorizations, by demanding that the new regulations be in force first. In December 2001, Belgium declared once again that the *de facto* moratorium would have to be maintained until there was proper legislation on traceability and labelling.

4.929 Consequently, the European Communities was clearly announcing its intention to maintain the *de facto* moratorium, even if Directive 2001/18 was to enter into force. This refutes the European

Communities' allegation that any delays should have ended with the entry into force of Directive 2001/18.

4.930 Since 2000 new applications under Directive 90/220 received positive scientific opinions before Directive 2001/18 came in force (October 2002). These applications did not go through any "Inter-Service Consultation" phase (except NK603 maize at a late stage), but they were stalled, some before reaching the Regulatory Committee stage, some within that stage due to the negative vote of certain member States which ignored the positive scientific opinions. In any case, these applications were stalled until Directive 2001/18 came in force and had them all resubmitted with new requirements.

4.931 Additionally, some products received positive scientific opinions under Regulation 258/97, starting a little earlier (September 1999). These products, it will be recalled, did not go through any "Inter-Service Consultation" phase, but were also stalled, both before reaching the Regulatory Committee stage and within that stage.

4.932 In this connection, Argentina cites the situation of GA21 maize: Maize GA 21 C/GB/97/M3/2 (withdrawn in July 2001 due to the decision to discontinue the application, on 21-03-2001) and C/ES/98/01 received a positive scientific opinion from the SCP under Directive 90/220 in September 2000. The application did not reach the Regulatory Committee stage and had to be resubmitted in January 2003 under Directive 2001/18. It was finally withdrawn in September 2003.

4.933 As demonstrated, further applications received positive scientific opinions, favouring their approval, but were stalled within their procedures and some had to be withdrawn.

(ii) Conclusion

4.934 In Argentina's opinion, this element of intent, of deliberate action, which – through the "Common Position", the Declaration of Denmark, Greece, France, Italy and Luxembourg, and the additional "Inter-Service Consultation" phases – is reflected in the approval proceedings, shows that the *de facto* moratorium constitutes a measure and that it is not the mere outcome of a situation that has existed since 1998. From 1998 on there were no more approvals of agricultural biotech products because the European Communities decided that there should be no more approvals of agricultural biotech products. This intention within the European Communities was expressed, made effective, and reiterated over time by several member States.

4.935 After considering the European Communities' reasons for the absence of approvals of new agricultural biotech products between 1998 and the present – insufficiency of Directive 90/220 and the need for replacement by Directive 2001/18, the need for further legislation on traceability, labelling, monitoring, liability, coexistence, etc. – Argentina concludes that they do not release the European Communities from its WTO obligations. None of these reasons should prevent the approval of agricultural biotech products that have received a positive scientific opinion within the European Communities.

4.936 The European Communities referred to the need for even newer legislation on traceability, labelling, monitoring, liability and coexistence. None of this new legislation deals with risk assessment – which the positive scientific opinions by the Scientific Committees do address – so the European Communities cannot disregard the risk assessment undertaken and suspend all approvals without infringing the *SPS Agreement*.

4.937 Argentina not only maintains that the *de facto* moratorium is a current existing measure – and it certainly was at the time that the terms of reference of this Panel were established – but also reiterates that the WTO Agreement is meant to deal with *de facto* measures as well, including any actions or omissions of WTO Members. Otherwise, WTO Members could circumvent their WTO obligations by merely issuing informal measures, which have not been set forth in positive legislation.

(b) The "suspension of processing and failure to consider individual applications for specific products of particular interest to Argentina"

(i) General comments

4.938 Having received the final information from the European Communities relating to the products of interest of Argentina, we realize that the European Communities has not refuted the information, but rather confirmed Argentina's allegations and, consequently, does not overturn the positive scientific opinions from the EC Scientific Committees. Starting from the positive scientific opinions issued by the European Communities itself, and given the resulting non-approval due to the European Communities' deliberate actions aimed at having no agricultural biotech products approved, we once more state that this claim goes far beyond a mere question of delay – as the European Communities would have us believe.

4.939 As Argentina has stated before, since the *de facto* moratorium affects all applications, these relevant additional stages also apply to the products of interest of Argentina, namely, Bt-531 cotton, RRC 1445 cotton, NK 603 maize, GA 21 maize and Soy Lines A2704-12 and A5547-127. In this respect, Argentina reaffirms its arguments contained in its Written Rebuttal.

(ii) Specific products

4.940 In this section, Argentina will refer to the information provided by the European Communities on the last five CD ROMs on 30-09-2004. However, it is useful to recall that the "suspension and failure to consider" has been argued by Argentina starting from when the applications submitted under Directive 90/220 and under Regulation 258/97 were stalled.

4.941 Argentina will once again go through the applications relating to the agricultural biotech products of interest, analysing the documents provided by the European Communities, and demonstrating once again that the additional information does not overturn the positive scientific opinions of the EC Scientific Committees. In fact, all the information demonstrates that the European Communities and/or some of its member States put forward arguments or concerns of a non-scientific nature.

Bt 531 cotton

The proceedings were stalled

4.942 As regards the relevant stages identified by Argentina in its Rebuttal, the additional information submitted by the European Communities confirms that the approval proceedings for Bt 531 cotton under Directive 90/220 (and later Directive 2001/18) were stalled.

Comments on the information provided on the CD ROMs

4.943 Regarding the specific documents submitted by the European Communities relating to Bt 531 cotton under Directive 90/220 and Directive 2001/18, Argentina affirms its position that the positive

scientific opinion by the Scientific Committee on Plants dated 14 July 1998 is the relevant document to be taken into account. The following does not refute this SCP opinion: the launching of the "Inter-Service Consultation" on the draft Commission Decision (4 September 1998); is non-scientific in nature and did not refute the positive scientific opinion; the launching of the vote in the Regulatory Committee (26 November 1998); the Danish request to extend the deadline for a vote to review additional information (30 November 1998); the letter by the *Commissie Genetische Modificatie* (NL) (3 December 1998); the COM note to the effect that the deadline for voting had been extended (4 December 1998); the Belgian request to postpone the vote (10-12-1998); the UK request to postpone the vote (21 December 1998); the note to the effect that the deadline had been extended (23 December 1998); the Opinion of the *Commission du Génie Biomoléculaire* (13 January 1999); the note on the lack of a qualified majority (22 February 1999); the launching of the "Inter-Service Consultation" phase (7 May 1999); the letter (25 July 2001) (as well as the translations (18 February2002)). The European Communities was unable to invoke any scientific evidence capable of refuting the positive scientific opinion dated 14 July 1998.

4.944 Any EC concerns regarding further information on certain issues had been properly answered as of February 2002, but the process remained stalled thanks to the "Inter-Service Consultation" phase that had been in force since May 1999 and continued until Directive 2001/18 came into force in October 2002, requiring all applications to be updated at member State level. For these reasons, Argentina does not accept the European Communities' allegation that it was due to the applicant that the approval procedure did not proceed. From the Regulatory Committee voting stage and the "Inter-Service Consultation" phase the approval procedure for Bt 531 cotton was stalled because of the European Communities, not because of any action or omission on the part of the applicant.

4.945 Additionally, we observe that although it came into force in October 2003, Directive 2001/18 was published in the Official Journal in April 2001. Since the applicant had to submit information under the new legislation, Argentina cannot accept the European Communities' statement concerning "29 months" to fulfil the requirements.

4.946 Argentina will now turn to the last documents at member State level. The following documents does not refute the SCP opinion of July 1998: the letter from the lead CA (1 August 2003); and the NCB letter (2 October 2003).

4.947 In Argentina's opinion, it has been proved that the application for Bt 531 cotton had to pass through several procedural stages not included in the European Communities' legislation, and that reveals a clear intention within the European Communities not to allow the final approval of this agricultural biotech product.

RRC 1445 cotton

The proceedings were stalled

4.948 As to the relevant stages identified by Argentina in its Rebuttal, the additional information submitted by the European Communities has confirmed that the approval proceedings for RRC 1445 cotton under Directive 90/220 (and later Directive 2001/18) were stalled.

Comments on the information provided on the CD ROMs

4.949 Regarding the specific documents submitted by the European Communities relating to RRC 1445 cotton under Directive 90/220 and Directive 2001/18, Argentina reaffirms its position that the positive scientific opinion by the Scientific Committee on Plants dated 14 July 1998 is the relevant

document to be taken into account. The following does not refute the SCP opinion: the launching of the "Inter-Service Consultation" on the draft Commission Decision (4 September 1998); the launching of the vote in the Reg. Comm. (26 November 1998); Denmark's request for an extension of the deadline for a vote to review additional information received by Monsanto (30 November 1998); the letter from the *Commissie Genetische Modificatie* (3 December 1998); the COM note extending the deadline for the vote (4 December 1998); the Belgian request to postpone the vote (10 December 1998); the statement by Austria (13 December 1998); the UK request to postpone the vote and discuss further information recently submitted (21 December 1998); the COM note extending deadline (23 December 1998); the Opinion of the *Commission du Génie Biomoléculaire* (13 January 1999); the COM note concerning a further extension of the deadline for a vote at the request of the lead CA – 26 January 1999 – was procedural in nature and did not rebut the positive scientific opinion of July 1998; the UK response to the European Communities (10 February 1999); the note on the lack of a qualified majority (22 February 1999); the launching of the "Inter-Service Consultation" phase on the draft Council Decision (7 May 1999).

4.950 In the light of the above and according to the European Communities' information, from the launching of the "Inter-Service Consultation" phase in May 1999 to the update under Directive 2001/18 in January 2003, the applicant received no request for further information or clarification, so the European Communities cannot even suggest that the process was ongoing. Additionally, the European Communities was unable to invoke any scientific evidence capable of refuting the positive scientific opinion dated 14 July 1998.

4.951 Argentina will now refer to the last documents at member State level: the following documents do not refute the positive scientific opinion of July 1998: the letter from the lead CA (1 August 2003); the NCB letter (2 October 2003).

NK 603 maize

The proceeding was stalled

4.952 As previously stated, the applications for NK 603 maize were initiated in 2000 under Directive 90/220 (later Directive 2001/18), and in 2001 under Regulation 258/97. In both proceedings, the application received a positive scientific opinion in November 2003. Although NK 603 maize was finally approved after the initiation of this WTO proceeding, this should not impair the ability of the Panel to deliver a finding on the claim relating to this specific product.

Comments on the information provided on the CD ROMs

4.953 The NK 603 maize application under Directive 90/220 was originally submitted in August 2000 and later had to be resubmitted under Directive 2001/18. In this connection, Argentina will refer to information provided by the European Communities on the CD ROMs. NK 603 maize received a positive scientific opinion from EFSA dated 25 November 2003, which is the relevant document to be taken into account. The following does not refute the EFSA opinion: the documents and stages prior to the positive scientific opinion (25 November 2003); the launching of the "Inter-Service Consultation" on the draft Commission Decision (8 December 2003); the lack of a qualified majority in the Regulatory Committee (18 February 2004) – does not reflect the positive scientific opinion and is rather procedural in nature; it demonstrates that some member States continue to vote negatively despite the scientific evidence; the transmission of the proposal to the Council (26 March 2004); the position of Denmark (4 June 2004).

4.954 Regarding the specific documents submitted by the European Communities relating to NK 603 maize under Regulation 258/97 (originally submitted under this Regulation in April 2001), a positive scientific opinion was received from EFSA, dated 25 November 2003 which is the relevant document to be taken into account. The draft decision presented to the Regulatory Committee (no qualified majority) – 30 April 2004 – was procedural in nature.

GA 21 maize

The proceeding was stalled

4.955 Although the application for GA 21 maize was withdrawn in September 2003 under the a Directive 90/220 (later Directive 2001/18), Argentina considers this withdrawal to be evidence of a *de facto* moratorium proceeding and of the "suspension and failure to consider". The application made no progress in the proceedings and was withdrawn.

Comments on the information provided on the CD ROMs

4.956 Concerning the specific documents submitted by the European Communities relating to GA 21 maize under Directive 90/220 and Directive 2001/18, Argentina reaffirms its position that the positive scientific opinion by the Scientific Committee on Plants dated 22 September 2000 is the relevant document to be taken into account.

4.957 The positive opinion dated 22 September 2000 was followed by: the letter (19 January 2001); the Spanish letter (21 March 2001); the letter (decision to discontinue UK notification) (21 March 2001); the undertakings to fulfil the requirements of Directive 2001/18 (21 September 2001); the updates and commitments (18 March 2002); the new SNIF and updated risk assessment (15 January 2003). These documents are either of a non-scientific nature or are specifically refuted by the scientific arguments submitted by Argentina. The application was finally withdrawn (15 September 2003).

(c) "Undue delay"

4.958 With respect to "undue delay", after analysing the information and chronologies submitted by the European Communities, Argentina affirms and demonstrates that the delays that occurred during the proceedings were not on the part of the applicants, but on the part of the European Communities and/or its member States. We do not accept the European Communities' allegation in this respect.

4.959 Concerning Bt 531 cotton, there were no delays on the part of the applicant following the issuance of the positive scientific opinion (July 1998). The alleged objections in the Regulatory Committee were scientifically contested by Argentina, inasmuch as they do not match the positive opinion of the Scientific Committee. Additionally, we do not accept the delay of 29 months plus 7 months attributed to the applicant either, since, as previously stated, there are no EC documents specifically requesting information that might suggest delay on the part of the applicant. As to the European Communities' assertion regarding the need to have the monitoring plan completed, the monitoring plan was originally presented in December 1996 with the applicant's first notification, and that this monitoring plan received a positive scientific opinion in July 1998. Thus, we cannot accept a vague and general assertion that the monitoring plan was incomplete.

4.960 In connection with the European Communities' statements concerning RRC 1445 cotton, we consider them to be irrelevant as well. The outcome of the written procedure in the Regulatory

Committee that the European Communities mentions has already been scientifically addressed by Argentina.

4.961 As regards the monitoring plan to be completed, Argentina agrees with the European Communities that this monitoring plan was requested under Directive 2001/18. For the same reason, we also stress that this plan was presented by the applicant on January 2003, and that the European Communities' requests for additional information were made in August and October.

4.962 With reference to the case of NK 603 maize under Directive 90/220 and Directive 2001/18, as well as under Regulation 258/97, Argentina reiterates that these two proceedings were started in August 2000 and April 2001 respectively, and that there had been no further progress as of August 2003. For the above-mentioned reasons, Argentina considers that the specific agricultural biotech products of particular interest were affected by "undue delay" in their approval procedures following their submission to the European Communities.

(d) *TBT Agreement*

4.963 As stated at the outset of this Supplementary Rebuttal, Argentina would like to elaborate further on its alternative arguments relating to the *TBT Agreement*.

(i) Technical regulation

Article 2.1 of the *TBT Agreement*

4.964 The European Communities has not explained in any detail the supposedly proper interpretation to be given to the words "in respect of technical regulations" contained in Article 2.1 of the *TBT Agreement*. However, it can be inferred that the European Communities considers this phrase to refer to less favourable treatment within the limited scope of a single regulation, without explaining the reasons why.

4.965 However, there is no basis for considering that likeness should properly be understood "as relating to products within the field of application of the technical regulation", as the European Communities asserts. If this were the case, it would be very easy for Members to circumvent their WTO obligations. Moreover, the only practical result of such an interpretation would be that simply by applying different legislation to products that are actually "like" a Member could avoid scrutiny under WTO rules and, thus, engage in "less favourable treatment" without any legal consequences.

4.966 Argentina considers that Article 2.1 of the *TBT Agreement* basically develops obligations similar to those of Article III.4 of the GATT 1994. Thus, the phrase "in respect of technical regulations" simply reflects the difference in scope between Article 2.1 of the *TBT Agreement* and Article III.4 of the GATT 1994, which applies the same disciplines but to a much broader range of measures.

Article 2.2 of the *TBT Agreement*

4.967 With reference to this part of the European Communities' rebuttal, Argentina would first like to point out that it has challenged, in the alternative, the application of the EC legislation under the *TBT Agreement*. In this respect, as Argentina has made clear throughout its presentations in these proceedings, the European Communities' legislation *per se* has not been challenged, only the application of that legislation.

4.968 The European Communities affirms that "… the prohibition on marketing, pending authorization is the very essence of the GMO legislation – not an application of it …". Contrary to this assertion by the European Communities, Argentina considers that the "very essence of the GMO legislation" is not "the prohibition on marketing pending authorization" but assessing the suitability of products in order to approve or reject them for release into the environment or for consumption as food or feed.

4.969 It should also be pointed out that the concept of "application" includes not only the act of approval (or rejection) but also the failure to approve (or reject), as in the case before the Panel.

4.970 The European Communities also repeats its recurrent allegation that what the complaining parties are actually claiming is a delay that is more restrictive than necessary. Argentina has already made its claim clear enough in this regard. Argentina wonders whether it is possible to consider that, for example, in the cases of Bt 531 cotton and RRC 1445 cotton, the passage of six years after a positive assessment by the competent scientific committee with no approval or rejection can somehow be regarded as "the provisional absence of a final decision". Argentina considers the answer to this is obviously no.

4.971 Moreover, WTO Members are being adversely affected by this EC infringement of Article 2.2 of the *TBT Agreement*, since according to that Article "*Members shall ensure that technical regulations are not … applied with … the effect of creating unnecessary obstacles to international trade …* ". It seems reasonable to infer that, although the article refers to the way in which Members apply technical regulations, it also refers to non-compliance of those regulations (in the present case, the European Communities' approval system).

4.972 The European Communities also asserts that there is no obligation to conduct a risk assessment under Article 2.2 of the *TBT Agreement*. However, probably as a second thought, immediately after this assertion the European Communities makes clear that "In any event, the European Communities is currently in the process of assessing the risks in order to authorize these products". It seems that the European Communities is acting in this way 'just in case', which to some extent reveals the inconsistency of its own arguments.

4.973 The European Communities' argument has no basis in the text of Article 2.2 of the *TBT Agreement* because this article establishes that "*… In assessing such risk, relevant elements of consideration are, inter alia: available scientific and technical information …*".

4.974 The European Communities is therefore bound to make an 'assessment' because Article 2.2 of the *TBT Agreement* refers to this obligation. Moreover, in assessing such risk, 'available scientific and technical information' constitutes 'relevant elements' of consideration. These "relevant elements" of consideration are the positive scientific opinions of the European Communities' scientific committees. The European Communities also challenges the assessment of its own Scientific Committees by asserting that "The European Communities fundamentally disagrees that it has been demonstrated that there is no risk associated with the relevant products" although, three paragraphs earlier it asserts that "EC GMO legislation is not a matter before this Panel". The Scientific Committees being so relevant to the European Communities' approval legislation, it is difficult to see how they can be challenged without challenging the relevant legislation.

4.975 Moreover, the European Communities does not explain why it is wrong to break the provision down into three components. The European Communities' assertion that "whether or not the objective is actually fulfilled in fact is irrelevant provided that the measure contributes or is capable of contributing to that objective", is not explained either.

4.976 However, in Argentina's view, the phrase "technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create" in Article 2.2 of the *TBT Agreement* must be considered to entail a meaning. If the objective is not achieved, the application of the respective technical regulation becomes inconsistent with that article.

4.977 It must be pointed out that the European Communities is definitely "avoiding risk assessment" since it has not taken the positive scientific opinions into account, and is "making decisions not based on a risk assessment", for similar reasons.

4.978 The European Communities' assertion to the effect that "Those opinions (EC Scientific Committee opinions) may or may not be sufficient for the Commission or the Council, and may at the same time be insufficient for the member States" only reveals the lack of a basis for the European Communities' arguments since there is no scientific evidence that might jeopardize the opinions of those Committees.

4.979 Finally, the European Communities alleges that "Article 2.2 of the *TBT Agreement* does not even use the precise words 'risk assessment'". However, as that article is worded "*In assessing such risks*", it is difficult to see how a Member can 'assess a risk' other than by carrying out an assessment of it (the risk). It is important to note that this article stipulates that " … *In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information* … ".

4.980 However, as already explained, the European Communities has insisted and confirmed that it "is currently in the process of assessing the risks in order to decide whether to authorize these products". What would be the reason for undertaking such an assessment if there was absolutely no obligation to do so under Article 2.2 of the *TBT Agreement*?

(ii) Conformity assessment procedure

Article 5.1.1 of the *TBT Agreement*

4.981 It has been shown that the application of the European Communities' legislation is inconsistent with this provision since agricultural biotech products receive less favourable treatment than non-biotech products.

Article 5.1.2 of the *TBT Agreement*

4.982 The European Communities only refers to "release into the environment" and does not explain the situation of products which have received positive opinions from the EC Scientific Committees to the effect that they do not entail any risks for the environment. In other words, the European Communities simply denies any inconsistency with this article on its part.

Article 5.2.1 of the *TBT Agreement*

4.983 The European Communities simply refers to the meaning of "as expeditiously as possible", and asserts that Argentina has not proved inconsistency in the context of the specific product applications. The paragraph affirming that the complaining parties have not proved it sounds strange since there have been no approvals or rejections at all since 1998. Nor has there been any scientific evidence to refute the opinions of the EC Scientific Committees. Moreover, Argentina has awarded an argument elsewhere and the European Communities has not developed a competing argument.

T. THIRD WRITTEN SUBMISSION OF THE EUROPEAN COMMUNITIES

1. Introduction

4.984 The European Communities welcomes the course that the Panel has followed in this dispute after the Second Written Submissions. Rightly, the proceedings have come to focus on certain delays that are alleged to have occurred in individual product applications; and on the question whether such delays were justified.

4.985 At the same time, it has become clearer what the dispute is not about: The dispute is not about a general moratorium, but about individual delays. Furthermore, neither the Panel nor the experts consulted in this dispute are required to decide whether genetically modified organisms (GMOs) *per se* present a risk or not. Nor are they required to decide whether specific GMOs should or should not be authorized in the European Communities: those decisions will in any event have to be made by the authorities of the European Communities on the basis of the relevant legislation, whatever the outcome of this dispute may be. Rather, the experts have the important, but more limited, task to assist the Panel in understanding the scientific background of a number of requests for additional information or objections that have caused delays in the processing of individual product applications.

4.986 The Complaining parties have come to realize that they can only prove their case if they demonstrate instances of 'undue delay' for each individual product application. In their Second Written Submissions they had still relied almost exclusively on the existence of an ominous 'general moratorium'. Manifestly, the assertion of such a moratorium (whatever the exact definition of such a non-measure may be) was to serve one main purpose, namely to relieve the complaining parties of their burden of proof with respect to specific problems that the complaining parties allege to have occurred during various product applications. To the extent they have at all addressed individual product applications their allegations are sketchy or manifestly unfounded. Supposedly it is with this third written submission that the complaining parties now intend to finally address the issue of delay in a proper way.

4.987 The European Communities put all relevant facts 'on the table' in its First Written Submission. Since the complaining parties have not so far come back to the facts and the legal arguments presented by the European Communities, there is little that the European Communities can add to its previous Submissions at this stage. In light of the course the proceedings have taken, however, the European Communities would like to take the opportunity to address a few key issues it considers pertinent at this stage of the proceedings.

4.988 First, it would like to point out that the complaining parties have not met the onus of proving their case. The European Communities then wishes to draw the Panel's attention to the role of panels and expert advice under the DSU with a view to assisting the Panel in making its factual findings. Finally, the European Communities will sketch certain implications that the principle of procedural fairness has on the Panel's selection of potential questions to experts in the complaining parties' third written submissions.

2. The burden of proof

4.989 As the European Communities explained in detail in its Second Written Submission[83], it is for the complaining parties to establish a *prima facie* case. The failure of the complaining parties to

[83] Paras. 10 et seq.; paras. 248 et seq.

address each and every delay in its Second Written Submission is particularly regrettable in view of the fact that the European Communities presented detailed chronologies and additional documentation since the very beginning of this procedure. Documents subsequently made available by the European Communities merely serve to support the facts known to the Panel, without adding any substantive new facts. On the basis of this information, the European Communities has entirely refuted the complaining parties' original contention that the procedures have been "stalled". It has demonstrated that all notifications have been continuously processed and that, to the extent that delays have occurred, these delays occurred for legitimate reasons.

4.990 Since the European Communities has, thus, refuted the contention that procedures have been "stalled", it is for the complaining parties to present a *prima facie* case of undue delay with respect to each individual product application. The complaining parties have not taken this opportunity in their Second Written Submissions.

4.991 Instead of presenting detailed facts and arguments which would warrant the conclusion that 'undue delays' occurred, the complaining parties' discussion of individual product applications is mostly reduced to a particular *legal* argument, which runs like a red thread through their Submissions: that the European Communities is under a WTO obligation to authorize a product application, once an advisory scientific committee has issued a 'favourable' scientific opinion. The European Communities has demonstrated that this legal argument is simplistic and erroneous as a matter of law.[84] In any event, a legal argument – persuasive or not – is never a substitute for a rigorous presentation of the facts that are necessary for the Panel to reach its conclusions.

