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

(WT/DS291, 292, and 293)

Oral Statement of the United States

June 2, 2004

INTRODUCTION

1. The European Communities has adopted approval procedures for agricultural products produced with the benefit of modern biotechnology. Up to October 1998, the European Communities implemented those procedures and approved more than ten biotech products.

2. However, after the last agricultural biotech product approval in October 1998, the European Communities suspended its own approval procedures. In particular, the European Communities suspended consideration of applications for, or granting of, approval of biotech products under the EC approval system. Particular product applications might make some progress, in fits and starts, through the EC approval system, but the EC has failed to allow any biotech product to move to final approval starting in October 1998 and through August 2003, when the terms of reference for this panel were established.

3. The EC's adoption of a moratorium on product approvals was not adopted in a transparent matter. Indeed, it was not published in any official journal or otherwise memorialized. Nonetheless, the moratorium is widely-recognized, including by leading EC officials. And, the moratorium is just as effective as any amendment to the EC approval legislation formally enacted into law in blocking prompt and transparent evaluation of the products currently at question in this dispute.

4. The United States submits that the EC's adoption of the moratorium – both across-the-board, and with respect to individual pending product applications – is inconsistent with the EC's obligations under the WTO Agreement, and in particular the *Agreement on the Application of Sanitary and Phytosanitary Measures*. While Members are allowed to maintain approval systems – and the United States is not objecting to the EC maintaining such a system for