4.992 The failure on the part of the complaining parties to present a *prima facie* case with regard to each individual product application cannot be 'compensated' by reference to additional information that may be contained in expert opinions. The Panel must not make the case for the complaining parties. In *Japan – Agricultural Products II*, the Appellate Body confirmed this fundamental rule of evidence valid also in WTO proceedings:

> "Article 13 of the DSU and Article 11.2 of the *SPS Agreement* suggest that panels have a significant investigative authority. However, this authority cannot be used by a panel to rule in favour of a complaining party which has not established a *prima facie* case of inconsistency based on specific legal claims asserted by it. A panel is entitled to seek information and advice from experts and from any other relevant source it chooses, pursuant to Article 13 of the DSU and, in an SPS case, Article 11.2 of the *SPS Agreement*, to help it to understand and evaluate the evidence submitted and the arguments made by the parties, but not to make the case for a complaining party."[85]

4.993 Hence, the Panel can only base its findings on expert advice to the extent that complaining parties have asserted all such facts necessary to substantiate their claims. The Appellate Body in *Japan – Agricultural Products II* overruled the panel on the ground that it based itself on information not expressly asserted by the complaining party:

> "In the present case, the Panel was correct to seek information and advice from experts to help it to understand and evaluate the evidence submitted and the

[84] The procedure requires the *regulator* (other than the scientific body) to take account of various non-SPS concerns and the Community legislation which sets this procedure is not at issue in this case. *See* second written submission of the European Communities, paras. 27 et seq.

[85] Appellate Body Report, *Japan – Agricultural Products II*, para. 129.

> arguments made by the United States and Japan with regard to the alleged violation of Article 5.6. The Panel erred, however, when it used that expert information and advice as the basis for a finding of inconsistency with Article 5.6, since the United States did not establish a *prima facie* case of inconsistency with Article 5.6 based on claims relating to the 'determination of sorption levels'".[86]

4.994 The European Communities welcomes the fact that the Panel took the opportunity to seek extensive background information and technical advice from experts. At the same time, it invites the Panel to be mindful of the fact that such expert advice does not alter the burden of proof. It is entirely on the complaining parties to present a *prima facie* case of inconsistency with WTO law; and to refute any such evidence presented by the European Communities to the contrary.

3. The role of the Panel

4.995 The present dispute has arrived at a very delicate junction. The Panel has used its right pursuant to Article 13 of the DSU and Article 11.2 of the *SPS Agreement* to consult several experts on certain aspects of GMOs. The Panel has sought expert advice both with a view to receiving general background information and to clarifying specific questions of science regarding individual product applications. As a result, the Panel will need to evaluate extensive scientific evidence to reach its finding. To assist the Panel in this task, the European Communities wishes to draw the Panel's attention to the particular role of panels and experts under the DSU.

4.996 The role of panels in WTO dispute settlement is set by Article 11 of the DSU. It provides that a panel must make an "objective assessment" of the facts. Consequently, the standard of review to be applied by panels is neither 'total deference' to a factual determination by a Member's authority nor a *de novo* review of such a determination, allowing the panel complete freedom to come to a different view than the competent authority.[87] As the Appellate Body noted, a panel is not tasked to "substitute [its] own conclusions for those of the competent authorities."[88]

4.997 A distinguished, former chairman of the Appellate Body wrote on this issue: "the panel should accord a considerable degree of discretion to national authorities in the determination and assessment of facts." In particular, a panel cannot "displace the national authority" by rejecting findings made by such an authority on the grounds that it considers other findings more warranted. Finally, a panel is bound to "respect the parameters of the national authority's own investigation."[89]

4.998 In *US – Cotton Yarn*, the Appellate Body had the occasion to further elaborate on and clarify the line that is to be drawn between permissible "objective assessment" and prohibited *"de novo* review":

> "In our view, a *panel* reviewing the due diligence exercised by a Member […] has to put itself in the place of that Member at the time it makes its determination. Consequently, a panel must not consider evidence which did not exist *at that point in time*. A Member cannot, of course, be faulted for not having taken into account what it could not have known when making its determination. If a panel were to examine such evidence, the panel would, in effect, be conducting a *de novo* review and it

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[86] Appellate Body Report, *Japan – Agricultural Products II*, para. 130.
[87] Appellate Body Report, *EC – Hormones*, para. 117.
[88] Appellate Body Report, *US – Lamb*, para. 106.
[89] C.-D. Ehlermann, N. Lockhart, "Standard of Review in WTO Law", 7 *Journal of International Economic Law* (2004) 491, at 502.

> would be doing so without having had the benefit of the views of the interested parties. The panel would be assessing the due diligence of a Member in reaching its conclusions and making its projections with the benefit of hindsight and would, in effect, be reinvestigating the market situation and substituting its own judgement for that of the Member. In our view, this would be inconsistent with the standard of a panel's review under Article 11 of the DSU."[90]

4.999 The Appellate Body's ruling in *US – Cotton Yarn* is of perfect relevance for delimitating the panel's standard of review in the present case. The obligation "to put itself in the place of that Member at the time it makes its determination" has several consequences for the present Panel. Thus, the Panel must look at the state of scientific information and data existing at the time of the measure in question (in this case, the alleged "delay") rather than, from an *ex post* perspective, at the current state of scientific knowledge.[91] On this basis, all answers by the experts to questions which relate to specific products as well as to those that aim at giving the Panel a scientific background to the dispute need to take into account this *décalage* in time between the current scientific knowledge and the scientific knowledge at the time of the alleged "delay".

4.1000 Moreover, the requirement of an "objective assessment of the facts" largely depends on the concrete question at issue and the provisions of WTO law on which a claim is based. As the same distinguished commentator put it, "[c]ertainly, panels perform an 'objective assessment'; but the scope and intensity of the panel's assessment is not the same for every issue, in every dispute."[92] For the *SPS Agreement*, the Appellate Body stated in *EC – Hormones*:

> "The standard of review appropriately applicable in proceedings under the *SPS Agreement*, of course, must reflect the balance established in that Agreement between the jurisdictional competences conceded by the Members to the WTO and the jurisdictional competences retained by the Members for themselves. To adopt a standard of review not clearly rooted in the text of the *SPS Agreement* itself may well amount to changing that finely drawn balance; and neither a panel not the Appellate Body is authorized to do that."[93]

4.1001 Hence, in the present case, the Panel must take account of the carefully struck balance between jurisdictional competence of the WTO and the sovereignty of its Members as reflected in the relevant covered agreement. This balance, in turn, is expressed differently in different provisions of the covered agreement. In the case of the *SPS Agreement*, an Article 5.2 claim may warrant a relatively strict review of the examination undertaken by a Member's competent authority. By contrast, the more general wording of Article 1(a) of Annex C of the *SPS Agreement* ("without undue delay") indicates a more deferential standard of review.

4.1002 The latter provision is central to the present dispute. The "fine balance" drawn by the *SPS Agreement* is reflected in the notion of "undue delay". When considering the issue of "undue delay", the Panel is not required (or permitted) to engage in a *de novo* review of individual product applications. Rather, the Panel merely needs to look at the applications to satisfy itself that such delays that may have occurred were based on a reasonable justification. In other words, the Panel is

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[90] Appellate Body Report, *US – Cotton Yarn*, para. 78 (emphasis original).

[91] *See* also C.-D. Ehlermann, N. Lockhart, cited above, at 502: "This constraint influences the temporal scope of the panel's factual review. To remain in the 'place' of the national authority, the panel is not entitled to examine new facts that were not, or could not, have been included in the national authority's investigation."

[92] C.-D. Ehlermann, N. Lockhart, cited above, at 496.

[93] Appellate Body Report, *EC – Hormones*, para. 115.

not asked to determine whether a prudent government, in the abstract, *should* have behaved or not in a certain manner thus causing delay. It merely needs to find whether, in the concrete case and in light of the factual information and the legal arguments before the relevant authorities, that behaviour which in the end caused a delay *could* justifiably have been adopted.

4.1003 In this context, the European Communities notes that some questions to the experts[94] could be interpreted as coming close to a (prohibited) *de novo* review of product applications. For example, in the General Questions section, the Panel repeatedly asked whether "[o]n the basis of the information before the Panel, [*there is*] any scientific evidence to support the hypothesis that" certain risks may ensue from GMOs. The European Communities does not dispute the right of the Panel to request such *background* information that it considers useful for its understanding of the current scientific debate on GMOs. However, when making its findings, the Panel must be mindful of the proper standard of review. In line with the Appellate Body holding in *US – Cotton Yarn*, the relevant point in time is the time of the adoption of the measure alleged to be WTO inconsistent. For example, to decide whether a request for information was justified, it will be necessary to inquire in the state of scientific knowledge or uncertainty at the time the information was requested.[95]

4. The function of expert advice

4.1004 The proceedings have moved to the stage of expert consultation. In deciding to consult experts pursuant to Article 13 of the DSU and Article 11.2 of the *SPS Agreement*, the Panel has acknowledged the importance of certain scientific questions for resolving the present dispute.

4.1005 The European Communities notes that many of the questions invite the experts to respond "on the basis of the information before the Panel" or "given the information before the Panel".[96] As the European Communities has previously noted, the experts should also be requested to provide the Panel with other information of which they may be aware even if it is not "before the Panel". The European Communities, therefore, welcomes the fact that the Panel has invited the experts to do this in its letters to the experts.

4.1006 As the European Communities has previously argued[97], it is not open to the Panel to ignore the various scientific positions (in addition to the views expressed by the European Communities' own scientific Committees) that have evolved on risk assessment and risk management issues in the international scientific community. To understand the background of this dispute, the Panel must be aware of the various risks that were debated in the scientific world during the relevant period of time. The "General Questions" to the experts demonstrate that the Panel shares this view.

4.1007 Moreover, scientific expertise is essential to assist the Panel in determining whether certain delays that may have occurred were "undue". In this context, the Panel may need to decide whether, for example, the time needed to develop a monitoring plan was excessive, whether certain concerns by the Belgian Biosafety Council were legitimate and reasonable in light of a field study, or whether at the time of a delay, there was a degree of scientific uncertainty about a particular issue. The Panel has understood this second function of expert advice by asking several detailed questions regarding individual product applications.

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[94] Questions to Experts of 12 October 2004.

[95] The European Communities previously expressed this concern in its comments of 24 September 2004 on the draft questions to experts, cf. Explanation Nr. 2 regarding draft Question 1.

[96] *See* for example point 7 of Annex D to the letter of 23 September.

[97] Final Position of the European Communities on the Need to Seek Scientific or Technical Expert Advice, 21 July 2004; Letter of 27 July 2004 to the Chairman of the Panel.

4.1008 By contrast, neither the Panel nor the experts consulted in this dispute are called upon to decide whether GMOs *per se* present a risk or not. Expert advice under the DSU and the *SPS Agreement* does not have the purpose of resolving scientific controversies. Rather, expert advice is provided for assisting the Panel in its limited task of making findings in the dispute between the parties.

4.1009 It is implicit in the function of expert advice to "assist" the Panel that the power to make legal findings, as such, remains a prerogative of the Panel. Pursuant to Article 13.2 of the DSU, expert opinions serve to clarify "a factual issue concerning a scientific or other technical matter". Experts enable panels to fully understand any scientific and technical facts of a case. By contrast, expert opinions do not relieve the Panel of its duty to make an independent *legal* assessment of those facts.

4.1010 A final point on the role of expertise in the present dispute seems pertinent to the European Communities. Expert advice on GMOs is limited to clarifying certain questions relating to scientific risks (i.e. risk assessment in the narrow sense).[98] By contrast, expert advice cannot offer the Panel much indication as to whether certain conduct was reasonably justified from a risk management or risk communication perspective. Just as scientific opinions do not conclude the risk assessment process[99], scientific expert advice in WTO proceedings does not conclude the Panel's assessment whether certain measures could reasonably and justifiably be undertaken. Instead, the Panel will need to reconstruct a process of complex interaction with multiple actors – risk assessment bodies, risk managers or regulators – to evaluate the WTO consistency of the European Communities' actions. Expert advice can only assist the Panel in fulfilling part of this task. The ultimate, overall assessment remains the prerogative and the duty of the Panel.

5. Procedural fairness and the admission of additional questions

4.1011 The principle of procedural fairness requires that each party be able to comment on factual assertions and legal arguments put forward by the opposing party. As the flip side of the same coin, the principle of procedural fairness equally requires that each party present factual evidence as early as possible. This side of the principle is reflected in Appendix 3 to the DSU, which requires a party to present the facts of the case in its first written submission. Each party can, thus, legitimately expect the opposing party to prepare its submissions in accordance with the principles of sound administration of justice.

4.1012 The European Communities notes that the Panel, in its timetable circulated on 28 October 2004, afforded the parties an opportunity to suggest additional questions for the experts at this already exceptional third round of submissions. The complaining parties had extensive opportunity to comment and to suggest questions during the consultation on the draft questions in September. Indeed, the complaining parties, at the time, insisted on obtaining more time in order to review allegedly new information submitted by the European Communities.

4.1013 To the extent that the complaining parties, for reasons of strategy or negligence, failed to previously comment on the European Communities' Submissions and to propose the relevant questions, the European Communities respectfully requests that the Panel refrain from considering such questions now.[100]

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[98] Second written submission of the European Communities, paras. 21 et seq.
[99] Second written submission of the European Communities, para. 31.
[100] It may not be entirely coincidental that the complaining parties asked the Panel for an opportunity to submit third written submissions on 10 August 2004, i.e. right after the Panel's decision to consult experts.

4.1014 Such a selective approach would be in line with the Panel's previous practice in this dispute. The Panel has been very selective, even restrictive, in choosing from the parties' proposals such questions that would be addressed to the experts, rejecting a number of questions proposed by the European Communities. In exercising its discretion with regard to the selection of questions, the Panel has the opportunity to take into consideration the fundamental principles of procedural fairness outlined above.

4.1015 The European Communities reserves its right to suggest additional questions concerning any *new* facts and arguments presented in the complaining parties' third written submissions. For the rest, the European Communities considers it a question of procedural fairness not to re-address, in the disguise of questions to experts, any "old" issues that have already been on the table since its First Written Submission.

4.1016 The principle of procedural fairness raises another issue in this context. According to the timetable, the European Communities will be provided the opportunity to comment on any questions suggested by the complaining parties on 17 November. The European Communities notes that it will have merely four working days to comment on a potentially, large number of scientific questions. In view of the extensive time available to the complaining parties to prepare such questions, the European Communities doubts whether four days will offer sufficient time to study the questions in the appropriate detail and to provide well-founded comments. The European Communities, thus, respectfully invites the Panel to reconsider its timetable in this respect.

U. SECOND ORAL STATEMENT OF THE UNITED STATES ON THE MEETING WITH EXPERTS AND ADDITIONAL SCIENTIFIC EVIDENCE

1. Introduction

4.1017 As the United States has repeatedly explained, the central issue in this case is that the European Communities adopted a moratorium on biotech approvals. Under that moratorium, the European Communities allowed some products to make some progress through the lengthy European Communities' approval procedures, but allowed no product to reach the point of final decision.

4.1018 The central, dispositive legal issues in this dispute – whether the European Communities adopted a moratorium, and whether that moratorium is consistent with the WTO Agreement – do not turn on any scientific issues. However, the United States does believe that the answers to certain scientific questions provide further confirmation of the fact that the European Communities adopted a moratorium. In particular, when an application is delayed until an applicant responds to a scientific question that is not required as a matter of science for completion of a risk assessment, the application has been unduly delayed. Moreover, this evidence must then be added to all of the other evidence confirming the existence of the moratorium.

4.1019 In its third written submission, the United States provided over 20 examples where the questions by member States and EC regulators were not required for assessing risks. Time constraints do not allow us to address each of those examples, but – as the United States addressed in its comments on the experts' responses – the experts' comments confirm that questions were not scientifically justified. In addition, in their testimony last week, the experts did not alter their conclusions on these issues. In short, the scientific issues, and the consultations with the experts, has further confirmed the existence of the moratorium and undue delay in the processing of biotech applications.

2. Evaluating whether particular questions were scientifically justified

4.1020 As the United States has repeatedly explained, the resolution of this dispute does not turn on an examination of each and every member State objection. However, in the event the Panel makes findings on the member State objections examined by the scientists, the United States has three general comments on the issue of whether or not particular member State questions were required for assessing the risk of a product, and on how the Panel should evaluate the experts' views on this subject.

4.1021 First, as a matter of legal interpretation of the *SPS Agreement*, certain objection must be considered as resulting in "undue delay" under Annex C. In particular, where a member fails to make a decision on a product until the applicant answers a question that is so vague and general as to be unanswerable must be considered "undue delay." An example of such an unanswerable question would be "does the product have any adverse impact on any aspect of the environment," where the regulator does not specify what impacts are of concern and what impacts would be considered adverse. In essence, such a question means that the regulator is putting an impossible burden on the applicant to prove the negative – in this example, to prove that there are no adverse impacts on any aspect of the environment. That burden is compounded by the fact that the regulator gives the applicant no guidance. Such types of questions necessarily result in endless delay, which in turn must be considered "undue." Otherwise, a WTO Member could block all product approvals, indefinitely, by posing such vague and general questions. The views of the scientific experts may, however, be helpful in determining whether or not a question is so vague and indeterminate as to be unanswerable.

4.1022 Second, in deciding whether a question contributes to undue delay, or was legitimately posed to assist in assessing risks, the entire factual context of this dispute must be considered. In particular, in examining the objections, the fact that EC political-level officials and member States had announced a moratorium must always be kept in mind. In fact, unnecessary information requests often came from the same member States which had announced the moratorium. The United States submits that the Panel is entitled to employ its common-sense understanding of the entire situation in examining the facts of this case. Indeed, viewing all facts in context is simply part of making "an objective assessment of the matter before it," as provided under Article 11 of the DSU.

4.1023 Third, and relatedly, the fact that an expert is of the view that there was a plausible scientific rationale for a question does not necessarily inform the Panel that the member State asking the question shared that rationale. In many cases, the objection did not specify why additional information was needed, and the experts were left to speculate on the reasoning behind a question. Where the record provides no specific rationale for the question, the experts and the Panel are left to speculate. The experts, and very properly so, were not instructed to examine the member State objections in light of the entire factual context. In contrast, however, we submit that the Panel's objective assessment of the facts should take account of the European Communities' many announcements that it had imposed a moratorium on biotech approvals.

3. The European Communities' comments on the experts' responses

4.1024 I will now turn to the European Communities' comments on the experts' responses. Those comments, although impressive in length, have very little, if any, relevance to dispositive legal issues. Three sections of the European Communities' comments appear to be addressed to the moratorium and undue delay.

4.1025 Part V of the European Communities' comments addresses the experts' responses to the Panel's product specific questions. Time constraints do not allow us to present views on each and

every member State objection that the Panel has considered up to now in this dispute. However, I will make the following general points.

4.1026 Where one or more expert responded that a particular member State request for information was needed for a risk assessment of the products, the European Communities, understandably, supports those views. However, even if the European Communities and the experts' characterization of such member State objections are accurate, the fact that some objections by EC regulators were not unwarranted is still consistent with the existence of the moratorium. The complaining parties have never claimed that each and every member State objection or request for information was unwarranted or resulted in undue delay.

4.1027 Where one or more expert responded that a particular member State request for information was not needed for the assessment of risks, the European Communities, understandably, takes issue with those views. And, I would like to point out that the experts believed that a substantial number of different types of questions, when considered in light of the totality of information available, were unnecessary for conducting a safety assessment. Those types included:

- questions related to the safety of the antibiotic resistance marker genes in these products;
- requests for additional molecular characterization data;
- requests for quantitative, event specific detection methods;
- requests for detailed information on environmental effects when the application sought approval only for import and processing, and not for planting;
- vague and open-ended requests for information on environmental effects;
- requests for chronic toxicity studies;
- requests for additional whole-food studies; and
- requests for studies on the composition of food produced from animals that consumed biotech feed.

4.1028 At the experts' session, the European Communities directly challenged the experts on these issues. In the view of the United States, the experts were persuasive in defending their positions. Should the Panel decide it needs to make findings on those member State objections, based on all the evidence and explanation the United States has provided in its own submissions, the United States supports the views of the experts with regard to scientifically unjustified questions. Findings that such objections were not justified amount to "undue delay" under Annex C of the *SPS Agreement*, and such findings serve as further confirmation of the existence of the moratorium.

4.1029 Parts III and IV of the European Communities' comments on the expert responses address "general and methodological issues" and the Panel's general questions. The theme of these comments are "complexity," "scientific uncertainty," and "evolving science". The European Communities' elaboration on these themes is wildly overstated, which I will turn to shortly. But regardless of their accuracy or inaccuracy – the discussion of such broad themes has little or no role in the resolution of this case. To the extent such themes inform the evaluation of particular member State objections, the

experts and parties have incorporated those themes in their comments on the particular objections. And, to the extent those themes do not relate to individual member State objections, they touch on no issue in this case.

4.1030 The European Communities' general comments appear to be aimed toward the development of an argument that the moratorium falls within article 5.7 of the *SPS Agreement.* The European Communities' general discussion of themes such as "uncertainty," however, does not help the European Communities in the development of any argument under Article 5.7. In fact, Japan – the responding party in the *Japan – Apples* – similarly relied on a general theme of uncertainty, and the Appellate Body firmly rejected it:

> "The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence. The text of Article 5.7 is clear: it refers to 'cases where relevant scientific evidence is insufficient', not to 'scientific uncertainty'. The two concepts are not interchangeable. Therefore, we are unable to endorse Japan's approach of interpreting Article 5.7 through the prism of 'scientific uncertainty'".[101]

The Panel should do the same here with respect to the European Communities' suggestion.

4.1031 As I noted, the European Communities' discussion of uncertainties and risks associated with biotech products is wildly overstated. The United States addressed this matter comprehensively in Section II.A of its second written submission. I won't repeat that discussion here, except to note that the European Communities' contentions are inconsistent with its own public statements regarding biotech products. For example, the EC Scientific Steering Committee stated that "published review of data do not indicate the GM crops presently in cultivation pose any more risks for humans, animals, and the environment than do their conventional counterparts."

4.1032 In addition, the experts' responses do not support the European Communities' presentation on risks and uncertainties of biotech products. Regarding the potential for these products to present any human health effects, the advice from the experts – both in their written testimony, and during the discussions last week--identified no scientific issues that could justify the European Communities' inability to determine whether the products met its level of protection. Rather, the advice confirmed that the totality of the information presented was generally sufficient to allow the European Communities to evaluate any potential adverse human health effects, even if in the abstract a scientist might have preferred more detailed molecular characterization, or more precise information on a particular point.

4.1033 Furthermore, while the experts believed that issues relating to the evaluation of environmental effects were frequently more complex than those for food safety, the experts also presented various ways to analyse and resolve the issues the European Communities raised. For example, on issues relating to potential effects on non-target organisms, one expert confirmed that although the evaluation of potential effects on non-target organisms can be challenging because it is not possible to study all of the various species, systems, and biogeochemical cycles, several different methodologies to do so are available. The expert (Dr. Andow) mentioned two approaches, one using general environmental indicator species and the other focusing on those non-target organisms that would be expected to be exposed in the agricultural environment where the crops would be grown. The fact that these methods have been available since 1999 calls into question the European Communities' post-hoc justifications.

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[101] Appellate Body Report, *Japan – Apples*, para. 184.

4. Advice from IO's on definitions

4.1034 The European Communities asserts that their interpretations are "effectively confirmed" by various organizations' advice. However, the European Communities provides little or no explanation for its conclusion. In some cases, the European Communities has selectively relied on the advice provided, generally failing to acknowledge the advice regarding how such terms are typically construed and applied. For example, although the European Communities relies on the IPPC's definition of a pest, they do not address the fact that ISPM 11, which was also cited by the IPPC, directly contradicts many of the arguments presented in its first written submission.

4.1035 For other terms, the European Communities relies on artificial, and largely irrelevant, distinctions to support its claim. For example, the European Communities argues that the definition suggested for the term "additive" confirms that the GMO itself is not an additive. This argument is entirely beside the point. Whether the plant itself is an "additive" – a point the United States has never contested – in no way resolves the question of whether the genetic insert or construct in the product is properly considered as an "additive" within the meaning of the *SPS Agreement*. Applesauce that contains food colouring is not itself considered to be a food additive, but it is indisputable that the food colouring contained in the applesauce falls within the definition of an additive in food. And any measure applied to protect human health from risks arising from the food colouring in the applesauce would accordingly be considered an SPS measure.

4.1036 The European Communities raises this same argument with respect to "contaminants," "toxin," and "disease." Whether the organizations' advice confirms that the biotech products are not themselves contaminants or toxins, is utterly irrelevant to whether either the genetic inserts or the substances produced by the inserts are contaminants or toxins. Nor would advice that biotech products are not "diseases" resolve whether measures taken to address any risks that might be presented by the antibiotic marker genes could properly be characterized as a measure taken to address "risks arising from ... disease-causing organisms."

5. Experts' advice and safeguard measures

4.1037 Our discussion of the experts' advice on the safeguard measures is mostly a legal one, so we will present our views on that in our opening statement on legal issues.

V. SECOND ORAL STATEMENT OF CANADA ON THE MEETING WITH EXPERTS AND ADDITIONAL SCIENTIFIC EVIDENCE

1. Comments on the meeting with experts

(a) Introduction

4.1038 Canada has only a few comments to make concerning the discussion with the experts on 17 and 18 February 2005. Due to time constraints, Canada will not address in detail the European Communities' voluminous Comments on the Scientific and Technical Advice to the Panel. However, we would like to note that the European Communities' Comments express many of their own views on the Panel's Questions. Many of the European Communities' assertions appear to rely on scientific evidence dating back many years that was not previously in the record. If this information is or was truly relevant, it is indeed unfortunate that it was not put before the EC Scientific Committees assessing the safety of these products, referred to in the European Communities' Second Written Submission, or indeed, included in its remarkably slim Supplementary Rebuttal Submission.

4.1039 As a result, our comments now will focus on last week's discussion with the experts.

4.1040 As a preliminary point though, I would like to make the observation that the European Communities, throughout this proceeding, has attempted to remove biotechnology from the context of modern agriculture in order to exaggerate risks and scientific uncertainty. Canada, on the other hand, has sought to put biotechnology squarely back into its proper context.

(b) Herbicide Tolerant Crops

4.1041 Drs. Snow, Squire and Andow agreed that, in principle, the ecological effects of herbicide tolerant cropping are similar regardless of whether the HT crop was developed through transgenesis or mutagenesis. So apparently apples are in fact apples after all and not pears. All experts agreed that the potential ecological and agronomic effects depended on the type of herbicide to which the crop was tolerant and not the crop itself.

4.1042 Dr. Snow explained that the key issue is whether the herbicide is used to control weeds in general, but where this is not the case (for example, as with glufosinate-ammonium) then the possible negative effects associated with a loss of the benefit of that herbicide should be minimal. In other words, volunteers and weeds tolerant to glufosinate-ammonium could be controlled using the same methods used to control conventional oilseed rape – that is to say, a different herbicide or tillage.

4.1043 Dr. Andow agreed, pointing out that glyphosate-tolerant plants present a different type of problem because of the wide use of glyphosate generally and the fact that it is one of the safer herbicides on the market. There is obviously a concern about loss of use of that particular herbicide. Dr. Andow confirmed Dr. Snow's advice that there are weeds resistant to imidazolinone, and that there are no reported weeds resistant to glufosinate-ammonium. So, any problems with the development of weed resistance to glufosinate-ammonium HT crops would be no different, and perhaps even less, than resistance to the imi-HT crops.

4.1044 Dr. Snow indicated that she thought there was a problem in Canada with the control of multiple herbicide resistant weeds, but didn't have up-to-date information on this. Considering that over 80 per cent of oilseed rape grown in Canada is HT, it would be folly to expect that there are absolutely no problems. However, all published evidence indicates that HT oilseed rape can be controlled using the same methods as controlling ordinary oilseed rape. The Hall article (Exhibit EC-37), Senior article (Exhibit CDA-194) and the Bright Study (Exhibit CDA-188) all support this conclusion. To describe this as "an extremely difficult problem to manage" is yet another unwarranted exaggeration by the European Communities.

4.1045 Several experts indicated that gene flow amongst oilseed rape is a concern in the European Communities. However, the experts distinguished between the genuine environmental and agronomic concerns and those related to labelling thresholds and co-existence. Dr. Snow indicated that she would not classify the mere presence of a transgene as a problem unless it had adverse biological consequences. Drs. Squire and Snow stated that if the herbicide to which the crops were tolerant was not used for weed control, then no problems should be expected. Now this is entirely consistent with the SCP opinions regarding risks associated with Ms1/Rf1 and Ms8/Rf3 dating as far back as to 1998.

4.1046 As the experts pointed out, gene flow also gives rise to concerns related to so-called "co-existence". But, as the Commission itself has stated and I quote"[i]t is important to make a clear distinction between the economic aspects of co-existence and the environmental and health aspects dealt with under Directive 2001/18". (Here I refer you to Exhibit CDA-165.) Now the experts make this distinction. The European Communities does not. The purely economic aspects of co-existence

arise because of the European Communities' self-imposed arbitrary thresholds for labelling and traceability. The European Communities has attempted to disguise these concerns as environmental harm. Now the experts have unmasked this disguise and confirmed that herbicide tolerant crops that do not cause injury to plant and plant products or environmental hazards, where the herbicide to which the crop is tolerant is not used extensively to control weeds.

(c) Seed Spillage

4.1047 In relation to seed spillage, Dr. Squire cites three studies concerning the in-land transport of recently harvested seeds from the farm to a processing facility. He states that spillage occurs frequently along motorways and fields, but that the seeds eventually die out. He also confirms that seed spillage is a small pollen source compared to the crops themselves. He also agreed with the EFSA opinion regarding the potential for seed spillage and the necessity of a monitoring plan. This is the EFSA opinion in relation to GT73.

4.1048 Dr. Andow in his written opinion agrees that environmental harm from seed spillage is negligible if not nil. He states at paragraph 62.01 that and I quote "it would require escape during importation and/or processing and several years of multiplication at levels similar to the multiplication during oilseed rape production and the growing of these large quantities on a landscape". He concludes that even if such a scenario were possible "there would be many, many possible ways to manage this risk".

4.1049 Both Drs. Squire and Snow confirm that the real issue is not environmental harm but perhaps a concern about meeting thresholds for labelling.

(d) Molecular Characterization

4.1050 Dr. Healy puts molecular characterization into its proper context. Although important, it is but one tool used in conducting a safety assessment. Dr. Snape, during the expert hearing, reversed his written advice in relation to oilseed rape Ms8/Rf3, indicating that the information provided by the notifier on molecular characterization was comprehensive and of a high standard and that no more information was necessary to do the safety assessment.

4.1051 In the light of the modification of his original advice, Canada submits that Dr. Snape's written opinion should be given little weight, if any. Dr. Healy's compelling, well-organized advice should be accepted by this Panel without qualification. Dr. Healy confirmed that one needs to examine the totality of information in order to conduct the safety assessment. Dr. Healy also confirmed that it is possible to conduct a safety assessment without a comprehensive molecular characterization. Although a full molecular characterization of products developed through mutagenesis may not be possible, nonetheless a safety assessment would be possible. Dr. Healy also indicated that although it is possible to conduct a complete molecular characterization for biotech crops, it is not always clear how to interpret this data, given natural variations in plants.

(e) Biogeochemical Cycles

4.1052 Dr. Snow responded to this question very concisely. She has not heard of a problem with biotech crops affecting biogeochemical processes. She confirmed that the differences in impact on biogeochemical cycles as between biotech and non-biotech crops would not be significant.

4.1053 Every form of agriculture has the potential to affect biogeochemical processes. As Dr. Andow has indicated, there are literally hundreds of these processes occurring in the soil.

Tellingly, the European Communities appears to show little concern for this issue in relation to other agricultural practices.

(f) Pest Status

4.1054 Dr. Snow confirmed that the assessment of pest status under ISPM No. 11 is related to whether the weed is more difficult to control, not the economic harm to farmers arising from thresholds established for marketing purposes.

(g) Scale-up Effects

4.1055 Scale-up effects was a recurring theme in the experts' advice. Dr. Andow confirmed that changes brought about by biotech crops would be subtle at most if at all. He indicated that any subtle changes could cause a more serious impact if the scale and rapidity of use increased dramatically. This is an inherent risk in any form of monoculture, and as the experts stated, these issues are not limited only to biotech crops. In addition, Dr. Andow stated that any effects from scaling up, can be managed through the adaptation of agronomic practice.

4.1056 Dr. Squire stated that the impacts of current agricultural practices on biodiversity have not been asked before in relation to any other form of agriculture. He said that it is legitimate to ask these questions, but he acknowledged that it would be impossible to gain a better understanding of these impacts without large scale cultivation.

4.1057 Dr. Squire was clear – he said "it's incumbent on us to scrutinize other practices like we do for GMHT. We need consistency – it's not consistent right now."

4.1058 That Mr. Chair is part of the central theme of Canada's case.

(h) Differences in Risks

4.1059 I will now make a few brief comments on mutagenesis and other methods of introducing genetic variation into plants such as radiation and chemically-induced mutagenesis; somaclonal variation; and even conventional selective breeding. Drs. Andow, Healy, Snape and Nutti all agreed that all methods of introducing genetic variation have potential to produce unexpected or unintended effects. The likelihood of changes to the genome varies with the method of genetic modification. This has been discussed in the recent report of the National Academies on the safety of genetically engineered foods. The report placed different methods on a continuum, with selection breeding from within a homogeneous population having the least likelihood of causing unintended changes and mutagenesis techniques the most likelihood. Significantly, the various recombinant DNA techniques fell at different points between these extremes.

(i) Conclusion

4.1060 Under present time constraints, we have not been able to address every issue discussed last week. However, we would be happy to answer any questions the Panel may have.

2. Comments on additional evidence submitted by other parties

4.1061 At the meeting with the experts on 17-18 February 2005, the Panel sought the parties' views on the status of certain documents referenced by the European Communities in its comments on the

experts' replies, but not submitted by the European Communities as exhibits within the deadline set by the Panel.

4.1062 Canada recalls that on 14 February 2005, the European Communities submitted a list of the documents cited to by the European Communities in its comments on the experts' replies, and a CD-ROM that supposedly contained all of the documents on the list. The list included approximately 360 separate documents. Canada also notes that the European Communities' submission of these documents was already some two weeks late.

4.1063 In reviewing the documents on the CD-ROM, it became evident that in at least one case (an article by M.J. Crawley, et al.) the document indicated on the European Communities' list is not the same as the document on the CD-ROM. Canada has been unable to determine whether there are more "substitutions" of this nature.

4.1064 More importantly, the CD-ROM received by Canada actually contains less than half of the documents found on the European Communities' list. In fact, Canada estimates that approximately 170 documents found on the European Communities' list are neither on the CD-ROM, nor among the exhibits already filed by any of the parties.

4.1065 In Canada's view, with the exception of official WTO documents, documents that have not been submitted by the parties as exhibits are not part of the record. Furthermore, no weight should be given to factual assertions or arguments that purport to derive their authority from such documents. There are a number of good reasons that support this view.

4.1066 I refer you to paragraph 12 of the Panel's Working Procedures in this regard. Paragraph 12 reflects standard DSU practice. Its purpose is two-fold. It enables the panel to make an objective assessment of the facts of the case, in accordance with Article 11 of the DSU. It also ensures that the parties have available to them and can consider in a timely manner all of the evidence upon which an opposing party relies.

4.1067 If it were the case that a party could simply refer to evidence in its submissions but not provide that evidence to the Panel and the other parties, opposing parties would be forced to track down that evidence in order to be able to protect their rights. This would impose an extraordinary burden on all parties – including, or perhaps particularly, on developing country parties – and would encourage the proliferation of improper litigation techniques. It would also severely hamper the functioning of panels, and likely have a significant negative effect on the ability of the Secretariat to assist panels in their work.

4.1068 Furthermore, in disputes such as this one, where the Panel has sought scientific expert advice, and the documents in question are extremely technical in nature, it is important for the experts to have full access to all documents on which the parties seek to rely. This is necessary in order to afford the experts an adequate opportunity to prepare for the meeting with the parties, and to assist the Panel as effectively as possible.

4.1069 In short, this is a basic issue of both procedural fairness and efficiency.

4.1070 The question arises whether, at this very late stage in the proceedings, the European Communities should nevertheless be given a last opportunity to submit these documents. In Canada's view, to allow the European Communities to benefit from its own repeated failure to meet the Panel's deadlines would threaten the integrity of the Working Procedures and render Paragraph 12 meaningless. The European Communities has had ample opportunity to submit these documents.

There can be no good reason why the European Communities was unable to produce on a timely basis documents that would have had to be in its possession in order for the European Communities to be able to rely on them when preparing its comments.

4.1071 In addition to plainly being at odds with the Working Procedures, allowing the European Communities to submit these documents at this late stage in the proceedings would significantly undermine the objective of the meeting with the experts and the second meeting of the parties. Moreover, both meetings involve considerable commitments of time and resources by the other parties, the Panel and the experts. Allowing the European Communities to submit these documents now would require the Panel to delay the proceedings further in order to allow the other parties and the experts an adequate opportunity to review and comment on the alleged significance of the documents in question, and then to afford the parties an opportunity to comment on whatever further replies are submitted by the experts.

4.1072 On a final note, as Canada has observed previously in these proceedings, the European Communities' pattern of failing to respond in a timely manner to the Panel's instructions is troubling. To reward the European Communities for its own repeated failures by allowing it to file the missing documents at this stage is to impose the consequences of those failures on the Panel, the other parties, and the experts.

W. SECOND ORAL STATEMENT OF ARGENTINA ON THE MEETING WITH EXPERTS AND ADDITIONAL SCIENTIFIC EVIDENCE

1. Comments on the expert meeting (17-18 February)

4.1073 We respectfully remind the Panel that we did not request this technical advice to be necessary for this case. Argentina considers that this WTO case is of a legal nature, rather than of a scientific one. Nevertheless, after the meetings on 17 and 18 February 2005, we consider the following issues to be relevant for the present case:

(a) Mere information vs. scientific evidence

(i) The relevance of scientific evidence

4.1074 In the current dispute, the European Communities has made every effort to submit more and more information, whether it was relevant or not. This led to a hard work that only confirmed that our initially submitted scientific evidence remained unrefuted.

4.1075 Argentina recalls the Panel's Follow-up Question 4[102], related to the distinction between what regulators "need to know" vs. what is "nice to know", as Dr. Snow had correctly pointed out in her responses.[103] When answering this Follow-up Question 4, Dr. Squire correctly asserted that:

> "If we get what we need to know, we are there."[104]

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[102] Follow-up Question 4 from the Panel to Experts, dated 17 February 2005, referring to "General questions", "Safeguard measures" and "Comparison of biotech products to other type of products" (*"Dr. Snow commented that it is not always clear where to make the distinction between what regulators «need to know» vs. what is «nice to know». (…)"*).

[103] Dr. Allison Snow "Responses to Scientific Questions from the Panel", "B. Scientific uncertainty during 1998-2003", second paragraph; 5 January 2005.

[104] Response by Dr. Squire to Follow-up Question 4 from the Panel, on Friday, 18 February 2005.

4.1076 This statement confirms the importance of identifying the necessary scientific evidence in order to make a decision. In this respect, we believe the point has been made that not any kind of additional scientific information is capable of refuting solid scientific evidence. We submitted scientific evidence, while the European Communities submitted a huge amount of information, but not evidence capable of matching the evidence submitted by Argentina.

(ii) Scientific evidence and hypothetical statements

4.1077 We appreciate the fact that Dr. Andow clarified his initially ambiguous answers, during the meetings of experts. Specifically, we appreciate the clarifications referred to his use of hypothetical statements.[105] We believe that the clarification proved to be very useful in order to make our points that there is actually no scientific evidence that can justify the European Communities' measures towards agricultural biotech products since October 1998.

4.1078 In this sense, Argentina highlights the important answer by Dr. Andow in the sense that he certainly agrees[106] with the following statement made by Argentina:

> "The absence of information does not imply the presence of effects".[107]

4.1079 We believe that the European Communities has had more than enough scientific evidence at hand in order to take a valid sanitary or phytosanitary measure and approve the agricultural biotech products, but instead the European Communities has tried to ignore this evidence in this WTO case with a huge amount of information, collected through several publications and extracted from opinions, supposed to refute solid evidence with "uncertainties".

4.1080 As the experts pointed out, there will always be a degree of new scientific findings that will complete or refine the previous knowledge. But this gap of knowledge cannot be used as an excuse for ignoring scientific evidence and applying a sanitary or phytosanitary measure without any supporting scientific evidence. As examples, Argentina welcomes that, during the meetings of experts, two important matters have been finally clarified for us all, disregarding the European Communities' arguments. With regard to horizontal gene transfer, we thank the clarification made by Dr. Squire, which confirmed Argentina's point.[108] Being so, we cannot accept the European Communities' assertion[109] as a valid scientific statement. With regard to the impact of agricultural

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[105] When answering the Questions from Argentina referring to "General questions", "Safeguard measures" and "Comparison of biotech products to other type of products" on Thursday 17 February, Dr. Andow explained that, when making his responses to the Questions from the Panel, he had taken the task "not to weigh the evidence, but to say whether it existed".

[106] Dr. Andow answered to this statement by Argentina submitted in Question 13 (advanced as question 10, referring to "General questions", "Safeguard measures" and "Comparison of biotech products to other type of products"), with the words: *"Certainly. I agree."*

[107] Response by Dr. Andow to Question 13 from Argentina (advanced as question 10, referring to "General questions", "Safeguard measures" and "Comparison of biotech products to other type of products"), in connection with Dr. Andow's paragraph 07.06 in his Response to Questions by the Panel.

[108] Question 32 from Argentina to Dr. Squire, dated 18 February 2005, referring to "Product Specific Questions". In his response, Dr. Squire stated: *"The issue of unlikely refers to the frequency… considering frequency, it is extremely low, time-dependant… whether evolution or agricultural practice is uncertain… There are studies in place… I am not qualified… In general, I agree with the tone of this question."*

[109] *See* Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 95, in which the European Communities refers to *"circumstantial evidence… during evolution and confirms the likelihood of the scenario."* Besides, the European Communities immediately says *"However, in terms of risk analysis, the risk has not been properly quantified and is probably very low."*

practice, the known impact of agricultural biotech products is marginal. In this sense, Argentina highlights the fact that even the European Communities had to finally admit this.[110]

(iii) The excuse of waiting for more information to appear

4.1081 It has been made clear that there is no sense in neither approving nor rejecting the approval of agricultural biotech products, just because the European Communities claims that it is waiting for new information to appear, for new technologies to develop, or for new methods and techniques to be discovered, when there is solid scientific evidence at hand.

4.1082 Argentina has carefully read the information submitted by the European Communities, and has found no matching evidence that could refute the positive scientific opinions by the European Communities' scientific committees. The alleged "uncertainties" or "hypothetical risks" do not refute the scientific evidence, and thus cannot justify what the European Communities did towards its WTO obligations.

(iv) The twisted view of the biotechnology – Relevance of science

4.1083 Argentina welcomes the appropriate clarifications by the experts in their responses and during the meetings, for example the use of the concept "contamination". The malicious use of terms has distorted the view in which these products are considered and the way in which they should be treated. Particularly, we would appreciate if the European Communities would restrain itself from using concepts like, "cancer"[111], "may induce dramatic unintended changes"[112], "infestation … to cause contamination"[113], among others.

4.1084 The experts' conclusion is contrary to European Communities' assumption that all agricultural biotech products should be treated as a whole, regardless from the "case-by-case" analysis which Argentina firmly believes should be strictly applied for deciding upon approvals or rejections of agricultural biotech products. The European Communities has continuously invoked this approach as well, but it actually does not apply it since October 1998. Even at these later stages of this WTO proceeding, the European Communities states that agricultural biotech products deserve to be considered as a whole.[114]

4.1085 In this sense, we quote Dr. Snow:

> "… Furthermore, it is not logical to group all GM crops into a single category and conclude that they are either inherently safe or inherently dangerous (*see*

[110] Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 238.
[111] *Ibid*.
[112] Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 55.
[113] Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 191.
[114] Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 45, last sentence, in which the European Communities refers to the products in general (not "case-by-case"), regarding possible effects on human health.

> Question 103 below). It is important to evaluate new GM crops on a case-by-case basis in each country where the crop will be grown, …"[115]

(b) Agricultural biotech products and "non-biotech" products

4.1086 Considering the food safety assessment, it has been proved that agricultural biotech products with a positive scientific opinion by the EC Scientific Committees have shown no differences with their "non-biotech" counterparts. Dr. Nutti has been very clear in this matter and has always remained within her field of expertise and referring to the Codex guidelines. We also recall the point made clear on Friday 18 February, regarding the feed safety, in the sense that the given products -crops- proven to be safe for humans, are expected to be safe for animals as well.

4.1087 Considering the no lesser important environmental issue, Argentina had the three experts on this matter to confront their opinions[116], and the result was that they agreed in two decisive statements. Both Dr. Snow[117] and Dr. Andow[118] agreed with the following statement by Dr. Squire, when referring to whether "contamination" risk is greater than for non-GM varieties:

> "… there is no reason to suppose that biotech crops confer different degrees of impurity compared with crops produced from, say, induced mutagenesis."[119]

4.1088 Additionally, both Dr. Squire[120] and Dr. Andow[121] did agree with the following statement of Dr. Snow, when referring to whether any of the biotech products at issue in this dispute poses a substantially greater risk as regards the direct or indirect consequences of unintentional "contamination":

> "Another way to answer this question is to focus on the characteristics of biotech crops -their phenotypes- rather than the mere presence of transgenes. This is more appropriate if the goal is to avoid direct or indirect harms to human, plant or animal health, or the environment. (…)"[122]

4.1089 Argentina observes as well that Dr. Andow agreed with two important statements by Dr. Snow, used by the Panel to put Follow-up Questions 6 and 7 to the experts:

4.1090 On one hand, Dr. Andow did agree when he was asked:

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[115] Dr. Allison Snow "Responses to Scientific Questions from the Panel", "A. Which environmental concerns about GM crops are really «science-based»", second paragraph; 5 January 2005.

[116] Questions from Argentina to Experts, dated 17 February 2005, referring to "Comparison of biotech products to other type of products".

[117] When asked to clarify by Dr. Snow, Dr. Squire stated *"A lot of crops have impurities; some can be ignored, some can be managed."* Consequently, Dr. Snow answered*: "Being so, I agree, because it is related to gene flow, and that is common to GMOs and to non-GMOs."*

[118] After the answer of Dr. Snow, Dr. Andow replied: *"If it refers to gene flow, I agree. It will depend on the goal, on the impurity management."*

[119] Dr. Squire "Measures affecting the approval and marketing of biotech products", "Notes on ecological and environmental standards", Issue 3, response to the Panel's Question 103.

[120] Dr. Squire answered: *"In the context of this question, I agree. In Europe, maybe the presence is not wanted, although there is no effect."*

[121] Dr. Andow responded: *"I agree."*

[122] Dr. Allison Snow "Responses to Scientific Questions from the Panel", "Comparable novel non-biotech products (such as plant products produced by selective breeding, cross-breeding and induced mutagenesis), answer 103, second paragraph; 5 January 2005.

> "Dr. Snow indicated that the process of inserting genes can have unintended consequences such as abnormal growth or development, but it is unlikely that these effects will be ecologically significant in commercially-produced biotech crops or that they would be more risky than the types of side-effects that arise routinely from conventional breeding".[123]

4.1091 On the other hand, he did also agree when asked:

> "Dr. Snow stated that there is no reason to expect different effects on the genetic diversity of wild relatives to arise from the gene flow from biotech as compared to non-biotech crops."[124]

4.1092 This said, we consider that it has been confirmed by the experts that agricultural biotech products with a positive scientific opinion by the EC Scientific Committees do not require a different treatment from the "non-biotech" products, as regards the food and feed safety issue and from the environmental point of view.

2. Comments on "additional scientific evidence"

4.1093 Argentina believes that there is no more evidence needed to be submitted in these proceedings, particularly after the outcome of the expert meeting. Putting it in a different way, the scientific evidence submitted by Argentina – the EC Scientific Committees positive opinions – was not matched by the mere information presented by the European Communities.

X. SECOND ORAL STATEMENT OF THE EUROPEAN COMMUNITIES ON THE MEETING WITH EXPERTS AND ADDITIONAL SCIENTIFIC EVIDENCE

1. Comments on the meeting with experts

4.1094 We had the benefit of hearing directly from the six independent scientific experts appointed by the Panel. The dominant themes that emerge from the experts' advice cannot be ignored by the Panel. We heard that the underlying scientific issues are complex and difficult – two words which were used repeatedly over the two days. We were told that the level of scientific understanding is evolving and that knowledge today is very different from ten years ago, and that five years ago the debate could not even have been held. We were told that each product has to be treated on its own merits. We were told that there are no established international standards to determine levels of ecological safety. We were told that each environment is unique and that you cannot simply transfer experience from one region, such as might be found in the United States, to another, such as might be found in the European Communities. And we were told that comparing GM products with non-GM products was like comparing apples and pears.

4.1095 The complaining parties would have the Panel ignore all of that. They would have the Panel decide against the plain facts and the views of the scientific experts. They would have the Panel decide that the EU should have simply applied the American or Canadian or Argentine experience to its own very different geographic and biological reality; and that even in the face of the insufficiency

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[123] Follow-up Question 6 from the Panel to Experts, dated 17 February 2005, referring to "General questions", "Safeguard measures" and "Comparison of biotech products to other type of products". Dr. Andow answered: *"I would agree."*

[124] Follow-up Question 7 from the Panel to Experts, dated 17 February 2005, referring to "General questions", "Safeguard measures" and "Comparison of biotech products to other type of products". Dr. Andow answered: *"I would agree. There is no sense in «biotech vs. non-biotech»."*

of the science none of the delays or the measures adopted were justified. The complaining parties would even have the Panel decide that there is no difference between "apples and pears". We submit that this would bring the WTO system and the DSU to a place it was never intended to be. It was surely not the function of the WTO to be used to allow one country (or group of countries) to impose their own system of values and their own attitude to risk and biosafety on another country or group countries.

4.1096 When Dr. Squire wished the Panel "good luck", he undoubtedly had in mind, from his perspective as a scientist, the monumental task of sorting out definitively the complex, evolving, divergent and contradictory views on the scientific issues. In reality, of course, this Panel's legal task is far more limited than that. And to that end, the scientific advice will eventually have to be placed in its proper legal context.

4.1097 The European Communities believes that the legal rules determine the relevance and significance of the scientific advice. The complaining parties, on the other hand, right from the start of this case, have made several erroneous legal assumptions – not least the claim that the European Communities adopted in 1998 and then maintained thereafter a definitive and general decision not to approve any GM products in Europe. This false assumption has seriously distorted the complaining parties' presentation and appreciation of the science.

4.1098 The scientific experts' advice was generally untainted by the legal context in which it was given. That gives it a special value. It was indeed striking to listen to the closing views of the experts. Taken together, and placed in the proper legal context, in our view, those statements clearly support the legal position of the European Communities in this case. They plainly entitle a WTO member to proceed with prudence and caution in its decision-making processes.

4.1099 In particular, the European Communities invites the Panel to take careful note of the remarkably high degree of consensus among all the experts to the effect that the science of GMOs is highly complex, continuously evolving, and still contains many open questions and uncertainties. On that basis alone, it cannot be right for the Panel to follow the simplistic and reductionist "one size fits all" approach of the complaining parties. We heard was that there is a basis for concern and prudence.

4.1100 The European Communities would like to briefly recall the tenor of some of the advice. Time and again the experts came back to the differences between food safety and environmental protection. Dr. Andow repeatedly stressed that there is a world of difference between these two subjects. Traditional food is generally assumed to be safe for consumption – so GM risk assessment for food safety, whilst still methodologically controversial, can generally start on the basis of comparison. This is simply not true of the environmental risk assessment. Consequently, the complaining parties' central assumption – that there are reliable comparators for environmental purposes – is not supported by the advice. At this time the science is not sufficiently well known. There are many respects in which the overall effect of GM products on the environment – whether negative, neutral or positive – was in 1998 and remains still today uncertain. This was eloquently illustrated by Dr. Andow's description of the far reaching consequences of what he referred to as the "European" earthworm's invasion of the forests of North America; juxtaposed to the beneficial effects of earthworms on soil structure in European agro-ecosystems.

4.1101 Another very striking closing remark made by Dr. Andow – which has been a *leitmotif* of all the expert advice – is the novelty, evolution and rate of change of scientific knowledge on highly complex issues, such as the environmental impact of changes due to the introduction of new agricultural technologies. GM products, Dr. Andow observed, have, to some extent, been swept up in

such developments. This case concerns many issues at the frontiers of science, in which the situation is dynamic and rapidly evolving. Legislators are entitled to be prudent.

4.1102 Dr. Andow also reminded us that, in this increasingly complex and evolving situation, it is legitimate (and even necessary), for assessors and legislators to take into account the way in which different issues are connected. He referred to herbicide resistant GM crops. In this respect, it may be true that one thing is the assessment of the GM product, and another thing is the assessment, done in isolation from the GM crop, of the herbicide used. However, it is now clear that it is legitimate – from a scientific point of view – to take the view that there are cross-cutting issues between the approval of an HTGM crop and the approval of the corresponding herbicide. Most notably, the use of the herbicide may affect the composition of the food or feed resulting from the HTGM crop as compared with its non-GM equivalent. Furthermore, Dr. Andow also reminded us that the newness of some of the herbicide tolerant traits, introduced into several crops in an agricultural environment where these herbicides are already present for other purposes, certainly had raised legitimate scientific questions and concerns for a decision maker. With a growing awareness of such issues comes a growing awareness of the implications of the lack of reliable comparators as regards environmental effects, and a growing awareness of the need to obtain information that is as complete as possible for conducting a full assessment. Time and again the experts advised that prudence and caution were justified.

4.1103 With regard to resistance, Dr. Andow also recalled that, over the last 50 years or so, knowledge about resistance problems had developed progressively. First with respect to insecticides; then with respect to fungicides; and more recently with respect to herbicides. For years entomologists were telling the world, with the introduction of each new insecticide, that there was no way that insect resistance problems would develop. And each time resistant insects would nevertheless emerge. So eventually, during the 1980s, scientists understandably stopped making such predictions. There is now a much greater awareness that it is possible that such problems could arise with a similar or greater impact, in the light of the level of expression of tolerance in GM plants, in the context of herbicide resistance. And glyphosate is an area of particular concern because of the way in which it is already used in the Europe, which reflects the particular agricultural structures in different regions. And Mr. Chairman, Members of the Panel, I would like to add that Glufosinate, although currently of more limited use in Europe, is nevertheless widely used as a main weed killer in orchards and vineyards, close to oilseed rape transport routes and close to major crop fields in Europe. Contrary to Canada's assertion, these are matters of significant and legitimate concern.

4.1104 Dr. Healy confirmed the need for a case-by-case approach. She urged that there be a careful assessment of all the available information. She emphasised that the quality and the quantity of the information were important for the risk assessment. She confirmed that missing information – that is, insufficient science – could legitimately give rise to safety concerns, and that generally the more data one has, the better the safety assessment can be. She indicated her view that, in a number of the applications she looked at when formulating her advice, not all the expected information was present or of sufficient quality.

4.1105 Dr Healy also echoed Dr. Andow's comments about rapidly changing science. She confirmed that scientific knowledge about molecular characterisation techniques has developed extensively over the past decade, particularly as regards the sequencing of the insertion and of the flanking regions. She observed that there has been a rapid evolution in detection methods, and that this accelerated in the late 1990s, with significant implications on the question of specificity in identifying the GMO. Her observations lend support to one of the European Communities' basic legal points: at the frontiers of science, assessors and legislators are entitled to be prudent.

4.1106 Dr. Snow rather memorably noted that learning about the concerns and issues relevant for the agro-ecosystem in the European Communities was like learning about another planet. She indicated that she had appreciated this process, and that, by placing herself in the shoes of the European Communities, she had come to understand that many of the concerns and requests for information were, indeed, valid. Picking-up on the closing remarks of Dr. Andow, and foreshadowing those of Dr. Squire, Dr. Snow indicated a shared concern about mischaracterised comparisons with regard to possible changes in agricultural practices, and their environmental implications. She also confirmed her view that many of the issues remained open as regards co-existence and traceability.

4.1107 Dr. Squire underlined how much has been learnt over the last 5 or 6 years on the scientific and technical aspects of European agro-ecosystems; he observed that the current debate could not even have been conducted a few years ago; and he expressed satisfaction that the relevant issues were now being more fully aired.

4.1108 Dr. Squire also drew the attention of the Panel to the fact that the concerns that were expressed in Europe and the research that had been done in response to them were now reflected in the international consensus reflected in the Codex standards. Accordingly, even though these standards did not exist at the time the European Communities was making many of its requests for further information these requests were compatible with what was later reflected in the standards. Dr. Nutti also confirmed that the Codex process started around 1999-2000 and it took four years to adopt the standard. So in fact, what the complaining parties would perhaps qualify as unnecessary requests, or inaction, has turned out to be the basis for international consensus, and if we have the international standards that we have today is in part thanks to the efforts made by EC authorities to know more.

4.1109 Dr Squire also reminded us that, as regards the environment, we are discussing potential impacts that, whilst not immediately catastrophic or large, did concern small changes that could certainly be significant and that incrementally, over time, could lead to very significant impacts. In the case of co-existence, he expressed the view that even very small changes could have dramatic effects for farmers' livelihoods.

4.1110 Earlier, Dr. Squire had recalled that, in some parts of Europe, and in contrast to the Americas, a very large proportion of land is in agricultural use, so that, in those areas, the "environment" is essentially constituted by agro-ecosystems. Consequently, in these regions of Europe, agricultural management, environmental, conservation and biodiversity issues are inseparable. In this situation, it is perfectly reasonable that the authorities consider that one cannot afford to obliterate a species just because it does not appear to be immediately economically useful. That is because, in complex ways, such species contribute to sustaining the environment that, in turn, supports us. The European Communities shares this view. It does not support the contention of Canada that the purpose of agriculture is to reduce biodiversity, or the apparent view of the United States that the conservation of biodiversity must be limited to specific geographical areas. By contrast, the European geographic and environmental context is materially different, so that one of the objectives of agriculture is the sustainable management of biodiversity. Unlike Canada, the European Communities does not ask the Panel to consider these matters "with respect to the whole world" (as Dr. Snow remarked) – but rather with respect to the specific characteristics of the receiving environment that European decision-makers are charged with protecting.

4.1111 Dr. Snape's comments throughout the experts' meeting often recalled the basic truth that one cannot compare "apples and pears". He made abundantly clear his view that it is perfectly acceptable from a scientific point of view for assessors and legislators to take into account the basic differences between GM and non-GM products. He confirmed the need for an extensive molecular characterisation in order to ensure sufficient knowledge for a proper risk assessment – that is, in order

to identify potential hazards – and in order to be able to assess the potential impact of the GM product.

4.1112 The European Communities has already commented on certain differences in approach between Drs. Snape and Healy. But the meeting with the experts served to clarify that, in fact, Drs. Snape and Healy agree on many issues. For instance, both of them confirmed that sophisticated methods of molecular characterisation were available by 1995. Moreover, Dr. Snape has written, and Dr. Healy explained orally last Friday, that they were surprised by the poor quality of the data submitted by applicants as regards molecular characterisation (with one exception). The European Communities considers that risk assessors are not required to operate on the basis of assumptions or guesses. They are entitled to seek complementary data. If the technology to produce such data was available at that time – as has been confirmed – and it was therefore practicable for companies to provide the data, why shouldn't the EC authorities ask for it? Why should risk assessors rely on second-best, potentially inaccurate, alternatives to carry out their work?

4.1113 Finally, with regard to food safety, Dr. Nutti accepted the general proposition that, at least where international guidelines, such as the Codex, left certain matters open for interpretation, there could be different but equally valid scientific views about how best to proceed, or about the amount of data requested. Where there are no established international standards – as in the case of environmental assessment and protection and notwithstanding the recent adoption of the Biosafety Protocol, which will hopefully lead to the emergence of such standards – Dr. Nutti's point becomes even more valid. Dr. Nutti also clearly admitted that there is a lack of international guidance as regards feed safety assessments – a matter in respect of which, in any event, Dr. Nutti made it very clear that she had not offered any advice to the Panel – and that the issue was therefore much more open than in the case of food safety.

4.1114 Perhaps we should step back and try to achieve some kind of overall perspective on the expert advice. In this respect, the European Communities would like to recall that the complaining parties launched this case on the basis that the science was sufficiently complete and that the science mandates, as the only possible approach, the immediate approval of all the relevant products by the European Communities. The complaining parties' view was that this Panel did not even need any advice from independent experts. Plainly, in the light of what the experts have now advised, the complaining parties' position is untenable. The scientific advice justifies the Communities' prudence and caution. It confirms the need to consider each product on its own merits. It confirms that the European Communities was and is justified in taking the time necessary to obtain the appropriate information – information that the applicants had simply failed to provide – and to consider all of the concerns legitimately raised by scientists, legislators and stakeholders. After the closing statements from the experts, there can be no doubt that the complaining parties' assumptions – and the legal assertions based on those assumptions – have been demonstrated to be wrong.

2. Comments on additional evidence submitted by other parties

4.1115 The European Communities has some difficulties in understanding the Panel's approach to the submission of "additional scientific and technical evidence" and/or "comments". The Panel's invitation to comment, today, on additional evidence submitted by the other parties, for us, is a welcome opportunity to clarify a number of issues.

4.1116 First, the European Communities notes the Panel's and Canada's apparent understanding that "evidence" is solely constituted of scientific papers or other forms of documented scientific expertise (such as the experts' advice) and that *comments* on such evidence do not constitute "evidence". It notes that the United States has accordingly not submitted any scientific evidence at all.

4.1117 The European Communities submitted evidence within the above meaning in its 31 January submission as well as in its 10 February submission and referred to a considerable number of scientific papers. Which leads to the second point.

4.1118 The issue arises as to when evidence within the above meaning can be considered to have been submitted to the Panel. The European Communities notes that the Panel reserved further discussion on this issue for the second meeting. As the European Communities has explained (in its letter of 14 February as well as at the expert meeting), it takes the view that where scientific expertise is publicly available, a reference to the source is enough for the purposes of submitting that evidence to the Panel. Where, on the other hand, such evidence is not publicly available, a copy of the expertise needs to be submitted to the Panel. Based on this understanding, the European Communities has submitted copies of all papers that are not yet published and has provided references to all other published papers it has relied on in its comments. In order, however, to facilitate the Panel's work it has sent, on 14 February, a CD containing copies of papers referred to in its 31 January and in its 10 February submission. The European Communities notes that Argentina has not submitted any copies of the scientific papers it has referred to in its submissions.

4.1119 Third, it is not entirely clear to the European Communities whether there is a difference between comments on additional evidence on the one hand, and comments on comments (on additional evidence) on the other. In a previous version of the timetable of these proceedings, the latter notion had featured, but terminology has changed since then. What complicates issues further is that we have been invited to comment on additional evidence as provided by the other parties today, but will have another opportunity to do so again some time after the hearing.

4.1120 The European Communities does of course have comments on the complaining parties' contentions. They were contained in our 10 February submission, which we annex to the first oral statement at the second meeting of the Panel with the Parties. The complaining parties have had them since 10 February, and the Panel will also have read them before rejecting them.

Y. SECOND ORAL STATEMENT OF THE UNITED STATES ON THE EUROPEAN COMMUNITIES' SECOND AND THIRD SUBMISSIONS

1. Introduction

4.1121 Since the first substantive meeting, hundreds of pages have been written and many, many hours have been expended by all involved. But in terms of the development of the dispositive legal issues, the complaining parties' case has only been further confirmed and remarkably little else has changed. In particular, the central defence of the European Communities – despite the overwhelming evidence to the contrary – remains that the European Communities did not impose a moratorium. The European Communities still has not even attempted to rebut the complaining parties' arguments showing that the moratorium is inconsistent with the *SPS Agreement*. And likewise, the European Communities has still not attempted to explain how its member State safeguard measures could be consistent with the *SPS Agreement*.

2. Developments since the first substantive meeting

4.1122 The European Communities' submissions have provided additional confirmation of the complaining parties' case – even though the complaining parties' first written submissions were more than sufficient and no additional confirmation was required. The confirmation has followed a consistent pattern: the European Communities has repeatedly submitted information supposedly in support of its positions, but each time the European Communities' information is both consistent with

the existence of a moratorium, and indeed provide further support for the complaining parties' contentions that the European Communities has adopted a moratorium and has failed to process applications without "undue delay."

4.1123 The first US written submission provided overwhelming evidence that the European Communities adopted and maintained a moratorium under both its deliberate release and novel food directives. EC officials and bodies from across the range of EC institutions – the Commission, the Council, the Parliament, and member States – have acknowledged the existence of the moratorium. Although no further confirmation is needed, the United States is providing one further official acknowledgment of the moratorium. The United States does so only because the European Communities in this dispute has claimed ignorance of the moratorium, and has asked the complaining parties to explain it. The exhibit, from a French Government website, asks and answer the question, "What is the *de facto* moratorium on GMOs?" The United States suggests that if the European Communities wants a definition of the moratorium, the European Communities should refer to this exhibit, which describes the moratorium, at least in the view of the Government of France.

4.1124 The first US written submission went on to explain that the moratorium was inconsistent with various provisions of the *SPS Agreement*: Articles 2.2, 2.3, 5.1, 5.5, 7, and 8 and Annexes B and C. Among other things, the United States explained that many of the product applications caught up in the moratorium had received positive risk assessments from the European Communities' own scientific committees. But then those applications failed to make further progress when the applications reached a political level – in particular, when the European Communities refused to submit the applications to a vote by member States in the European Communities' regulatory committee.

4.1125 The European Communities in its first written submission attempted to rebut the US *prima facie* case by arguing that any and all delays were the result of legitimate scientific questions, and by relying on certain exhibits to its first written submission. Those exhibits contained chronologies of the approval process for a number of products, along with only a small selection of the underlying documents cited in the chronologies.

4.1126 As the United States explained at the first substantive meeting, the European Communities' chronologies were perfectly consistent with the existence of a moratorium. The chronologies showed some questions from regulators and some responses, and some progress, but at the end of the day no decisions were made. Moreover, certain chronologies contained lengthy, unjustified gaps – of over two years – for which no explanation other than the European Communities' adoption of a moratorium were plausible.

4.1127 Also at the first meeting, the European Communities represented to the Panel that each of the member State objections and questions resulted from conflicting risk assessments, and thus that all delays were warranted to address outstanding scientific issues. When the Panel asked the European Communities to point out those risk assessments in the exhibits provided with the European Communities' first written submission, the European Communities explained that such documents were held by the member States. In other words, the European Communities had made representations to the Panel about a set of documents even though – according to the European Communities – the Commission did not even have access to those documents and would need to request them from member States.

4.1128 By late June, the European Communities provided additional documents from the dossiers, although the dossiers were still far from complete. In its second written submission, the United States explained that the partial product dossiers provided by the European Communities did not, as the

European Communities had asserted, contain competing risk assessments. And, the documents provided yet further confirmation – though none was needed – that the European Communities had subjected applications to "undue delay" and had adopted a moratorium. The United States identified additional application histories – particularly those nearing the final stage of the decision-making process – that exhibited lengthy, unwarranted delays, unrelated to any requests for additional information. In addition, a number of product histories contained specific statements from member States acknowledging the existence of the moratorium. In each case, the member States wrote that regardless of any scientific issues regarding the particular application at issue, the member State asking for more information was not going to vote for approval, unless and until the European Communities had adopted new forms of legislation.

4.1129 In August, the Panel requested that the European Communities complete the application histories that the European Communities had relied upon for its defence. As a result, an amended set of application histories was made available to the complaining parties and the Panel by the end of September.

4.1130 As pointed out in the third US written submission, once again the European Communities' additional documentation did not include the competing risk assessments claimed by the European Communities, and the documentation was fully consistent with the existence of a moratorium. And once again, upon examination, the documentation provided further evidence – although none was needed – of "undue delay" and the existence of the moratorium. The United States showed 13 examples of how underlying documents in the product chronologies confirmed the existence of unwarranted delays in processing applications. The third written submission of the United States also provided over 20 examples where the questions by EC regulators were not required for assessing risks.

4.1131 The process of consultation with experts followed. The experts' written and oral responses were consistent with the US views, and the experts noted many types of questions which were scientifically unjustified.

4.1132 In sum, the documents submitted by the European Communities and the comments from the experts are entirely consistent with a political-level moratorium under which applications were allowed to make some progress but were never allowed to reach a final decision. Moreover, the documents illustrate many instances of unwarranted delays in the form either of inactivity by the European Communities or member State officials, or in the form of unjustified requests for additional information.

3. Burden of proof

4.1133 Throughout this proceeding, the European Communities has placed great emphasis on the issue of the burden of proof – for example, the European Communities' third written submission is devoted largely to this topic. This dispute, however, presents no difficult or unusual issues regarding burdens of proof.

4.1134 The European Communities argues that the United States has not met its burden of presenting a *prima facie* case because the first written submission of the United States did not address "each and every delay" in the processing of each product covered in the US panel request. This argument is baseless. The contention of the United States and the other complaining party is that the European Communities adopted a moratorium that never allowed products to reach final approval. The United States does not contend, as the European Communities' argument implies, that the European Communities suspended all processing of applications, nor does the United States contend that each

and every one of the European Communities' delays were unwarranted. Thus, nothing in the theory of the US case requires an examination of each and every delay for each and every product.

4.1135 The European Communities also asserts that the European Communities, as opposed to the complaining parties, has provided most of the evidence in this dispute. This contention is untrue: the complaining parties have provided extensive evidence. For example, the first written submission of the United States included over 100 exhibits, including positive risk assessments by EC scientific bodies, numerous statements by EC officials acknowledging the moratorium on biotech approvals, and copies of the relevant EC laws and member State safeguard measures. What the European Communities really objects to is that the European Communities, as opposed to the complaining parties, provided the documents in the product application histories. The United States, however, did not need the application histories to prove its *prima facie* case. It was the European Communities itself that chose to rely on the application histories in the European Communities' attempt to rebut that *prima facie* case. Having chosen to rely on the product application histories, the European Communities cannot complain when the complaining parties insist that this information must be complete, and that the European Communities not be permitted to rely on excerpts of information presented by the European Communities out of context for purposes of this dispute.

4. Member State safeguards

4.1136 With regard to the member State safeguard measures, the United States has explained that, in each case, the European Communities' own scientific committees had reached positive risk assessments, and had examined and rejected the reasons put forth by the member States for adopting the measures. Accordingly, these measures also were not "based on scientific principles" and were "maintained without sufficient scientific evidence," in violation of Article 2.2. The measures also were not "based on" a risk assessment, in violation of Article 5.1. Although the European Communities has since vaguely implied that the measures fall within the scope of Article 5.7, this provision cannot apply to the member State safeguard measures. The European Communities itself has completed positive risk assessments: therefore the scientific evidence cannot be considered "insufficient."

4.1137 The European Communities continues not to provide a serious defence of the member State safeguard measures. Since the first substantive meeting, the only new development regarding the safeguard measures is that the Panel posed some questions to experts on the safeguards, and certain experts responded to those questions.

4.1138 With regard to food safety, the expert specializing in food safety found no validity to any of the rationales put forward by the member States. With regard to environmental effects, experts specializing in environmental issues wrote that certain member States in certain instances may have had scientific concerns that were not adequately addressed in the European Communities' positive risk assessments. These views of the experts on environmental issues, however, have very little significance for the resolution of this dispute, and certainly cannot suffice to bring the safeguard measures within the scope of Article 5.7.

4.1139 As the European Communities itself has stressed in its third written submission, the role of the experts is to provide views on scientific questions posed by the Panel; it is not the role of the experts to make the case for a disputing party. But the European Communities has never explained how Article 5.7 might apply to any of the member State safeguard measures. In particular, the European Communities has not described (1) why the member State believed that the relevant scientific evidence was insufficient to assess a risk, or even the specific risk that was of concern to the member State, (2) what available pertinent information might serve as the basis for the safeguard

measure, (3) whether the member State sought to obtain additional information necessary for an objective assessment of the risk; and (4) whether the member State reviewed the measure within a reasonable period of time.

4.1140 The experts provided scientific opinions on some of the elements that might be relevant to an analysis under Article 5.7 of the *SPS Agreement*, but those statements do not come close to a full analysis under Article 5.7. Moreover, even if the European Communities were to tried to build an Article 5.7 argument from the responses of the experts, the European Communities could not do so.

4.1141 First, the safeguard measures are product bans, preventing cultivation, import and processing, and the use of the products as food. The experts' responses, however, entirely support the scientific findings of the European Communities' scientific committees with respect to food safety. In addition, the experts' scientific concerns addressed cultivation, not import and processing. Thus, the experts' responses cannot serve as the basis for an argument that the safeguard measures fall under Article 5.7.

4.1142 Second, the experts' responses cannot assist the European Communities in meeting the third and fourth requirements of Article 5.7. In particular, Article 5.7 requires Members adopting a provisional measure to seek to obtain additional information necessary for an objective assessment of the risk; and to review the measure within a reasonable period of time. There is no basis for finding that the member States adopting the safeguard measures sought the additional information necessary for an objective assessment. As the Appellate Body confirmed in the *Japan – Agricultural Products II*, where a Member fails to seek additional information as required under Article 5.7, the measure cannot fall within the scope of the Article 5.7 analysis.

4.1143 Third, even where the experts speak of risks associated with cultivation, the experts were left to speculate on the actual reason the member State had for adopting the measure. The experts' speculations of the rationales of the member States cannot stand in the place of actual assertions by the European Communities concerning any purported scientific basis for its member State measures.

4.1144 Fourth, and finally, in the event the Panel would engage in further analysis of environmental issues under Article 5.7, the United States notes that the same experts who disagreed with the risk assessments of the SCP also generally found that either (1) science has advanced since the date of the imposition of the measures so that a risk assessment is now possible, and (2) that management measures are available and that there would no longer be a scientific basis for a total ban on planting. In addition, the experts noted that in some cases studies could have been started as early as 1998 to address the member States' concern. Those opinions of the experts are summarized in Part II.C of the US comments on the experts' responses.

5. Mootness

4.1145 At the first substantive meeting, the European Communities argued that this dispute is moot because the European Communities had approved a single product – a sweet corn for food use – under the Food and Feed directive. As the United States explained it its second and third written submissions, the concept of mootness is inconsistent with the text of the DSU and longstanding GATT and WTO practice. The measure to be examined in this case is the moratorium at the time of Panel establishment, which is August 2003. Nonetheless, the United States would like to point out recent developments illustrating that the moratorium is still very much alive. To be clear, whether or not the moratorium is maintained after August 2003 is not a legal issue before the Panel. But the current status of the European Communities' moratorium should be of considerable relevance to an understanding of the European Communities' motivations, and to an objective assessment of the facts.

4.1146 The United States refers the Panel to US Exhibit 148, which is an article describing the latest state of play in the political manoeuverings that lie at the heart of the moratorium. The excerpt illustrates and supports the following points.

4.1147 First, even nearly a year after the April 2004 entry into force of the new tracing and labelling and GM food and feed directives, the European Communities must still fight a political battle to reach a decision on any biotech product. This undermines the European Communities' contentions that products were delayed because of the need for the new directives to enter into force.

4.1148 Second, the application described in the article (GA21) is for food use. The product received a positive opinion from the Scientific Committee on Food three years ago, and yet the European Communities still fails to submit it to a vote of the member States in the Regulatory Committee. Since the approval is for food use, none of the environmental issues discussed at length by the European Communities in its most recent comments are relevant to the application. Yet, the political battle remains.

4.1149 Third, the European Communities continues to ban a large range of products for reasons that are openly political – openly, that is, except in the meetings in this dispute. This is why it is so important to the complaining parties, and indeed for the rules-based trading system itself, for the Panel to find that the European Communities' moratorium is not consistent with WTO rules.

Z. SECOND ORAL STATEMENT OF CANADA ON THE EUROPEAN COMMUNITIES' SECOND AND THIRD SUBMISSIONS

1. Introduction

4.1150 In these proceedings, the European Communities has consistently tried to remove biotechnology from the context of modern agriculture to exaggerate risks and scientific uncertainty. In contrast, Canada has sought to put biotechnology squarely back into its proper context. The European Communities' suggestion that its approach to biotechnology reflects a more prudent and profound concern for the environment is starkly refuted by Dr. Squire's testimony regarding general agricultural practices in the European Communities. Not only has the European Communities been "slow to learn", it has applied whatever knowledge it has learned in an arbitrary and scientifically unjustified fashion. This case is really about the arbitrary and unjustified distinctions that the European Communities has drawn between products developed through rDNA technology and products developed through the use of chemical mutagens or radiation.

2. Overview of the dispute

4.1151 Canada's principal arguments run as follows:

- The European Communities has maintained a *moratorium* on the approval of new agricultural biotech products since October 1998.

- The *moratorium* has effectively stalled indefinitely all product applications in the system, giving rise to *de facto* product specific marketing bans.

- A number of EC member States have put in place national bans on biotech products that had been approved by the European Communities prior to the institution of the *moratorium*. The member States that are maintaining these national bans are the same Member States that have expressed support for the *moratorium*.

4.1152 Canada has shown that these are distinct measures, that they are subject to the WTO Agreement, and that they are inconsistent with the *SPS Agreement*. The scientific advice given to the Panel by the experts reinforces the case that Canada has established.

4.1153 To this date, the European Communities has denied even the existence of the moratorium. It largely bases its defence on what it calls scientific complexity and uncertainty. It purports, on one hand, to rely on the advice of the experts in this regard. Where the experts do not agree with the European Communities' general theme, the European Communities seeks to discredit the experts in question, ignore their advice, and/or answer the Panel's questions itself based on what the European Communities implies is the advice of better experts. None of this has any merit.

4.1154 The European Communities argues that there are qualitative differences in the risks associated with biotech products as compared to their novel non-biotech counterparts. The evidence of the European Commission's own Directorate-General for Research demonstrates that this premise is flawed. It is also inconsistent with the repeated conclusions of the EC scientific committees and EFSA.

3. Arguments and evidence relating to the *moratorium* and the product-specific bans

(a) The moratorium

4.1155 In what follows, Canada responds to the European Communities' most recent arguments in relation to Articles 5.1, 2.2, 5.7 and 5.5. Canada has already demonstrated the ways in which the European Communities has given effect to the *moratorium* since 1998, and that the *moratorium* is a SPS measure for the purposes of the *SPS Agreement*.

(i) The European Communities has failed to base its moratorium on a risk assessment in violation of Article 5.1

4.1156 Article 5.1 requires WTO Members to base their measures on a risk assessment. The risk assessment must meet the requirements of Annex A(4) and there must be "a rational relationship between the measure and the risk assessment". The *moratorium* does not meet either requirement.

4.1157 The European Communities claims that Directive 90/220 was inadequate for assessing the environmental risks posed by biotech products, requiring amendments to that legislation. The European Communities claims that it adopted an "interim approach" while the new legislation was being developed. However, the evidence shows that the EC member States were not interested in making decisions on product applications under this approach. Furthermore, the evidence shows that the true reason for amending Directive 90/220 was to streamline the approval procedure, including a need to harmonize risk assessment criteria. A desire for harmonization does not constitute a risk assessment for the purposes of Article 5.1.

4.1158 The European Communities also asserts that an absence of appropriate risk management measures in its legislation prevented it from finalizing risk assessments. However, these risk management measures were not related to identified risks. This fundamentally undermines the European Communities' assertion that it assesses risks and applies risk management measures on a case-by-case basis. Therefore the European Communities cannot credibly argue that the need for such measures is "based on" a scientific risk assessment.

4.1159 In trying to rationalize the *moratorium* under Regulation 258/97, the European Communities points to hypothetical *unanticipated* chronic effects on human health. In essence, the European Communities asserts that the new requirements for labelling, traceability and detection methods are necessary so that long-term chronic effects of biotech products could be appropriately studied. The European Communities claims that the absence of evidence of acute toxicity is not proof of an absence of long-term chronic effects. This applies to almost any novel food and reflects the European Communities' attempt to divorce biotechnology from its proper context. The argument that long-term chronic effects need to be studied for all biotech foods, as a class, also suggests the European Communities is not assessing risks on a case-by-case basis. In any event, the European Communities fails to put forth any evidence, much less a risk assessment, to suggest that a *moratorium* was necessary until such measures were put in place. This is because no scientific justification exists.

4.1160 The *SPS Agreement* does not permit a WTO Member to suspend existing SPS approval procedures, thereby effectively banning products with pending applications, simply because it wants to update its legislation. A suspension may be warranted in some circumstances, for example, where credible scientific evidence demonstrates actual risks to human health or the environment. That is not the case here. The legislative changes, for the most part, were related to hypothetical adverse effects or to facilitate the removal of a product from the marketplace in the unlikely event of a hypothetical risk arising.

(ii) The European Communities may not rely on scientific uncertainty to justify the moratorium under Article 5.7

4.1161 The European Communities attempts to rationalize the *moratorium* and the resulting delays in processing individual applications on the basis of scientific uncertainty, claiming that the scientific evidence was insufficient to complete risk assessments and adopt appropriate risk management measures. If this is so, the European Communities must demonstrate that the *moratorium* falls within the scope of Article 5.7 and that it meets all of the requirements of that provision. The European Communities fails to do so; instead it suggests that it is for the Panel to develop the European Communities' arguments. As a matter of law, this is not sufficient to discharge the European Communities' burden.

4.1162 In any event, the *moratorium* does not meet the requirements of Article 5.7. The European Communities has not established that the "relevant scientific evidence is insufficient" to complete a risk assessment. "Sufficiency" requires the existence of an "adequate relationship between two elements". These two elements are the scientific evidence and the obligation to base SPS measures on a risk assessment. Thus, the question is whether the relevant scientific evidence is sufficient for a Member to base its SPS measures on a risk assessment. If the evidence is sufficient, then Article 5.7 may not be used as a defence.

4.1163 The European Communities cannot credibly claim that relevant scientific evidence regarding biotech products is insufficient to permit the evaluation of the likelihood of entry, establishment or spread of a pest, or the evaluation of the potential for adverse effects on human or animal health from consuming biotech products. Prior to the *moratorium*, the European Communities considered the scientific information regarding biotech products to be sufficient to permit such an evaluation. Indeed, the European Communities approved several such products, all of which remain on the EC market. Community-level scientific committees have repeatedly performed risk assessments (and have found no evidence of risk), demonstrating conclusively that there is sufficient scientific evidence to permit the European Communities to perform a risk assessment.

4.1164 Much of the "scientific uncertainty" raised by the European Communities is really the "uncertainty that theoretically always remains since science can *never* provide *absolute* certainty that a given substance will not ever have adverse [] effects". The European Communities states that, "an absence of scientific evidence does not constitute evidence of an absence of impacts or risks." This may be true if a reasonable effort is not made to conduct studies to detect plausible hazards and evaluate the risks these hazards might pose. This is obviously not the case here. A considerable amount of research on potential risks has been carried out. The European Communities is in effect seeking "absolute certainty" and then suggesting that the absence of absolute certainty makes it impossible for this Panel to do its work. It seeks to equate the lack of absolute certainty with insufficient scientific evidence, even though the Appellate Body has made it clear that these concepts are not interchangeable.

4.1165 The question here is whether relevant scientific evidence is sufficient to perform a risk assessment, not whether, at the margins, some scientific uncertainty remains. In determining whether relevant scientific evidence is sufficient one must have regard for the context. The European Communities attempts throughout its submissions to shift the focus away from the large quantity of high quality scientific information available, to the margins of scientific uncertainty. This strips biotech products of the context within which they have been developed and are to be employed, and downplays the vast experience within the European Communities and around the world with plant breeding technology, food safety assessment, and the management of herbicide and pesticide resistance, amongst other things.

4.1166 A large body of research on transgenic plants has been carried out by university and government laboratories investigating aspects of rDNA technology, and a considerable part of that research has been undertaken in the European Communities. All of this forms part of the abundance of high quality scientific evidence concerning the risks or potential risks posed by the products in question in this dispute. Dr. Squire indicated that biotech products have been subjected to an "unprecedented" degree of regulatory scrutiny. As compared to their conventional counterparts, considerably more information is known at the molecular level about the currently available biotech products. Consequently, the European Communities cannot credibly claim that relevant scientific evidence was or is insufficient then to justify the suspension of the approval procedures for biotech products. Accordingly, Article 5.7 cannot be invoked to justify the *moratorium*.

4.1167 Similarly, the European Communities cannot credibly claim that relevant scientific evidence was insufficient to perform a risk assessment in relation to specific product applications. The determination of whether relevant scientific evidence was sufficient to undertake and complete a risk assessment is linked to the issue of "undue delay" under Annex C1(a). Article 5.7 informs the determination of "undue delay" under Annex C(1)(a).

4.1168 Given the *moratorium* and its demonstrated impact on the processing of applications, the European Communities must demonstrate in each case that "relevant scientific evidence is insufficient" to complete the risk assessment in that case. This requires a determination of "sufficiency". In other words, what information is "need to know" and what information is "nice to know". As indicated by the experts, many of the requests for additional information by EC member States were not necessary to ensure the validity of the risk assessments that had been performed. So, the absence of "nice to know" information cannot justify a claim of insufficiency of scientific evidence.

4.1169 Some of the EC member State questions have been based on a presumption that the product necessarily will be cultivated on a large scale. The European Communities asserts that, because the agro-environmental impacts from large-scale cultivation cannot be predicted with absolute certainty, a

failure to approve the product is justified. However, there is no *a priori* reason why cultivation cannot be introduced on a smaller and progressive scale. A gradual introduction of a product, with appropriate monitoring plans and agricultural guidelines, has already been demonstrated to be a feasible option in the European Communities.

4.1170 In determining whether relevant scientific evidence is sufficient, it is important to consider the totality of the information submitted in support of an application. This approach is endorsed by Drs. Healy and Nutti and has been adopted by the Community-level scientific committees. In the light of the large quantity of reliable scientific evidence developed over the years, in part by the European Communities itself, and the fact that the European Communities' own independent scientific committees have been able to complete risk assessments, any claim by the European Communities that "relevant scientific evidence is insufficient" is without merit. The European Communities has failed to meet the first requirement of Article 5.7. As the requirements under Article 5.7 are cumulative, and the European Communities has not and cannot meet the first requirement, it is not necessary to address the other elements of Article 5.7.

4.1171 For these reasons, the European Communities cannot successfully invoke Article 5.7 to excuse its failure to meet the obligations under Article 5.1 or Article 2.2 of the *SPS Agreement*.

(iii) The European Communities' application of its appropriate level of protection for biotech products results in discrimination or a disguised restriction on international trade, contrary to Article 5.5 of the SPS Agreement

4.1172 It is apparent from its most recent arguments that the European Communities is seeking a level of protection for biotech products that approximates "absolute safety". The European Communities has raised almost every imaginable hypothetical risk, often relying on scientific reports that have been widely dismissed. Despite rigorous risk assessments and no evidence of harm, the European Communities strenuously maintains that risk management measures are necessary.

4.1173 Despite the broad international consensus that biotech products should be contrasted on a comparative basis with their conventional counterparts, the European Communities' approach is to assess biotech products in a vacuum. The European Communities ignores the demonstrated benefits associated with these crops and the well-established risks to human health and the environment arising from the existing practices that some of these crops can help improve. By doing so, the European Communities seriously undermines its claim to be acting on a precautionary basis in order to protect the environment.

4.1174 The European Communities' level of protection for biotech products should be contrasted with the level adopted for novel crops developed through other forms of genetic modification, such as radiation and chemically-induced mutagenesis; somaclonal variation; and even conventional selective breeding. As confirmed by the experts, biotech and non-biotech methods of genetic modification do not differ inherently with respect to the types of risks to human health or the environment that they pose.

4.1175 All methods of introducing genetic variation have potential to produce unexpected and unintended effects. The experts agreed with this. The likelihood of changes to the genome varies with the method of genetic modification. This has been discussed in the recent report of the National Academies on the safety of genetically engineered foods. The report placed different methods on a continuum, with selection breeding from within a homogeneous population having the least likelihood of causing unintended changes and mutagenesis techniques the most likelihood. Significantly, the various recombinant DNA techniques fell at different points between these extremes.

4.1176 Unintended effects do not necessarily imply hazard. The potential for hazard arises from the product, rather than the method of production. It is interesting to note that the most striking unintended effects on human health from food production have resulted from conventional breeding (*e.g.* potatoes with high levels of glyco-alkaloid). The method used in developing the product does not alter the nature of the risks.

4.1177 Despite the fact that all forms of plant genetic modification have the potential to produce unintended adverse effects, the European Communities has not imposed a *moratorium* on products from other forms of plant breeding. Indeed, although plants produced via conventional breeding methods are routinely evaluated for changes in productivity, reproductive efficiency, reactions to disease and quality characteristics, they are not assessed for safety.

4.1178 One of the most striking examples of the European Communities' selective concern about risks is the difference in its treatment of herbicide tolerant (HT) oilseed rape crops developed through mutagenesis and recombinant DNA technology. The experts agreed that HT crops, regardless of the method of production, posed similar risks. The European Communities' entire discussion in its comments on the experts' advice about the risks posed by HT crops applies equally to biotech and mutagenic crops. However, despite the fact that the likelihood of unanticipated changes to the genome are at least as likely with mutagenesis as with transgenesis, the European Communities does not require a comprehensive risk assessment for HT crops developed through mutagenesis. For mutagenic crops, unlike their biotech counterparts, there appears to be little concern with the environmental or health effects. The panoply of regulatory requirements imposed on biotech products is completely absent in the case of mutagenic crops. Above all, there is no *moratorium*.

4.1179 Given the similarity of risks and the other factors set out in Canada's First Written Submission, these differences in appropriate levels of protection are arbitrary and unjustified and give rise to discrimination or a disguised restriction on international trade in violation of Article 5.5 of the *SPS Agreement*.

(b) Product-specific marketing bans

(i) Oilseed rape GT73

4.1180 Keeping in mind that the oil produced from GT73 oilseed rape has already been approved for human consumption, Dr. Nutti's conclusions concerning the impact on human health were entirely consistent with the Dutch Competent Authority and the EFSA opinions. In terms of animal feed, the European Communities has failed to cast doubt on the EFSA 2004 opinion concerning the safety of GT73 for use as feed. The European Communities' alleged concern about the pesticide residues and related metabolites was dismissed by Dr. Nutti.

4.1181 In terms of environmental release, the alleged concern cited by EC member States appears to be related to the potential of seed spillage. The experts dismissed this concern as not being scientifically justifiable, and the studies cited by Dr. Squire are of limited applicability, given that in-land transportation of imported seeds is unlikely. In any event, if seed spillage occurs around docklands and processing facilities, these weeds can be easily controlled. Dr. Squire also agreed with the EFSA opinion that the monitoring plan proposed by the notifier was acceptable given the factors set out in the EFSA opinion. Thus, the demands for more onerous monitoring are entirely unjustified.

4.1182 Because the product-specific ban for GT73 is not supported by a risk assessment, the European Communities is violating Articles 5.1 and 2.2. Moreover, a delay of seven years in approving this product is, by any reasonable standard, "undue" and therefore violates Annex C(1)(a).

Furthermore, by imposing the ban on GT73, continuously making unjustified demands for additional information and seeking to impose onerous and unnecessary monitoring requirements, the European Communities is violating Article 5.5. The main beneficiaries are European oilseed rape producers selling their products to European Communities' crushing facilities.

(ii) Oilseed rape Ms8xRf3

4.1183 In terms of molecular characterization, Dr. Healy confirmed that the requests for additional molecular characterization were not necessary to complete the safety assessment. Dr. Snape agreed with both Dr. Healy and, importantly, with the February 2002 opinion of the Belgian Biosafety Council. The experts also confirmed that the likelihood that Ms8xRf3 would establish or spread as a weed in the absence of the application of glufosinate-ammonium was no different than for conventional varieties of oilseed rape, and that the techniques in place to control conventional oilseed rape volunteers or weeds can be applied with equal effectiveness to Ms8xRf3.

4.1184 In assessing the legitimacy of the Belgians' request for additional information on farmland biodiversity, food web integrity, etc., the Panel should bear in mind the full context in which the request was made, as well as the advice provided by Drs. Snow and Squire.

4.1185 Although the experts indicated that, technically speaking, the Belgian request was justified, when placed in context, the request should be seen as an attempt to frustrate the approval procedure. The effects of herbicide use can be managed, and herbicide-tolerant crops provide additional flexibility in terms of weed control.

4.1186 The product-specific ban for Ms8xRf3 is not "rationally connected" to the risks identified in the risk assessment, contrary to Article 5.1 and by implication Article 2.2. Moreover, a delay of nine years in approving this product is by any reasonable standard, "undue" in violation of Annex C(1)(a). In terms of Article 5.5, by imposing this ban, continuously requesting unnecessary information and seeking to impose onerous monitoring requirements and agricultural practices, the European Communities is violating Article 5.5.

(c) National bans

4.1187 Canada stands by its previous legal arguments, which are supported by considerable documentary evidence, and which demonstrate that the EC member State national bans are SPS measures, and that they are subject to, and inconsistent with, Articles 5.1, 5.5, 5.6, 2.2 and 2.3 of the *SPS Agreement*. In contrast, the European Communities has yet to develop a fully coherent legal and factual argument for each of the measures that would refute Canada's initial *prima facie* case.

4.1188 Canada has a few additional comments in the light of the advice of the scientific experts and the European Communities' written comments on those replies. In brief, the experts' advice largely reinforces Canada's arguments that the national bans are not supported by sufficient scientific evidence or a risk assessment, contrary to Articles 2.2 and 5.1 of the *SPS Agreement*. Furthermore, the expert advice supports the proposition that Article 5.7, even if it may have been applicable to these measures at the time they were adopted, did not apply by the time this Panel was established, and that it does not apply today.

4.1189 Oilseed rape Topas 19/2 was approved by the European Communities for import and processing in April 1998. It has been banned by France and Greece. The experts agreed that no scientific rationale exists for these measures given that the product was only approved for import and processing. Although Dr. Andow suggested that France could have justified its measure in 1998 –

albeit on grounds other than those actually cited by France – he concluded that France and Greece would have had sufficient data could have made a decision no later than 2001. The European Communities, in its comments on the experts' replies, misrepresents the essential question that must be answered. Indeed, France's own scientific experts did not consider herbicide-tolerant oilseed rape – when imported for processing purposes – to give rise to any more risks than conventional oilseed rape.

4.1190 The experts also agree that the "scientific evidence and other information" provided by France does not meet the definition of a risk assessment as set out in either the *SPS Agreement* or the IPPC. Although Dr. Andow suggests that the documentation does fall within Annex III of the Biosafety Protocol, in Canada's view, Annex III does not constitute an international standard for the purposes of the *SPS Agreement*, and is therefore not relevant to a determination whether the materials submitted by France meet the requirements of the *SPS Agreement*.

4.1191 Finally, based on the draft decision it has tabled in the Regulatory Committee, the European Commission shares the view that there is no scientific justification for maintaining a prohibition on the import and processing of oilseed rape Topas 19/2. The conclusion is inescapable that the French prohibition and the Greek import prohibition on Topas 19/2 is being maintained without sufficient scientific evidence, contrary to Article 2.2 of the *SPS Agreement*, is not based on a risk assessment, contrary to Article 5.1 of the *SPS Agreement*, and cannot be justified on the basis of Article 5.7 because sufficient scientific evidence exists to complete such a risk assessment.

4.1192 In relation to maize T25, according to Dr. Andow the emergence of weed resistance was the only plausible concern raised by Austria. Even then, it is not clear from the evidence that Austria was truly concerned about this potential risk. In any event, the reality, as the European Communities must recognize, is that glufosinate ammonium has been remarkably successful in terms of preventing the emergence of resistance, and herbicide resistance management strategies were well developed by the late 1990s.

4.1193 T25 has undergone an exhaustive scientific scrutiny. In each and every instance, the European Communities' own scientific experts came to the same conclusion. The European Communities' evidence cannot be considered an adequate basis to find that Austria's ban was or is consistent with either Articles 2.2 or 5.1, or justifiable under Article 5.7. Were it otherwise, the disciplines found in these provisions would be rendered largely meaningless.

4.1194 Finally, with T25 as with other products, the European Commission has tabled a draft decision asking Austria to repeal the ban prohibition on maize T25. Evidently, the Commission shares Canada view that there is no scientific evidence to justify the maintaining the measure.

4.1195 Regarding the Italian ban on maize MON809, MON810, Bt11 and T25, Canada seeks clarification from the European Communities with respect to the ban's current legal status. There is some evidence that the measure is no longer in effect, but this evidence is not conclusive. Canada therefore seeks confirmation from the European Communities (with supporting documentation) that the Italian measure has been repealed or has otherwise been rendered null and void.

4.1196 Assuming that the measure remains in effect, the absence of evidence to support a national ban in this case is, if anything, even more pronounced as compared to the other product specific bans. Dr. Nutti was the only expert who addressed the Panel's questions with respect to Italy's national ban. For each of these maize varieties, she concluded that Italy had sufficient scientific evidence available to it to complete the risk assessments, and that the information provided to the European Commission by Italy in support of its measure "did not support a temporary prohibition" of MON810, MON809,

Bt11 or T25. In its comments on Dr. Nutti's replies in relation to the Italian national ban, the European Communities offers scant scientific evidence in its efforts to discredit or contradict her opinion. It also gets some of the facts wrong. For instance, it confuses the *bla* gene, which confers antibiotic resistance to ampicillin, with the *nptII* gene. Furthermore, the *nptII* gene is not present in the final construct and, in any event, it has a 13-year history of safe use in food and feed.

4.1197 In short, as with the other EC member State national measures, the advice of the experts, and all other available scientific evidence strongly supports Canada's arguments that the Italian measure is not based on a risk assessment, contrary to Articles 5.1 and 2.2 of the *SPS Agreement*. Furthermore, it seems clear that sufficient scientific evidence exists to complete a risk assessment, and that Article 5.7 therefore is inapplicable.

4. Other issues

4.1198 Canada turns briefly to the European Communities' arguments with respect to standard of review and the definitions provided by international organizations (IOs).

4.1199 In regard to the standard of review, the European Communities makes two assertions, neither of which has any merit. First, the European Communities argues that the Panel should limit its examination of the scientific evidence and data to that existing at the time of the measure was put in place. Second, the European Communities argues that the Panel should take a deferential approach in its assessment as to whether the European Communities has violated Article 1(a) of Annex C. For each argument, the European Communities misrepresents the proper role of the Panel by misconstruing and misapplying the language of Article 11 of the DSU and the relevant jurisprudence.

4.1200 First, regarding the temporal issue, the European Communities' reliance on *US – Cotton Yarn* is misplaced; the standard of review in safeguard cases is different from the standard of review in SPS cases. To limit the inquiry to the "state of scientific information and data existing at the time the measure" arose would not enable the Panel to determine whether the measure was justifiable at the time the Panel was established, contrary to the object and purpose of the *SPS Agreement*, and inconsistent with the requirement in Article 11 of the DSU. The reference in Article 2.2 to the "maintenance" of an SPS measure would lose all meaning, contrary to the principle of effective treaty interpretation.

4.1201 Second, the European Communities' attempt to create a distinction in the application of the standard of review as between Article 5.2 and Annex C1(a) is not supported by the jurisprudence. The Panel should review the European Communities' measures based on how a reasonably diligent government would and should have behaved in view of the factual information at its disposal. A deferential approach to the interpretation and application of Annex C1(a) would not be consistent with the jurisprudence. In any event, there is no doubt that the European Communities has failed to meet its procedural obligation under Article 1(a) of Annex C. Accepting that 6.5 years amounts to a justifiable delay would render Annex C(1)(a) meaningless; this would be inconsistent with the principle of effective treaty interpretation.

4.1202 In regard to the definitions provided by the IOs, the European Communities asserts that the definitions support the European Communities' case. Canada disagrees. On their face, the definitions found in the materials provided by the IOs do not support the European Communities' assertions as to the meanings of the terms in question. Despite the European Communities' contentions that a GMO cannot, *a priori*, be considered as toxins, contaminants, allergens, pests, disease-causing or disease-carrying organisms, definitions of these terms, or elements of them can all be found in documents that expressly address biotechnological issues. If the European Communities' assertions were correct,

there would be little rationale for these terms to appear in glossaries and international standards documents pertaining specifically to biotechnology.

4.1203 Furthermore, and in any event, the definitions provided by the IOs are not dispositive of what the enumerated terms mean in the context of either the *SPS Agreement* or the *TBT Agreement*. This is particularly true of those enumerated terms that appear in these agreements. Terms such as these must be interpreted in accordance with the customary rules of treaty interpretation, as expressed in Articles 31 and 32 of the *Vienna Convention on the Law of Treaties.*

AA. SECOND ORAL STATEMENT OF ARGENTINA ON THE EUROPEAN COMMUNITIES' SECOND AND THIRD SUBMISSIONS

1. The *de facto* moratorium measure

(a) The measure addressed in these proceedings

4.1204 Referring to the *de facto* moratorium, which is the lack of any approvals or rejections of any new agricultural biotech product since 1998, the European Communities has failed to approve a single application until 2004. Faced with this lack of approvals or rejections, the European Communities has limited itself to deny the existence of the *de facto* moratorium or, alternatively, to assert that if such a measure exists it would not be challengeable under WTO Agreements. Argentina has demonstrated throughout these proceedings that both assertions have no basis.

4.1205 The existence of the *de facto* moratorium has been recognized by high EC officials with jurisdiction over the matter addressed in this dispute in a number of opportunities, and this evidence was put before the Panel. Hence, Argentina will not repeat references to this striking evidence.

4.1206 The *de facto* moratorium consists in a persistent conduct of the European Communities that reflects a practice. This pattern of conduct is a compound of acts and omissions that have as effect the stalling of all applications in the European Communities' approval system. The *de facto* moratorium operates at the crucial stages of the procedures under EC regulations. Although some applications have moved within the approval procedures, this movement in no case has resulted in approval or rejection. This fact lies at the heart of the concept of the *de facto* moratorium.

4.1207 The European Communities' assertion about the impossibility of challenging the *de facto* moratorium under WTO Agreements was rebutted by Argentina in these proceedings. Argentina's arguments are supported by GATT/WTO jurisprudence and they were explained in its First Written Submission.

4.1208 Argentina would like to stress that if we were to follow a narrow definition of "measure", it would result in allowing WTO Members to circumvent legal scrutiny of their measures simply by not putting them in a piece of legislation. Moreover, it would also devoid WTO law of its meaning.

4.1209 The first of these consequences (circumvention of legal scrutiny) was already referred to in Argentina's First Written Submission, and even pointed out by third parties in these proceedings. However, Argentina would like to refer to the second of these consequences (to devoid WTO law of its meaning).

4.1210 According to Argentina's point of view, from the GATT/WTO jurisprudence arises quite clearly that one central feature of WTO system is to ensure that Panels and the Appellate Body are able of scrutinizing all measures regardless the way by which WTO Members may have put them in

place. A narrow definition of "measure" would lead not only to foster the lack of transparency by the WTO Members but also to deprive panels and the Appellate Body from analysing any measure which infringes the covered Agreements. Jurisprudence was clear in interpreting GATT/WTO law in a broad sense, in order to assure that compliance with WTO law would not be circumvented simply because of the form in which a measure is imposed. Argentina deems that in the present dispute the European Communities should not use its own lack of transparency to avoid legal scrutiny of the *de facto* moratorium.

(b) Inconsistency of the *de facto* moratorium with Article 5.1 of the *SPS Agreement*

4.1211 The European Communities' legislation establishes that the assessment of biotech products must be on a "case-by-case" basis. However, the European Communities has imposed, without any scientific evidence, an across the board measure to all biotech products in the European Communities' approval system. Since this measure lacks of any basis on scientific evidence, it infringes basic obligations contained in the *SPS Agreement*. Besides, this *de facto* moratorium undermines the European Communities' assertion that it has been assessing the risks on a "case-by-case" basis.

(c) The European Communities cannot justify the *de facto* moratorium under Article 5.7 of *SPS Agreement*

4.1212 Argentina considers that the European Communities has had sufficient relevant scientific information at hand, namely the positive opinions issued by its Scientific Committees. These positive opinions constitute sufficient scientific evidence in terms of Articles 2.2 and 5.1 and have not been refuted either by the European Communities or by the experts appointed to assist the Panel.

(d) The *de facto* moratorium infringes Article 5.5 of *SPS Agreement*

4.1213 The experts have ratified that the treatment given by the European Communities to agricultural biotech products compared with "non-biotech" products is inconsistent with Article 5.5. This is because it was demonstrated that agricultural biotech products entail similar risks than those arising from "non-biotech" products.

2. The "suspension and failure to consider" is not based on scientific evidence, and therefore violates WTO obligations

4.1214 Regarding Bt 531 cotton, we believe that the EC's alleged scientific arguments remain refuted as the evidence submitted by Argentina has not been contested by other relevant scientific evidence. As regards the meetings on 17-18 February, the issue affecting Bt 531 cotton has been analysed in a broader scope, and from the responses from the experts the European Communities cannot invoke any valid or relevant scientific evidence which could refute the positive scientific evidence arising from the opinion of the EC Scientific Committee from July 1998.

4.1215 Regarding RRC 1445 cotton, Argentina considers that the meetings from 17-18 February did clarify the questions, and confirmed our argument in the sense that there is no scientific evidence within the information submitted by the European Communities that could refute the positive opinion by the EC Scientific Committee dated July 1998 which favored the approval of RRC 1445 cotton. We particularly mention the clarification made by Dr. Squire referred to the alleged possibility of horizontal gene transfer, confirming Argentina's point.

4.1216 With regard to NK-603 maize, Argentina is pleased that it has been properly addressed by the experts. We agree with Dr. Andow, when he asserted that there were no reasons to dismiss the

positive opinion from the European Communities' scientific committees in the way the European Communities tried to do in these proceedings. As regards the meetings on 17-18 February, the original extent and value of the positive opinions by the European Communities' scientific committees have been clearly established, especially when Dr. Nutti specifically addressed an issue contained in the positive assessment and which the European Communities tried to turn into an hypothetical question. Additionally, we also appreciate that the experts did recognize that monitoring is not needed when the product is intended to be only for import and not for cultivation.

4.1217 With regard to GA 21 maize, the application was withdrawn in September 2003, and Argentina states that this withdrawal precisely demonstrates the effect of the *de facto* moratorium and the "suspension or failure to consider". GA 21 maize did receive a positive scientific assessment both under Directive 90/220 and under Regulation 258/97. The European Communities did ignore for years this scientific evidence favouring approval, until the applications were withdrawn.

4.1218 Summing up, Argentina respectfully requests the Panel to find that the "suspension and failure to consider applications of products of particular interest of Argentina" are inconsistent with the European Communities' WTO obligations.

3. The "undue delay"

4.1219 Article 8 of *SPS Agreement* establishes two different obligations: the first one refers to the commitment to comply with Annex C, and the second one establishes the obligation to ensure that "their procedures are not inconsistent with the provisions of this Agreement". Given the fact that Argentina has demonstrated that Article 5.1 has been infringed, the delay in the approval of agricultural biotech products of interest to Argentina is not justified, as it is not based on scientific evidence. Therefore, there is no reason that justifies the delay. This is without prejudice of the particular infringement to paragraph a), b), c) and e) of Annex C.1 of *SPS Agreement*.

4. The member State bans are not based on scientific evidence, and therefore violate the *SPS Agreement*

4.1220 The specific products affected by the measures applied by Germany, Austria, Italy and Luxembourg had prior approval by the European Communities, based on scientific opinions issued by the European Communities' own Scientific Committees. These member State bans have ignored this scientific evidence and maintain restrictions on the entry of these products into their territories. Furthermore, some of these countries have attempted to seek protection under safeguard procedures to try to justify their measures, which has resulted in new scientific opinions issued by European Communities' scientific committees. These new opinions refuted the grounds for the state measures.

4.1221 The foregoing, as well as the experts' responses, demonstrate the lack of scientific evidence supporting the measures currently maintained by those member states, and confirm the arbitrary and unjustified distinction made with respect to the affected products. For this reason, as in the foregoing sections, we request that the Panel confirms the inconsistency with the *SPS Agreement*.

BB. SECOND ORAL STATEMENT OF THE EUROPEAN COMMUNITIES ON THE COMPLAINING PARTIES' SECOND AND THIRD SUBMISSIONS

1. Delays

4.1222 The central issue in this case is delay. The European Communities has resisted the complaining parties' attempts to present the issue of delay in an oversimplified manner, both on the

factual and the legal level. On facts, the European Communities has demonstrated that applications have not been put on hold since 1998, as the complaining parties initially claimed. It has presented detailed chronologies that show in all cases valid reasons to delay procedures, while requests for further information were pending. Scrutiny of individual delays has shown that in the overwhelming majority of cases there were valid reasons at the origin of these delays. On law, the European Communities has resisted the complaining parties' attempts to translate these individual delays into a measure which they call "moratorium". The complaining parties' presentation of their "moratorium" has gradually changed from the description of a ban, to that of a stalling of all procedures to that of individual delays arising out of the greater scheme, which is the alleged "moratorium". We are now in the grotesque situation that the complaining parties see proof of the existence of the moratorium even in individual delays which they themselves acknowledge to be warranted. The Panel has rightly focused on assessing individual delays.

(a) Burden of proof

4.1223 As regards the individual delays, it is clear that the complaining parties' initial *prima facie* claim that all procedures have been stalled has been extensively rebutted by the European Communities through the individual product histories presented in its submissions as well as in the chronologies submitted. It is for the complaining parties to rebut this evidence by putting forward arguments and evidence as to why the reasons for delays are unjustified, with the consequence of making the delay undue.

(b) Delays identified as "undue" by the complaining parties

4.1224 Falcon GS40/90, EC 62: The United States was the only complaining party to include it in its terms of reference. The only argument raised is that the Commission refused or failed to submit a draft measure to the Regulatory Committee. The European Communities has already addressed this. As for the points addressed by the Panel's questions, the United States say that the experts were confirming its claims. The European Communities fails to see which claims. In its comments on the experts' replies, the United States refers back to sections of its supplementary rebuttal where no mention is in fact made of Falcon.

4.1225 MS8xRF3, EC 63: Similarly to Falcon GS40/90, the United States, has only challenged the interim approach (and the fact that the Regulatory Committee was not consulted) as "undue delay". The European Communities has already addressed these issues. Canada, on the contrary, has analysed at some length the process. It has repeated the arguments on the failure to vote, that the European Communities addressed. It has agreed with some steps taken, such as an agreed code of good agricultural practices and a monitoring plan. It has identified a number of requests for information that it considered problematic. On these, the Panel has asked the views of the experts, whose advice has yielded a host of divergent views showing that these issues are far from settled. For instance, on the request for further molecular characterisation, the views of Dr. Healy and Dr. Snape diverge substantially. The European Communities views on the rationale for these requests is in its comments on Scientific Advice and it stands by those views, considering that such requests were justified.

4.1226 The Canadian contention that the Belgian Advisory Council "approved" Ms8xRf3 for import and processing is wrong. National bodies only provide "opinions"; "approval" or not occur at Community level. The product is, in fact, currently under evaluation by EFSA for all uses. Canada's assertion that one objection by Belgium to approval for cultivation is "that coexistence rules are not yet in force" is misleading. One of this authority's main concern was about gene transfer, both in wild relatives and in neighbouring fields. Canada also alleges that "Belgium rejects the 'interim approach'", "rebuffing" the notifier attempts to comply. Again, Canada's selective quotations are misleading. A

careful reading of the relevant minutes (EC-63) makes clear that the authority debated about whether the application should be supplemented. The conclusion was, however, positive and the application indeed proceeded. Canada also raises that Belgium has authorized glufosinate for GM crops. As can be seen, that authorization is for a different use (seed production only) for a different event (MS1xRF2).Hence the European Communities fails to see the relevance of this fact for this authorization.

4.1227 Roundup Ready Fodder beet A5/15, EC-64: A5/15 is only within the terms of reference of the United States. Its claims are all generic and refer to issues such as the Commission refusal/failure to submit a draft measure and the application of the "interim approach". The European Communities has already addressed these. The Panel has addressed a number of points through the scientific experts, and their advice on these has been rather supportive of further requests by the CAs. Thus, Dr. Andow has concurred with the Dutch request for a theoretical safety assessment, the Dutch and UK requests for additional data on molecular characterisation, and the Italian request for transfer and recombination of genes in natural conditions, as being relevant for an environmental risk assessment and not previously addressed.

4.1228 Bt Cotton (531), EC 65: Both Argentina and the United States have included 531 in their terms of reference. Their claims are that the Regulatory Committee failed to vote and the interservice consultation amounts to the moratorium. The European Communities has addressed these, highlighting that the Regulatory Committee failed to reach a vote because of Member States' objections related to issues such as ARMG, non-target effects and the monitoring plan. Argentina does not come back to it but just skims through and dismisses some documents without proper analysis, and limiting its rebuttal to saying that a monitoring plan had already been submitted and positively assessed. The United States spends some time on this, but provides no argument to counter the validity of the concerns, and only says that all information had been provided. The Panel has not reverted to its experts on the scientific justification of these concerns and the European Communities maintains that they were legitimate and scientifically sound, not previously addressed. As for the remark that the applicant was not requested to submit specific data, requests by other CAs or by the Community's committees for additional information is automatically transmitted to the applicant. This being an automatic procedure, no trace is kept of such transmission.

4.1229 Roundup Ready Cotton (RRC1445), EC 66: As for 531, Argentina and the United States do not identify specific delay and limit the claims – yet again – to issues such as the Regulatory Committee failure to vote and the interservice consultation. In its Supplementary Rebuttal the United States dismisses the scientific concerns highlighted by the European Communities as "missing the point" of an undue delay of four years. However, the Panel's experts have considered that the objections concerning the adequacy of the monitoring plan are scientifically justifiable.

4.1230 Amylogene starch potato, EC 67: The United States was the only one to include it in its terms of reference. The only argument raised is that the Commission refused or failed to submit a draft measure. The European Communities has already addressed this issue, highlighting also the concerns expressed by the SCP on this product. The European Communities notes that three out of four Panel's experts that provided an opinion on these concerns warranted their scientific validity.

4.1231 Oilseed rape Liberator, EC 68: Yet another product included only within the terms of reference of the United States, for which it has not put forward claims apart from the usual allegation that the Commission refused to submit a draft measure. Once again, the European Communities has addressed this issue. It explained that this application was subject to a number of objections related to issues such as molecular characterisation, compositional analysis and long term environmental effects. The European Communities also highlighted current issues raised by the lead CA on molecular

characterisation and post marketing monitoring plan. The Panel has not considered necessary to assess whether these concerns were scientifically justified or not. The European Communities therefore maintains that these were legitimate and scientifically sound concerns.

4.1232 Maize Bt 11, EC 69: The United States has raised a number of claims here. Apart from the Commission's alleged failure to submit a draft measure, the United States has also alleged a two years and a half delay after the SCP's opinion. The European Communities has dealt with both claims, highlighting that the applicant has still to submit the surveillance plan requested in 2000. The argument that such plan is only to be applied after commercialisation is beside the point. If it is true that it will only be applied after commercialisation, it nonetheless needs to be submitted before authorization, with all information necessary to be properly assessed. As with regard to the US claims that concerns on compositional analysis, biogeochemistry, ecological effects, weediness, are unfounded and already addressed, the European Communities contests this. The Panel has not asked to assess whether these concerns are scientifically justified or not. The European Communities, therefore, sustains that these were legitimate and scientifically sound concerns.

4.1233 Oilseed rape GT73, EC 70: On GT73, the United States claims that the Member States opposed it on the basis of the need for legislation on traceability, labelling and coexistence. Canada appears to identify an overall delay of forty-two months, plus a number of "unreasonable or [ ] unjustified questions or objections". The European Communities stands by the arguments it has put forward and notes that some concerns arisen in this application (molecular characterisation, feeding studies, monitoring plan) have been taken up in the Panel's questions to the experts, which have given a rather positive assessment of these concerns. For the others, the European Communities maintains its position that these were either legitimate and scientifically sound concerns or regulatory requirements outside the scope of this dispute (traceability and labelling).

4.1234 Bt corn Cry1F (1507), EC 74: The United States identifies here four requests for additional information which it claims are not justified and cause undue delay. The European Communities notes that none of these have been raised for another application for the same product (EC 75). The United States claims that, apart that Member States blocked it, they opposed the application for the need for legislation on traceability, labelling and coexistence. The European Communities has dealt with these claims, highlighting a number of issues identified both by the lead CAs and by other Member States with regard to molecular characterisation, allergenicity and toxicity, environmental effects, monitoring effects, sampling and detection methods. The United States claims that some of these concerns (whole food studies, safety assessment, non-target organisms, protein analysis) are unfounded. Some of these have been taken up to the experts, which gave a rather positive assessment. For the others, the European Communities maintains that these were either legitimate and sound concerns or regulatory requirements outside the scope of this dispute (traceability and labelling).

4.1235 Nk 603, C/ES/00/01, EC 76: The United States raises issues which, in its view, support an undue delay. The United States claims that the application remained at Member State level for 25 months. Acknowledging several requests for information, the United States dwells on the fact that 12 were spent by the CA to assess the information received. The US' idea that a CA is to immediately digest and process information which the applicant has taken 13 months to gather, is somewhat naive. The United States refers to delays occurring at the Community procedure. The European Communities points out that the procedure is set out in the legislation which the complaining parties have not attacked. The United States refers to two requests for information it considered to be invalid, causing in their opinion undue delays. One is an Austrian request for data and studies on subchronic, mutagenic, reproductive and ecotoxic effects. This has not been addressed by the Panel's experts. The European Communities disagrees that that request was "unfounded and unreasonable." The European Communities notes that Austria's request was broader, covering central issues

(compositional analysis, molecular characterisation), the scientific validity of which the United States has not contested. The other request is from Spain, to use PCR to screen for putative random insertions of fragments and possible transcription. This was covered by the Panel's Question 38, but no expert replied. The European Communities refers to its comments on the experts replies and which explain why this request was scientifically valid.

4.1236 Roundup Ready Corn GA (21) EC 78 and 85: The United States admonishes certain delays at the Member State level conveniently omitting that there were numerous requests for information. All the requests identified by the United States have been covered in the Panel's Questions 40 & 40bis. These have been extensively discussed by the experts and the European Communities refers to paras. 476ff of its own comments on the experts replies, in which it explains that these requests were scientifically reasonable.

4.1237 MaisGuard x Roundup Ready (MON810 x GA 21), EC 82: The United States identifies some delays that occurred at Member State level. These can be explained: one of the parents of this hybrid, GA 21, had not been assessed yet and the CA was awaiting the assessment. Whether a safety assessment for a hybrid can be put on hold while the assessment of the parental lines is awaited was not discussed by the experts. However, it would seem obvious that the hybrid cannot be assessed conclusively as long as one of its parental events' assessment is still open.

4.1238 GA 21, Food Use, EC 91: The United States raises some arguments for "undue delay" in this application. The European Communities has already replied to most of them, and notes that the United States seems to be raising a scientific issue, which has not been addressed by the experts, about a comment by the Greek CA concerning toxicity tests of the whole product, and not only the protein. It is merely an observation from Greece that no such data exist, but not a suggestion or request to perform the tests. The European Communities fails to see how that observation could caused delay whatsoever. It would seem that the United States has singled out this comment on an arbitrary basis.

4.1239 Bt Sweet Corn, EC 92: The United States and the European Communities disagree on the nature of comments and objections made. However, irregardless of whether one would call them risk assessments or not, they were based on valid and reasonable scientific reasons, a fact which the United States does not contest. The United States addresses some requests for information on compositional analysis and substantial equivalence. These requests are not covered by the Panel's questions and the European Communities disagrees with the United States on the scientific validity of these requests.

4.1240 MaisGuard (MON810) x RoundupReady (GA 21), EC 94: The United States raises two issues on EC 94. One is a delay due to the uncompleted assessment of GA 21, one of the parental lines. As discussed for EC 82 (release into the environment, same hybrid), this question was not discussed by the experts, and the comment on the necessity of hybrid's parental assessment still applies. The second issue is a request for a whole food study in mice. This was addressed by the Panel's Question 44 and discussed by the experts. The European Communities refers to its comments on the experts' replies at paras. 555ff. It maintains that such studies were necessary to assess unintended effects caused by possible additional DNA fragments, and that the request was made on valid grounds. Therefore, the delay caused by it cannot be considered "undue."

4.1241 Roundup Ready corn NK 603, Food Use, EC 96: The United States takes issue with certain procedural delays that occurred at Community level, which are due to the way the procedure is set out. The European Communities has already commented on this on previous applications. The United States also challenges certain requests for information as invalid. These have been covered by

the Panel's Questions 53 and 54. The European Communities refers to its comments on the experts' replies at paras. 615ff, in which it explains why these requests were scientifically valid.

(c) Assessment of delays under the different claims made by the complaining parties

4.1242 Annex C 1(a) of the *SPS Agreement*. As regard the individual product claims made, on a possible violation of Annex C 1(a), first, to the extent the products for which the complaining parties have alleged "undue delays" are withdrawn or have been authorized since, the claim is *sans objet*. In this respect we refer to our comments later on mootness. Second, a delay is not undue if and to the extent it has occurred for a number of reasons, of which at least one is clearly valid. This is very clear from the text, which states: "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". It is not any cause of delay that is prohibited but *undue* delay in the undertaking and *completion of procedures*. If the procedure cannot be completed for some reason other than the factor under consideration, there is no violation of this provision. Third, nobody contests at this stage that the scientific knowledge on possible harmful effects of GMOs is still insufficient. The experts have painted the picture of a rapidly evolving, in parts highly controversial scientific debate and it is against this background that they – without always agreeing- have confirmed the justification for, but sometimes also criticised certain requests for additional information. It is against this background that Canada and the United States are proposing to apply the requirements of Article 5.7 of the *SPS Agreement* when assessing what is undue and what not. However, Article 5.7, just like Article 5.1, does not apply to a failure to act. The European Communities agrees that the precautionary principle is to be taken into account when assessing "undueness" in paragraph 1(c) of Annex C. As the Appellate Body has made clear in *EC – Hormones:* "there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle". Fourth, there has been considerable debate on "mixed delays," i.e. delays relating to concerns that cannot be assessed under the *SPS Agreement* but need to be assessed under another agreement. Notwithstanding the European Communities' position on the scope of the *SPS Agreement*, the complaining parties' argument that: "Nothing in the text of the *SPS Agreement* suggests, as the European Communities contends, that a Member is excused from this obligation if the delay stems from a consideration outside the scope of the *SPS Agreement*." misses the true point: if a non-SPS concern is legitimately delaying completion of a mixed SPS/non-SPS approval procedure, then that procedure is not "unduly delayed" within the meaning of the *SPS Agreement*. If WTO Members are allowed to have approval procedures covering SPS and non-SPS concerns (and no-one has said they cannot), it cannot be that WTO Members are obliged to approve products which come within the scope of the *SPS Agreement* when there are non-SPS concerns outstanding. In any event, all concerns reflected in requests for additional information were scientifically valid and reasonable.

4.1243 Delays and "*de facto* moratorium". The Panel's experts have confirmed most concerns raised by CA as valid. Where they have not done so, the experts have acknowledged that the authorities' cautious approach was certainly valid or legitimate in the context of the complex and difficult scientific issues raised at the time. Faced with this, the United States abandons logical reasoning and now invites to "put this all back in context, and to use common sense", but the reality is that the examination of individual measures is logically inconsistent with the existence of an *a priori* moratorium. The complaining parties started off this case thinking that they could attack in WTO dispute settlement the fact that GMOs are what the United States has called "a controversial political issue in the EC". However, public opposition and political perceptions are not regulated by the *WTO Agreement* and are not the proper subject of dispute settlement. Nor of course is the voting behaviour or the "intransigence" of any individual political actor. If they were, panels would be constantly discussing the internal workings of WTO Members. On the contrary, it is necessary to identify a measure within the meaning of the DSU and demonstrate that that measure is contrary to a WTO

obligation. The reality is that the European Communities has adopted legislation to regulate GM products (legislation that is not itself the subject of these proceedings) and has examined the applications that it has received.

2. Mootness

4.1244 The Panel is competent to consider those measures which were in effect in August 2003, including the Member State safeguard measures. But a measure can only be in effect in August 2003 in respect of a product application that remains "live". For those products which had been withdrawn by that date a measure can no longer be considered to be in effect. The United States appears to accept that proposition.

4.1245 The same principle must apply where a measure ceases to be in effect after the Panel has been constituted, for example because the product has been withdrawn or has been approved. In such circumstances the application is *sans objet*. It is not the European Communities' position that in such circumstances the Panel is bound not to consider the measure. Consistent with international practise, including that of the International Court of Justice, there is no longer any utility in considering a measure which ceases to be in effect because there does not exist, in respect of that measure, a dispute between the Parties. In such circumstances courts decline to proceed to consider such measures. The reason relates to the absence of any remedy which can be ordered. That is particularly pertinent in the context of the WTO DSU: how is a member to implement a Panel recommendation in respect of a measure which is no longer in effect?

V. ARGUMENTS OF THE THIRD PARTIES

5.1 The arguments of the third parties, Australia, Chile, China, New Zealand and Norway are set out in their written and oral submissions to the Panel and in their answers to questions. The third parties' arguments as presented in their submissions are summarized in this section.[125]

A. THIRD PARTY ORAL STATEMENT OF AUSTRALIA

1. Introduction

5.2 As a third party to this dispute, Australia welcomes this opportunity to present its views to the Panel.

5.3 The Panel has an important and challenging task in front of it. The first written submissions of the principal parties have raised a wide range of complex factual, scientific and legal issues, which may, or may not, be pertinent to the Panel's resolution of the dispute. The issues raised include:

- the nature of risks associated with biotech products and relevant approaches to risk assessment;
- the legal characterisation of the contested measures;
- whether these measures are subject to the WTO covered agreements, and if so, which provisions are applicable;

[125] The summaries of the third parties' arguments below are based on the executive summaries submitted by the third parties where the third parties made available such summaries to the Panel.

- whether the European Communities has acted inconsistently with any of the applicable WTO provisions; and

- the relevance, if any, to the Panel's deliberations of the European Communities' extensive references to the Biosafety Protocol and to the concept of precaution as reflected in legal texts other than the WTO covered agreements.

5.4 These issues clearly have a systemic dimension as well.

5.5 Given the facts and circumstances of this dispute and the obvious care and attention taken by the complaining parties in framing their legal claims and arguments narrowly, Australia is of the view that the Panel should adopt a measured approach and limit its rulings and recommendations accordingly. Australia notes that the Panel has considerable discretion to exercise 'judicial economy' in making an objective assessment of the matter before it, and in making its recommendations and ruling.[126]

5.6 Whatever approach is adopted by the Panel in making its objective assessment, Australia has a substantial interest in the matter before the Panel, particularly in relation to the interpretation and application of the cited provisions of the covered agreement, and in any consideration by the Panel of any legal claims and arguments regarding the relationship between the WTO Agreement and any other international laws or standards that may be considered relevant.

5.7 Given these interests, which we would expect are shared by other third parties, Australia would expect the Panel to provide all third parties with the fullest possible opportunity to express views on any specific issue of law or legal interpretation considered by the Panel to be relevant to the resolution of the dispute.

5.8 Accordingly, Australia requests the Panel to ensure that all third parties are given an opportunity to respond in writing to all relevant written questions presented to the parties following this meeting, as well as to any relevant subsequent written questions that might be raised at a later stage in the proceedings.

2. Australian interests

5.9 I would like to expand on the issues of interest to Australia.

5.10 Australia has a strong interest in any assessment by the Panel of the applicability and interpretation of the provisions of the *SPS Agreement* raised by the parties (Articles 1, 2, 5, 7, 8 and 10, and Annexes B and C). Areas of particular interest to Australia, should the Panel consider these to be of any relevance to the resolution of the dispute, are the scope of the *SPS Agreement* and its applicability to the contested measures, and the relationship of Article 5.7 with other provisions of the *SPS Agreement* or with any other relevant agreements.

5.11 Australia also has a strong interest in any assessment by the Panel of the applicability and interpretation of the provisions of the *TBT Agreement* (Articles 2, 5 and 12) and of the GATT 1994 (Articles III and XI) which have been raised by the parties. Areas of particular interest to Australia, should the Panel consider these to be of any relevance to the resolution of the dispute, include the scope and application of the *TBT Agreement* in general, and of the term "like products" under the relevant TBT and GATT provisions in relation to biotech products.

[126] Appellate Body Report, *US – Wool Shirts and Blouses*, page 18.

5.12 Finally, in relation to the European Communities' extensive references to the Biosafety Protocol and to the concept of precaution as reflected in non-WTO legal texts, in Australia's view the matter before the Panel can be resolved solely by reference to the WTO covered agreements. Given the facts of this dispute, there is no need for the Panel to consider the applicability of such non-WTO legal texts. Of particular relevance is the fact that none of the three complaining parties are parties to the Biosafety Protocol.

5.13 However, should the Panel consider the Biosafety Protocol or non-WTO reflections of the concept of precaution to be of any relevance to the resolution of the dispute, Australia has a strong interest in ensuring that its views on these issues be taken into account.

3. Third party participation rights

5.14 I want to conclude by registering clearly with the Panel Australia's expectation that all third parties will be provided with the fullest possible opportunity to express views on specific issues of law or legal interpretation considered by the Panel to be relevant to the resolution of the dispute. As noted earlier, Australia expects this view is shared by other third parties.

5.15 Article 10 of the DSU requires the Panel to ensure that the interests of third parties are fully taken into account during the Panel process. At this point in the process, an extraordinarily wide range of factual, scientific and legal issues have been raised. It is also apparent that the fundamental nature of the dispute and legal claims is vigorously contested; this is most clearly indicated in paragraph 11 of the European Communities' first written submission which purports to reserve the right to provide a "a full refutation of the Complainants first written submission" for its second written submission. Given this situation, it is simply not possible for third parties to determine which of these issues will be the subject of an objective assessment by the Panel, and it would be unproductive for third parties to present views on the full range of issues on a completely speculative basis.

5.16 Against this background, Australia has therefore not presented any substantive views on the wide range of factual, scientific and legal issues raised by the principal parties. Instead, we have sought to identify issues on which Australia wishes to present its views, in the event those issues are considered by the Panel to be relevant to the resolution of the dispute. As indicated earlier, given the circumstances in this dispute, the most appropriate approach for the Panel to take into account Australian and other third party interests under the covered agreements is to provide third parties the fullest possible opportunity to provide responses to any written questions presented to the parties following this meeting, as well as to any subsequent questions that might be raised at a later stage in the proceedings. This approach is within the Panel's discretion and is fully consistent with relevant DSU provisions, such as Articles 10 and 13.[127])

B. THIRD PARTY ORAL STATEMENT OF CHILE

5.17 Chile is grateful for the opportunity to express its views in this dispute. We are motivated by a genuine interest in the discussion of this subject matter in respect of which my country, like many other developing countries, is currently developing a national policy. We also have a systemic interest in the proper interpretation and application of the provisions of the WTO agreements, in particular the *SPS Agreement*, the *TBT Agreement*, and the GATT 1994.

5.18 The purpose of this statement is to provide the Panel with certain items of information regarding the objectives of a biotech policy in a country like Chile. We recognize that the work of

[127] Appellate Body Report, *US – FSC (Article 21.5 – EC)*, para. 243.

this Panel is determined by its terms of reference, and specifically, by the legal provisions which Argentina, Canada, and the United States consider to have been violated by the measures adopted by the European Communities. However, we cannot simply disregard the possible implications of a ruling like the one that has been requested for the developing countries that are currently drawing up their policies and legislation in that area.

5.19 The development of a biotech policy is seen by Chile as a way of maintaining and enhancing the competitiveness of certain economic sectors that rely on scientific and technological innovation, such as the agricultural, forestry and aquaculture sectors. Indeed, modern biotechnology would help to improve competitiveness by fostering the protection and preservation of genetic material while at the same time paving the way to involvement in areas such as biomedicine.

5.20 All of this calls for an appropriate regulatory framework, one that would consolidate the role of public institutions with legal authority in the biotech area. At the same time, there is a need for coordination among these agencies and proper consultation with civil society, for adequate entrepreneurial institutions, and for scientific and technological capabilities and the capacity to train human resources.

5.21 For all of these reasons, Chile is highly interested in the systemic implications of the WTO consistency of product approval measures within the European Union. In particular, we are concerned by the failure to approve the release of biotech products since 1998, in spite of the existence of Community legislation in that respect (Directive 90/220, replaced by 2001/18). Likewise, we are concerned by the bans on the release of biotech products in certain EC member States that would appear to be inconsistent with Community legislation. Finally, we are interested in the relationship between the failure to approve the applications for entry with the new Community legislation on traceability and labelling of biotech products.

5.22 Mr Chairman, let me turn to the two unsolicited submissions received by the Panel from third parties that are not party to this dispute.

5.23 I begin by stressing that there is no provision under the DSU that enables panels to accept unsolicited and unwanted information. The Appellate Body has ruled on this issue in the past, but that does not constitute a precedent. On the contrary, most WTO Members expressed their opposition to this kind of submission at a special meeting of the General Council at the end of 2000. On that occasion, participants reaffirmed the intergovernmental nature of the Organization on which the participation of Members rests, particularly under the DSU. Chile and the other Members represent a national stance which, as a rule, has been developed taking account of all of the sectors and interests involved. Chile cannot negotiate – or seek the settlement of a dispute – with each one of these interests separately. Nor can the other Members negotiate with the Chilean actors separately. We assume that the national position of a Member is reflected in its submissions, arguments and defence, and that these do not represent the vision of certain sectors only.

5.24 Secondly, the rights and obligations of Members can only be modified by consensus following a formal negotiation process such as the one that has been conducted since the Doha Ministerial Declaration, in which, once again, the opinion of the majority of Members was that the participation of non-governmental third parties in WTO disputes should be rejected.

5.25 Thirdly, the developing countries already suffer from serious limitations during the dispute settlement process: for example, it is not easy for them to meet deadlines, or to deal with the formalities and other procedures, not to mention the growing complexity of the subjects submitted to

the mechanism and of the arguments of the disputing parties. Having to examine and reply to the questions raised in third-party submissions further increases the already considerable burden.

5.26 Finally, we understand that the Panel has consulted with the Parties on the possibility of requesting an expert opinion on certain issues raised in this dispute, in accordance with Article 13 of the DSU. Regardless of whatever position the disputing parties may have concerning the wisdom or appropriateness of such an expert opinion, we think that this is the only path to follow.

5.27 Chile respectfully requests the Panel to take these views into consideration when deciding on the issue raised by Argentina, Canada and the United States.

C. THIRD PARTY WRITTEN SUBMISSION OF CHINA

1. Introduction

5.28 Although this dispute raise a host of issues that are important to the operation of the *SPS Agreement*, *TBT Agreement* and GATT 1994, the application of Article 5.7 of the *SPS Agreement* and the likeness of biotech products and non-biotech products under Article III: 4 of the GATT 1994 call for close attention and analysis by the Panel.

2. China's view on Article 5.7 of the *SPS Agreement*

5.29 China believes that "insufficient scientific evidence" referred in Article 5.7 does not imply that Article 5.7 can be invoked without risk assessment, but merely that such an assessment can be made on the basis of factors, which would not fulfil the Article 5.2 risk assessment requirements. Thus, the application of Article 5.7 will depend not only upon the nature of the risk, but also the nature of the risk assessment. In order to prove "relevant scientific information is insufficient" the following two criteria must be met:

(1) There is a risk assessment for the subject goods; and

(2) Available pertinent information falls short to complete the examination of the risk factors listed in Article 5.2 of the *SPS Agreement*.

5.30 In *EC – Hormones*, the Appellate Body states that risk factors listed in Article 5.2 are not exclusive.[128] In this case, traceability could be a risk factor to be considered under Article 5.2 of the *SPS Agreement*. Before European Communities passed its Regulation 1830/2003, the available pertinent information could be insufficient to examine traceability of biotech products. Only after European Communities passed its regulation on traceability and labelling a more objective assessment of risk can be completed.

5.31 Article 5.7 requires the measure to be adopted "on the basis of available pertinent information". In China's view, "available pertinent information" includes not only scientific information, but also all information having logical relevance to this matter. The words "including" in Article 5.7 indicates that information "from the relevant international organizations" and "from SPS measures applied by other members" is not exhaustive in nature. Thus, in this case, the panel may consider background of so-called product-specific delay and the EC member State safeguard measures as a whole to determine whether European Communities or the EC member State adopted it on the basis of available pertinent information.

[128] *See* Appellate Body Report, *EC – Hormones*, para. 187.

5.32 In *Japan – Agricultural Products II*, the Appellate Body stated that the additional information sought must be germane to conducting a more objective risk assessment.[129] China believes that such additional information may not be narrowly interpreted as scientific information only. In this case, the European Communities' legislation process on biotech products could be considered as one aspect of the information collection.

5.33 The Appellate Body in *Japan – Agricultural Products II*, stated that "what constitutes a 'reasonable period of time' has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review and the characteristics of the provisional SPS measure".[130]

5.34 China is of the opinion that "reasonable period of time" depends on the capability of a WTO Member to obtain additional information. For instance, to obtain the same information to conducting a more objective risk assessment, a developing country with less research ability is more likely to take longer period of time than developed countries. In this case, GMO technology is at the frontiers of science, and each WTO Member, including European Communities, may not have capability to obtain additional information to conduct a more objective risk assessment at current stage. Thus, in order to obtain such additional information, longer period of time may be considered reasonable.

3. Biotech products and non-biotech products are not "like products" under Article III: 4 of the GATT 1994

5.35 China is of the opinion that biotech products are not like products of non-biotech products. In *EC – Asbestos*, the Appellate Body identified four general criteria in analysing "likeness" under Article III:4: (1) the properties, nature and quality of the products; (2) the end-uses of the products; (3) consumers' tastes and habits; and (4) the tariff classification of the products.[131] And none of them alone is determinative, all of the evidence, taken as a whole, must be weighted.[132]

5.36 First, when the panel considers the physical and natural similarity of biotech products and non-biotech products, the anti-natural character of biotech products must be given more weight in evaluation. "Genetically Modified Organism (GMO)" is defined as an organism, with the exception of human beings, in which the genetic material has been altered in a way that *does not occur naturally by mating and/or natural recombination*.[133] (emphasis added) Even the term "biotech products" is use instead of GMO, the panel shall bear in mind through its analysis that biotech product does not occur naturally by mating and/or natural recombination.

5.37 Second, in *EC – Asbestos*, the Appellate Body noted that: "Although we agree that it is certainly relevant that products have similar end-uses for a 'small number of … applications', or even for a 'given utilization', we think that a panel must also examine the other, *different* end-uses for products".[134] (emphasis original) There are some unique characters for biotech products intertwined with its end-use, such as insect-resistance, pesticide-tolerance. Those differences should not be ignored by this panel, on the contrary, this panel shall give more weight on the unique character of biotech products.

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[129] *See* Appellate Body Report, *Japan – Agricultural Products II*, para. 92.
[130] *See* Appellate Body Report, *Japan – Agricultural Products II*, para. 93.
[131] *See* Appellate Body Report, *EC – Asbestos*, para. 101.
[132] *See* Appellate Body Report, *EC – Asbestos*, para. 103.
[133] *See* Article 2 of Directive 2001/18.
[134] *See* Appellate Body Report, *EC – Asbestos*, para. 119.

5.38 Third, the consumers' tastes and preferences in Europe, which are unfavourable towards biotech products, shall be taken into consideration by this panel to conclude biotech products are not like products of non-biotech products.

5.39 Finally, because commercial applications of biotechnology came into being in 1990s, it is understandable that there is no distinction under tariff classification between biotech products and non-biotech products. However, the labelling requirements set forth in new legislations, such as Regulation 1830/2003, show a tendency to separate biotech products from non-biotech products. Therefore, no differences under tariff classification between biotech and non-biotech products shall be given little practical weight.

5.40 In sum, China believes that the factual evidence relating to each of the four criteria makes it clear that biotech products and non-biotech products must not be considered to be "like products".

D. THIRD PARTY ORAL STATEMENT OF CHINA

5.41 Mr. Chairman and members of the Panel, on behalf of China, I would like to thank you for providing the opportunity to present our views. Today, I will focus on two key issues in this dispute. The first issue is the requirement to invoke Article 5.7 of the *SPS Agreement*; the second issue is the "likeness" of biotech products and non-biotech products.

5.42 Article 5.7 permits Members to adopt provisional SPS measures where relevant scientific evidence is insufficient. China believes that "insufficient scientific evidence" referred in Article 5.7 does not imply that Article 5.7 can be invoked without risk assessment. In order to prove "relevant scientific information is insufficient" two criteria must be met: (1) There is a risk assessment for the subject goods; and (2) available pertinent information falls short to complete the examination of the risk factors listed in Article 5.2 of the *SPS Agreement.*

5.43 Article 5.2 lists seven risk factors that shall be considered. In *EC – Hormones*, the Appellate Body states that risk factors listed in Article 5.2 are not exclusive. In this case, traceability could be a risk factor to be considered under Article 5.2 of the *SPS Agreement*. Before the European Communities passed its Regulation 1830/2003, the available pertinent information could be insufficient to examine traceability of biotech products.

5.44 Pursuant to the second sentence of Article 5.7, a provisional measure may not be maintained unless the Member which adopted the measure seeks to obtain additional information necessary for a more objective assessment of risk. China believes that such additional information may not be narrowly interpreted as scientific information only. In this case, the European Communities' legislation process on biotech products could be considered as one aspect of the information collection.

5.45 Article 5.7 requires the Member to review the SPS measure within a reasonable period of time. The Appellate Body in *Japan – Agricultural Products II* stated that "what constitutes a 'reasonable period of time' has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review and the characteristics of the provisional SPS measure".

5.46 China believes that "reasonable period of time" depends on the capability of a WTO Member to obtain additional information. For instance, to obtain the same information to conducting a more objective risk assessment, a developing country with less research capability is more likely to take longer period of time than developed countries. In this case, GMO technology is at the frontiers of

science, and each WTO Member, including European Communities, may not have capability to obtain additional information to conduct a more objective risk assessment at current stage. Thus, in order to obtain such additional information, longer period of time may be considered reasonable.

5.47 As regard to Article III:4, China is of the opinion that biotech products are not like products of non-biotech products. In *EC – Asbestos,* the Appellate Body identified four general criteria in analysing "likeness" under Article III:4: (1) the properties, nature and quality of the products; (2) the end-uses of the products; (3) consumers' tastes and habits; and (4) the tariff classification of the products. And none of them alone is determinative, all of the evidence, taken as a whole, must be weighted.

5.48 First, when the Panel considers the properties, nature and quality of the products, the anti-natural character of biotech products must be given more weight in evaluation. "Genetically Modified Organism (GMO)" is defined as an organism, with the exception of human beings, in which the genetic material has been altered in a way that *does not occur naturally by mating and/or natural recombination.* (emphasis added) Even the term "biotech products" is use instead of GMO, the panel shall bear in mind through its analysis that biotech product does not occur naturally by mating and/or natural recombination.

5.49 Second, in *EC – Asbestos*, the Appellate Body noted that: "Although we agree that it is certainly relevant that products have similar end-uses for a 'small number of ... applications', or even for a 'given utilization', we think that a panel must also examine the other, *different* end-uses for products. There are some unique characters for biotech products intertwined with its end-use, such as insect-resistance, pesticide-tolerance. Those differences should not be ignored by this panel, on the contrary, this panel shall give more weight on the unique character of biotech products.

5.50 Third, the consumers' tastes and preferences in Europe, which are unfavourable towards biotech products, shall be taken into consideration by this panel to conclude biotech products are not like products of non-biotech products.

5.51 Finally, because commercial applications of biotechnology came into being in 1990s, it is understandable that there is no distinction under tariff classification between biotech products and non-biotech products. However, the labelling requirements set forth in new legislations, such as Regulation 1830/2003, show a tendency to separate biotech products from non-biotech products. Therefore, no differences under tariff classification between biotech and non-biotech products shall be given little practical weight.

5.52 Mr. Chairman and members of the Panel, China believes that the factual evidence relating to each of the four criteria makes it clear that biotech products and non-biotech products must not be considered "like products".

E. THIRD PARTY WRITTEN SUBMISSION OF NEW ZEALAND

1. Introduction

5.53 The Panel in this dispute is asked to determine whether certain measures adopted by the European Communities affecting the approval and marketing of biotech products[135] meet the requirements of the *SPS Agreement*. New Zealand is one of many WTO Members that has exercised

[135] New Zealand uses this term throughout the submission in the same sense as it is used by Canada. *See* first written submission of Canada, para. 27.

its right under the *SPS* Agreement to adopt measures to regulate the entry and release of new organisms, including genetically modified organisms, necessary for protection from any adverse effects of those organisms. The *SPS Agreement* guarantees to WTO Members the right to take measures for the protection of human, animal and plant life or health.[136] The complaining parties in this dispute do not contest that right.[137]

5.54 However, sanitary and phytosanitary measures adopted by WTO Members are subject to the disciplines set out in the *SPS Agreement*.[138] Those disciplines seek to ensure that such measures do not restrict trade unnecessarily. At issue in this dispute is whether the European Communities has complied with those disciplines.

5.55 As both a significant producer and exporter of agricultural products, New Zealand has a strong interest in ensuring that the delicate balance of rights and obligations set out in the WTO Agreements, especially the *SPS Agreement*, is maintained.

5.56 This dispute raises a number of specific issues regarding the interpretation of the *SPS Agreement* upon which New Zealand will comment. This submission will first argue that the European Communities' moratorium and its product-specific marketing bans[139] are "measures" within the meaning of the *SPS Agreement* and thus are subject to scrutiny for compliance with the disciplines of the *SPS Agreement*. Second, this submission will discuss the procedural requirements that Members must comply with in adopting sanitary and phytosanitary measures, particularly under Articles 7 and 8 of the *SPS Agreement*. And third this submission will comment on issues relating to the right of Members to adopt measures in accordance with the *SPS Agreement* and to determine their appropriate level of protection from risks to human, animal or plant life or health under the *SPS Agreement*.

5.57 Insofar as the European Communities' product-specific marketing bans may not be subject to the provisions of the *SPS Agreement*, the *TBT Agreement* would apply as argued in the alternative by Canada and Argentina. New Zealand has chosen not to address arguments concerning the *TBT Agreement* in this submission, but reserves the right to do so in the Third Party Session of the Panel.

5.58 Given the limited time that New Zealand has had to consider the first written submission of the European Communities[140], New Zealand reserves the right to make any further comment on it during the Third Party Session of the Panel. New Zealand will not comment on the European Communities' presentation in Part II of the European Communities' submission ("Factual Part"), including the European Communities' presentation of aspects of New Zealand's legislation or policy which are not in issue in this dispute.[141]

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[136] Article 2.1.

[137] First written submission of the United States, para. 68; first written submission of Argentina, para. 195.

[138] Article 2.1.

[139] New Zealand uses the terms "moratorium" and "product-specific marketing bans" in the same sense as they are used by Canada. *See* first written submission of Canada, para. 1. New Zealand will not address issues relating to the national measures adopted by particular EC member States.

[140] First written submission of the European Communities.

[141] This should not be read, however, as endorsing the EC representation of any aspect of New Zealand's policy or legislation.

2. Legal arguments

(a) The moratorium and product-specific marketing bans are "measures" for the purposes of the *SPS Agreement*

5.59 Annex A paragraph 1 of the *SPS Agreement* defines what are "sanitary or phytosanitary measures" and are therefore subject to the provisions of the *SPS Agreement*. What distinguishes sanitary and phytosanitary measures from other measures that affect international trade is their purpose, that is, they seek to provide protection from certain sanitary and phytosanitary risks.

5.60 Sanitary or phytosanitary measures include, *inter alia*, measures applied to protect plant life from risks arising from the entry, establishment or spread of pests, and measures applied to protect human or animal life or health from risks arising from contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs. The evidence of the complaining parties[142] shows that the European Communities' regulatory approvals processes have been adopted by the European Communities for the purpose of providing protection from one or more of these risks. Both the moratorium and the product-specific marketing bans are thus sanitary or phytosanitary measures within the meaning of the *SPS Agreement*.

5.61 An illustrative list of the types of sanitary and phytosanitary measures that a member might adopt is also provided in paragraph 1 of Annex A of the *SPS Agreement*. It is clear that this list is not exhaustive and that a measure of a type not listed, but which is adopted for one of the purposes listed, would still be a sanitary and phytosanitary measure falling within the jurisdiction of the *SPS Agreement*.

5.62 WTO jurisprudence has clarified that the term "measure" in the context of the WTO Agreements has a broad content. Accordingly it captures not just acts, but also omissions;[143] and not just legally binding or mandatory acts or policies, but non-mandatory measures.[144] The reason for interpreting the term "measure" as having such a broad content is clear. Primarily, it means that actions of a Member that affect trade, whether formal or informal, are comprehensively subject to scrutiny for consistency with their WTO obligations. A broad interpretation of "measure" is also specifically consistent with the object and purpose of the *SPS Agreement*. The *SPS Agreement* imposes disciplines on WTO Members' use of sanitary and phytosanitary measures in order to avoid unnecessarily restricting trade. A narrow interpretation of "measure" would allow WTO Members to circumvent their WTO obligations simply by resorting to less direct means than transparent, formally adopted laws or procedures.

5.63 As acknowledged by the complaining parties, the existence of the European Communities' moratorium and product-specific marketing bans has to be inferred from the actions and statements of the European Communities. That is because the European Communities has issued no written document, regulation or legislative provision establishing either the moratorium or the marketing bans. In the present dispute a narrow interpretation of the term "measures" would allow the European Communities to avoid scrutiny of its actions that impact on trade in biotech products because the Panel could look no further than the legislated approvals process that the European Communities has in place. New Zealand submits that such an interpretation and approach must be rejected. The *SPS Agreement* and WTO jurisprudence provides sufficient basis for the Panel in this dispute to

[142] First written submission of Argentina, paras. 36-63; first written submission of the United States, paras. 74-80; and first written submission of Canada, paras. 160-174.
[143] Appellate Body Report, *US – Corrosion-Resistant Steel Sunset Review*, para. 81.
[144] Panel Report, *Japan – Agricultural Products II*, para. 8.111.

consider the European Communities' moratorium and product-specific marketing bans to be "measures" and therefore must submit them to scrutiny for compliance with the European Communities' WTO obligations under the *SPS Agreement*.

(b) Procedural requirements of the *SPS Agreement*

(i) Failure to "publish promptly"

5.64 The need for transparency in the adoption and application of sanitary and phytosanitary measures is an important aspect of the protections provided by the *SPS Agreement* against undisguised restrictions on trade. Under Article 7 Members are required to meet the requirements for transparency set out in Annex B, including the requirement in paragraph 1 to "publish promptly" all sanitary or phytosanitary regulations that they adopt.

5.65 Applying Appellate Body jurisprudence regarding the interpretation of the term "sanitary or phytosanitary regulations"[145], it is clear that the European Communities' moratorium and product-specific marketing bans are subject to the requirement that they be "published promptly". As presented by the complaining parties, the European Communities has failed to publish the existence of either the moratorium or the bans, and thus has also failed to do so "promptly" as required.

(ii) Undue delay

5.66 Under Article 8 of the *SPS Agreement* WTO Members must observe the provisions of Annex C in the operation of their approval procedures associated with sanitary and phytosanitary measures, including the requirement in paragraph 1(a) of Annex C that approval procedures are "undertaken and completed without undue delay". In their submissions the complaining parties discuss the meaning of the term "undue delay" and conclude that in the context of paragraph 1(a) of Annex C it refers to "the 'unjustifiable' and 'excessive' 'hindrance' in undertaking or completing an approval procedure."[146] As the European Communities acknowledges[147], both the reason for the delay and its duration are relevant considerations in determining whether the delay is undue.

5.67 Thus whether there has been "undue delay" within the meaning of paragraph 1(a) must be determined on a case by case basis. In New Zealand's view there must be a strong presumption that "undue delay" has occurred where a Member has in fact suspended the operation of the approval procedures provided for in its own legislation without providing any justification in terms of the *SPS Agreement* for doing so. Accordingly in the present dispute the European Communities has acted with "undue delay" in undertaking or completing its approval procedures for biotech products.

(c) Substantive requirements of the *SPS Agreement*

5.68 The *SPS Agreement* imposes substantive, as well as procedural, disciplines on the use of sanitary and phytosanitary measures. Article 2.1 gives Members the right to establish measures, including for biotech products, that are necessary for the protection of human, animal or plant life or health and that are not inconsistent with the provisions of the *SPS Agreement*. Article 2.2 sets out the basic requirement that such measures must be based on scientific principles and may not be maintained without sufficient scientific evidence.

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[145] Appellate Body Report, *Japan – Agricultural Products II*, para. 105.

[146] First written submission of the United States, para. 89; first written submission of Canada, para. 239; and first written submission of Argentina, para. 315.

[147] First written submission of the European Communities, para. 479.

5.69 Successive Panels and the Appellate Body have now provided considerable guidance on the interpretation of provisions of the *SPS Agreement* that are relevant to this dispute. In considering the arguments before it the Panel should apply that guidance in order to ensure that the balance is maintained between a Member's right to adopt sanitary and phytosanitary measures on the one hand, and its obligation not to unnecessarily restrict trade on the other.

5.70 This balance is evident in the provisions of the Agreement relating to a Member's determination of its appropriate level of sanitary or phytosanitary protection. Annex A, paragraph 5, of the *SPS Agreement* defines the "appropriate level of sanitary or phytosanitary protection" as that "deemed appropriate by the Member establishing a … measure". However, Members may not adopt measures that are more trade restrictive than necessary to achieve their desired level of protection, taking into account technical and economic feasibility. The *SPS Agreement* also provides guidance as to when a measure could be considered to be more trade restrictive than necessary, namely where another significantly less trade restrictive measure is technically or economically feasible that would achieve the same level of protection.[148]

5.71 It is not necessary in this case to examine in great detail the level of protection afforded by the European Communities' legislated approvals processes. The legislative framework adopted by the European Communities must be taken to represent at least the level of protection deemed appropriate by the European Communities to manage risks arising from biotech products. If the measure actually applied is more trade restrictive than that, then the *SPS Agreement*, and basic logic, supports the conclusion that the measure applied is more trade restrictive than necessary to achieve the level of protection deemed appropriate. The European Communities' moratorium and product-specific marketing bans are measures that are clearly more trade restrictive than necessary to meet the level of protection that the European Communities itself has deemed to be appropriate in respect of biotech products. Accordingly, the moratorium and product-specific marketing bans are measures that are more trade restrictive than necessary for the protection of human, animal or plant life or health and thus are inconsistent with the provisions of the *SPS Agreement*.

F. THIRD PARTY ORAL STATEMENT OF NEW ZEALAND

5.72 Mr Chairman, Members of the Panel, New Zealand's views on the issues of concern in this dispute are set out in our Third Party Submission of 24 May 2004. In our statement today we briefly summarise those views.

5.73 As outlined in our submission, New Zealand has joined this dispute because of our systemic interests and our desire to ensure that the delicate balance of rights and obligations set out in the WTO Agreements, especially the *SPS Agreement*, is maintained.

5.74 The *SPS Agreement* guarantees to WTO Members the right to take measures for the protection of human, animal and plant life or health, including measures to regulate the import and marketing of biotech products. That right is not contested in this dispute.

5.75 However WTO Members that adopt SPS measures must comply with the disciplines of the *SPS Agreement* that are designed to ensure that SPS measures do not restrict trade unnecessarily. These disciplines include provisions requiring transparency in the adoption and application of such measures as well as provisions imposing substantive requirements that such measures must be based on scientific principles and not maintained without sufficient scientific evidence.

[148] Footnote 3, Article 5.6.

5.76 The "measure" at issue in this dispute is not the European Communities' legislated approvals process, but the actions taken by the European Communities that have in fact impacted on the approval and marketing of biotech products. These actions have been described by the complaining parties as a general moratorium on approval of biotech products, or product-specific moratoria or marketing bans. It is well established that the term "measure" in the WTO context is broad in content and thus a Panel may look beyond the formal laws and regulations of a Member to assess overall the nature and impact of a Member's actions on trade. Accordingly in New Zealand's view the Panel should find that these actions – the moratorium and product-specific bans – are "measures" adopted by the European Communities that affect trade in biotech products and are thus subject to scrutiny with the European Communities' WTO obligations.

5.77 The complaining parties have also demonstrated that the European Communities' measures are SPS measures within the meaning of the *SPS Agreement*. New Zealand's Written Submission highlighted three ways in which the complaining parties have demonstrated that the European Communities' moratorium on biotech products and its product-specific marketing bans failed to comply with the European Communities' obligations under the *SPS Agreement*.

5.78 The European Communities' measures fail to meet the clear procedural requirements of the *SPS Agreement* that SPS measures must first be "published promptly" and second that approvals processes that Members adopt must be undertaken and completed without "undue delay". These procedural requirements operate to provide protection against such measures being used to restrict trade unnecessarily. The European Communities' failure to publish the moratorium or the bans is clear.

5.79 In respect of whether there has been "undue delay" in the application of the European Communities' approvals processes, there must be a strong presumption that a delay is "undue" where a Member has in fact suspended the operation of its legislated approvals process without providing any justification in terms of the *SPS Agreement* for doing so.

5.80 The European Communities also failed to meet the substantive requirement of the *SPS Agreement* not to adopt measures that are more trade restrictive than necessary to achieve their desired level of protection. The legislative framework adopted by the European Communities for the approval and marketing of biotech products must be taken to represent at least the level of protection deemed appropriate by the European Communities to manage risks arising from biotech products. The European Communities' moratorium and product-specific marketing bans – more trade restrictive than the European Communities' legislative framework – are therefore clearly more trade restrictive than necessary to achieve the European Communities' appropriate level of protection.

5.81 In conclusion, for the reasons set out in New Zealand's written submission, the Panel should find that the European Communities' moratorium and product-specific marketing bans fail to meet the requirements of the *SPS Agreement* .

G. THIRD PARTY WRITTEN SUBMISSION OF NORWAY

1. Introduction

5.82 While recognizing the many potential benefits from GM products, Norway underlines that GMOs have been used for a relatively short time and that important effects on health and the environment remain not fully understood. The approval of GMOs and GM products raise several complex issues of a scientific and factual nature. The process of risk assessment is therefore

particularly time-consuming. A prudent approach to GMOs in WTO members' regulatory frameworks is therefore warranted.

5.83 Norway restricts its third party submission to certain legal issues concerning Bt. 176[149], MS1xRF1[150], and Topas 19/2.[151] These are three out of totally seven GMOs in relation to which national EC member State measures are contested.

2. Factual background, with emphasis on consequences of use of antibiotic resistance marker genes (ARMGs)

(a) Overview

5.84 GMOs are one of the results of modern biotechnology. They are created by a particular set of techniques which are used to genetically modify (or "genetically engineer") organisms. In short, they require a change of genetic material within an organism through genetic recombinant nucleic acid techniques. This is explained in more detail in chapter 2.1 of Norway's first written submission.

5.85 Contrary to what has been claimed, there is no "proven safety record" [152] with regard to GMOs. National and international regulatory developments demonstrate that GMOs are not a mere continuation of traditional breeding. This is shown in Chapter 2.3 of Norway's first written submission. GMOs should therefore not be treated as equivalent to non-GM products. Little is known about long-term effects of foods from transgenic crops. Moreover, little scientific agreement exists regarding their environmental impacts. New scientific evidence concerning environmental and health impacts is constantly emerging.

5.86 Among the possible environmental effects outlined by scientists are the spreading of genes through hybridisation between GM plants and closely related domesticated or wild species, population growth, spreading and invasion of GM plants into natural ecosystems, increased competition from GM plants or their hybrids with natural species, the spreading of genes through horizontal gene transfer from plants to microorganisms in the environment, development of herbicide resistant weeds, development of insects resistant to insecticides, effects on non-target organisms and secondary environmental effects as a consequence of changed agriculture practises e.g. new use of insecticides, herbicides, fertiliser's etc. [153]

[149] Subject to safeguard in Austria, Luxembourg and Germany.
[150] Subject to safeguard in France.
[151] Subject to safeguard in France and Greece.
[152] As stated in the first written submission of the United States, ref. heading preceding paragraph 27.
[153] Keeler K.H. 1985 (Exhibit NOR-77); Crawley, M.J., 1988. Meeting report: COGENE/SCOPE at Lake Como. Special combined issue: Trends Biotechnology & Trends Ecology, Evol 3. 2-3 (Exhibit NOR-78); Ellestrand N.C. 1988. Special combined issue: Trends Biotechnology & Trends Ecology, Evol 3. 30-32 (Exhibit NOR-79); Tidje J.M (and 6 others) 1989. Ecology. Vol 70, No 2 (Exhibit NOR-80); Williamson M. 1989. Special combined issue: Trends Biotechnology & Trends Ecology, Evol 3. 32-35 (Exhibit NOR-81); McNally R. 1994. The Ecologist, Vol 24, No. 6 Nov/Dec, 207-212 (Exhibit NOR-82); Doyle J.D, Stotzky G, McClung G, Hendricks C.1995. Advances in Applied Microbiology, Vol. 40, 237-287 (Exhibit NOR-83); The Royal Society of Canada. 2001. Elements of Precaution: Recommendations for the regulation of food biotechnology in Canada. An expert panel report on the future of food biotechnology prepared by the Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada (ISBN-0-920064-71-x) (Exhibit NOR-22); Snow A.A. *et al.*, 2004; "Genetically engineered organisms and the environment: Current status and recommendations" ESA position paper (Exhibit NOR-4).

5.87 Some of these hypothesises have been debated in the scientific literature and many of them have been verified by research in some species and environments. A consequence may be population decrease or extinction of species in natural ecosystems, or different type of problems for agriculture. Whether these types of effects will occur is difficult to predict a priori, and will depend on the species and genetic modification in question, the receiving environment or the farming and agro-ecosystem in use.

5.88 Among the scientific concerns that have been raised in connection with public and animal health are insufficient studies on putative effects of GM nucleic acids or food/feed on potential animal or human consumers, whether the transgene DNA sequences given in the notifications are the same as the insert sequences found in the GM plants, persistence and uptake of DNA and proteins from mammalian GIT (gastro intestinal tractus), transgenic or altered host cell proteins and production of chemicals and pharmaceuticals in plants. Some of the concerns will also be relevant for environmental risk assessments of GMOs due to the fact that the processes can take place in the environment.

5.89 These possible effects and concerns are explained in more detail in chapter 2.2 of Norway's first written submission.

5.90 A prime concern is the potential spreading of genes through horizontal gene transfer from plants to micro-organisms in the environment, particularly in respect of *antibiotic resistance marker genes (ARMGs)*

5.91 As described in Chapter 2.4 and documented by risk assessments, these effects were the main reason for prohibiting the three GMOs in Norway.

5.92 Horizontal gene transfer is unknown. This means that intentional genetic modification of for example plants could lead to unintentional genetic modification of other organisms. Today no scientists deny the occurrence of horizontal gene transfer, and different mechanisms have been described for the process. An increasing amount of genes and traits in different species that most probably have been spread through horizontal gene transfer, have been reported. The consequences of such unintentional genetic modifications on human health and the environment, including possible long-term effects, are not well known.

5.93 ARMGs are used as a selection tool during the process of modification. In most cases they remain within the plant as an intact genetic trait.[154] Resistance towards antibiotics is an increasing problem in therapeutic human and veterinary medicine. Most likely, this is a result of unwise use and spread of antibiotics in general. Two uncertainties exist: Firstly: When GM plants are digested, what possible increased spread of antibiotic resistance genes may occur through horizontal gene transfer to organisms in the environment and in the human and animal digestical tract? Secondly: What consequences may this have with regard to resistance development of pathogenic bacteria in the future?

5.94 Norway has explained the risks associated with Bt 176, MS1xRF1 and Topas 19/2 which led to their prohibition in Norway. The essence is described below:

[154] Droege M. *et al*., 1998 (Exhibit NOR-105); Nielsen K. M. *et al.*, 2000 (Exhibit NOR-106), 2003 (Exhibit NOR-76).

(a) Maize Line Bt 176

Concerns are here related to risks associated with a possible horizontal transfer of the *amp* gene for resistance to the antibiotic ampicillin contained in the product, as well as with ecological effects of the insect toxin encoded by the *cryIA (b)* genes. A transfer of the *amp* gene to pathogenic bacteria in such a way that the gene is successfully incorporated and expressed would be highly undesirable. This is because it might impede clinical treatment. As is documented in the attached risk assessment, studies indicate that there is a risk for horizontal transfer of the *amp* gene.

(b) Oilseed rape line MS1 x RF1

Concerns are here related to the risks associated with a possible horizontal transfer of the *nptII* gene for resistance to the antibiotics neomycin and canamycin contained in the product, as well as with the consequences of gene flow from the genetically modified oilseed rape to wild plants and crops. Transfer of this gene to pathogenic bacteria could contribute to worsening the problem of development of antibiotic resistance. When the risks of this particular genetically modified oilseed rape were assessed, some results indicated a risk of horizontal transfer of the *nptII* gene. As with Bt 176, further studies were needed. A further concern was documented in the above-mentioned risk assessment. This was related to hybridisation between genetically modified oilseed rape and several wild and domesticated plant species in Norway. Introgression of the gene conferring gluphosinate-tolerance into cross-compatible species could lead to the development of gluphosinate-resistant weeds. In addition, hybridisation with other crop plants could have undesirable effects. These may include future agricultural problems connected to weed management.

(c) Oilseed rape line Topas 19/2

It contains the *npt II* gene encoding resistance to the antibiotics kanamycin and neomycin. The assessments and comments with regard to ARMGs in oilseed rape MS1xRF1 above are also applicable to oilseed rape line Topas 19/2.

3. Legal discussion

(a) Overview

5.95 Norway submits that risks related to ARMGs are not covered by the *SPS Agreement*, or by Article 2 of the *TBT Agreement*. The applicable WTO Agreement is thus the GATT. The member State measures are not in breach of Article III: 4 of the GATT 1994, and are at any rate justified under Article XX of the GATT 1994.

5.96 If the Panel nevertheless were to consider that such bans should be addressed under the *SPS Agreement*, Norway argues in the alternative that the national EC member States bans conform to Article 5.7 under the *SPS Agreement*.

(b) The *SPS Agreement* is not applicable to measures against ARMGs

5.97 The definitions in Annex A point 1 are quite precise. The application of the *SPS Agreement* will depend on the purpose of each particular measure, and more specifically which risks the measure is intended to protect against. If a particular objective is not covered by the *SPS Agreement*, a decision

which invokes this particular risk shall not be assessed under SPS, but rather under the *TBT Agreement* or the GATT 1994. Should the Panel decide that only one objective falls under the SPS, the remaining part of the decision must be assessed under the other Agreements.

5.98 The protection from risks arising from GMOs or GM products, is not mentioned *per se* in the wording of Annex A. Whether a measure falls under Annex A, point 1 will therefore be decided by the objective(s) of a measure in relation to the concrete risk(s).

5.99 The concern with ARMGs is that the antibiotic resistant trait in the GM crop or product DNA might be transferred to bacteria, particularly in the digestive tract of humans or animals. This might have negative impact on clinical and veterinary medicine, which relies heavily on antibiotics (and therefore on the absence of resistance to antibiotics). As explained by the European Communities[155], plant DNA is in itself not an organism. Even if it were, it would however not be the plant DNA that caused the disease. The disease would have to arise from other sources. Therefore, plant DNA is not covered by the definitions set out in Annex A point 1. Accordingly, the *SPS Agreement* is not applicable.

(c) Alternative argument in respect of Article 5.7 of the *SPS Agreement*

5.100 Should the Panel, nevertheless, decide to assess member States' national measures regarding any of the three GMOs under the *SPS Agreement*, Norway will argue, in the alternative, that the measures against the risks of ARMGs fully conform with the *SPS Agreement*, in particular Article 5.7 thereof.

5.101 The European Communities has convincingly shown that the national measures of member States – if they are to be assessed under the *SPS Agreement* – are "provisionally adopted".[156] This follows *inter alia* from the legal basis in internal EC law. We refer to the European Communities' first written submission for further details.[157] Since these member States' measures are provisional, any evaluation of the conformity of the bans with the *SPS Agreement* must be made under Article 5.7 and not under Article 5.1.

5.102 Norway argues that the four cumulative requirements set out in Article 5.7 are satisfied and accordingly that there is legal basis for adopting and maintaining the provisional phytosanitary measures.

5.103 Firstly, Norway argues that we are faced with a situation where "relevant scientific evidence is insufficient". Biotechnology is still in its infancy. Many of the scientific findings are inconclusive or ambiguous. GMOs are exceedingly complex to analyse. It may take years before one may find reliable evidence, which allows to conclude as to their possible harmful impact on health and/or the environment.

5.104 Secondly, the measures in question were adopted "on the basis of available pertinent information". The EC member States could collect information from open sources and they could depend on risk-assessments delivered by other member States due to internal transparency mechanisms within the EU. They could also depend on the Norwegian risk-assessment due to the same kind of mechanisms within the European Economic Area. On the whole, there exists a

[155] *Ibid*, paras. 431-432.
[156] At least Canada does not seem to contest that these are provisional measures, *see* first written submission of Canada, para. 379.
[157] First written submission of the European Communities, para. 589.

presumption that sufficient information was at hand for the EC member states to identify the risks posed by GMOs.

5.105 Thirdly and fourthly, the European Communities fulfils the requirement of seeking "to obtain the additional information necessary for a more objective assessment of risk and will review the measure within a reasonable period of time". In order to gain better insight a considerable amount of research is continuously carried out world-wide. An expert panel recently established under the European Food Safety Authority has recently assessed ARMGs, and a working group within the European Communities is currently considering the use of ARMGs in GMOs. In conclusion, the requirements under SPS Article 5.7 are thus met in relation to the three GMOs.

(d) The *TBT Agreement* is not applicable to measures against ARMGs.

5.106 Canada and Argentina argue that to the extent that the *SPS Agreement* is not applicable, the member State national measures could be reviewed under various subparagraphs of Article 2 to the *TBT Agreement.*[158] In Norway's view the arguments of Canada and Argentina do not correctly reflect the content of Article 2.2. The reason is that EC member State national measures are not "technical regulations" within the meaning of the *TBT Agreement.*[159] They do not contain general descriptions of a normative nature applicable to an undetermined number of producers. In the case in *EC – Asbestos*, the Appellate Body *inter alia* held that since the national measure "lays down "characteristics" for <u>all</u> products that might contain asbestos"[160] (underlining added), the measure was covered by Article 2.2 of the *TBT Agreement*. In our dispute, however, the national measures do not apply to <u>all</u> GMOs or even all GMOs coding for antibiotic resistance. Rather, each measure contains a single ban on one particular GMO. Each measure is addressed to one specific manufacturer or right holder and creates legal rights and obligations only upon this addressee. Therefore, they fall outside the scope of Article 2 of the *TBT Agreement*.

(e) The GATT 1994

5.107 Canada and Argentina claim that [some] of the member State national measures violate Article III: 4 of the GATT 1994.[161] These allegations are unfounded.

5.108 In order for a violation of Article III: 4 to occur, several conditions have to be fulfilled. A main requirement is that imported products are treated less favourably than domestic products. In this dispute, the national origin of the manufacturers is not a relevant issue. As shown throughout this submission, quite different concerns have led to these national measures. Indeed, most of the GMOs subject to member State national measures have in fact been notified by companies incorporated in the European Communities and belong to such companies.[162] Thus, the national measures do not distinguish on the basis of nationality. Moreover, there is no evidence that the national measures are in particular addressed at the imported GMOs. This is also the case with the Greek national measure, which according to its intended legal effects applies *erga omnes*.

5.109 Moreover, in order to be caught by Article III: 4 of the GATT 1994, the complaining parties must show that these GMOs are "like" products. Several factors will contribute to deciding whether

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[158] First written submission of Canada, paras. 473-505; and First written submission of Argentina, paras. 547-592.
[159] First written submission of the European Communities, para. 642.
[160] Appellate Body Report, *EC – Asbestos*, para. 75.
[161] First written submission of Canada, para. 444; and first written submission of Argentina, paras. 338.
[162] *See* first written submission of the European Communities, paras. 632-633.

these are "like" products or not. As demonstrated in Chapter 2.3, most WTO members distinguish between GMOs and its conventional counterparts as regards regulatory regimes. This is because GMOs in fact may have different effects on health and environment than their conventional counterparts. Also, as shown in Chapters 2.4.2.2 and 2.4.3.2, international organisations are increasingly viewing products containing GMOs with genes coding for antibiotic resistance as distinct from conventional products. Also, the growing requirement for labelling of GMOs, which come as a respond to consumer demands, indicate that GMOs should not be treated as "like" products.

5.110 In conclusion, the member State measures in relation to the three GMOs are not in breach of Article III: 4 of the GATT 1994.

5.111 Even if there should be a breach, other Articles of the GATT 1994, Article XX of the GATT 1994, in particular sub-paragraph (b), provide a defence with respect to the three GMOs discussed here.

4. Concluding remarks

5.112 Norway respectfully requests the Panel to take the facts and arguments presented above fully into consideration when making its findings and recommendations.

H. THIRD PARTY ORAL STATEMENT OF NORWAY

1. Introduction

5.113 Norway has in its written submission addressed the risks associated with three particular GMOs: Bt 176[163], MS1xRF1[164], and Topas 19/2.[165] These are three out of seven GMOs in relation to which national EC member State measures are contested in the present case. Norway's focus on these three GMOs today is due to the fact that they contain *antibiotic resistance marker genes (ARMGs)*. This is also the main reason why their marketing is prohibited in Norway.

5.114 In my oral intervention I will focus on two issues of legal interpretation. Firstly, I will argue that the *SPS Agreement* is not applicable to risks arising from ARMGs. And secondly I will show that these national measures are not infringing the GATT 1994. In respect of the scientific evidence relating to GMOs in general, as well as our other legal arguments, I refer to our written submission.

2. Application of the *SPS Agreement*

5.115 The complaining parties argue in the first instance that the member State national measures fall under the *SPS Agreement*. This argument is based on a simplification on how the *SPS Agreement* is to be understood. Only national measures that have certain specified objectives and which address certain specified risks are covered by the *SPS Agreement*.

5.116 It is clear from Annex A of the *SPS Agreement* that the "risks" covered must "arise" or be caused by the risk factors mentioned in point 1. Measures against other risks, no matter how serious their consequences may be, are not covered by the *SPS Agreement*, but may be covered by the *TBT Agreement* or the GATT 1994.

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[163] Subject to the safeguards in Austria, Luxembourg and Germany.
[164] Subject to the safeguard in France.
[165] Subject to the safeguards in France and Greece.

5.117 In respect to the risks posed by GMOs with ARMGs – as is the case with the 3 above-mentioned GMOs – the specific concern is that antibiotic resistance genes might be transferred to bacteria, particularly in the digestive tract of humans and animals (so-called "horizontal transfer"). If this should happen, the treatment of infections by certain antibiotics – ampicillin, kanamycin and neomycin – could be impeded both in human and veterinary medicine, because of resistance acquired by bacteria to these antibiotics.

5.118 According to Annex A point 1 litra b), an SPS measure is *inter alia* a measure whose purpose is to protect human or animal life or health from disease-causing organisms in foods, beverages or feedstuffs. Although the protection against ARMGs is a clear human and animal health concern, these risks do not fall under Annex A point 1. Firstly, the inserted DNA which contains the antibiotic resistance gene, is not an organism in itself. Secondly, the gene is not disease-causing, but may merely prevent the treatment of diseases caused by ordinary bacterial infections. Therefore, the *SPS Agreement* is not applicable to the national bans insofar as their object is to protect against the risks of antibiotic resistance.

3. Application of the GATT 1994 – Article III:4

5.119 Canada and Argentina have presented arguments alleging that the national EC member States bans infringe Article III:4 of the GATT 1994. As far as Article III:4 of the GATT 1994 is concerned, we have in our written submission argued that imported products are not treated less favourably than domestic products. The GMOs in question are prohibited, irrespective of their country of production.

5.120 Furthermore, Norway argues in its written submission that GMO-products are not "like" products, and we refer to our written submission for more details. Let me just point to para 105, which refers to the Codex decision of July 2003, whose guidelines now treat antibiotic resistance marker genes in food production, differently from foods which do not contain such genes. I would also point to the many national legislations that have enacted separate approval procedures for GMOs. This clearly demonstrates that most WTO Members consider GMOs to be something different from the original non-modified organisms. In conclusion Article III:4 is not infringed.

4. Application of the GATT 1994 – Article XX

5.121 If the Panel, nevertheless, were to conclude that Article III: 4 or Article XI: l of the GATT 1994 – in the case of Greece – have been violated, it must assess whether the national EC member States measures can be justified under Article XX. The burden of proof in this respect rests upon the European Communities.

5.122 Norway would like to note that in respect of the three GMOs with ARMGs, the policy pursued by the European Communities and its member States with regard to GMOs would seem to fall directly under Article XX of the GATT 1994, sub-paragraph (b) as measures to protect "human, animal or plant life or health". The risks that these GMOs pose, have been explained in detail in the Norwegian written submission and the documents annexed thereto.

5.123 Limiting myself to comment briefly upon the requirement of "necessity" in sub-paragraph (b), it is difficult to see that there could be reasonable – and less trade distorting – alternative measures available, in order to fulfil the established policy objective of avoiding antibiotic resistance. Labelling for instance, would clearly not achieve the declared health objectives. I should also note that no alternative measures seem to have been suggested by any of the complaining parties.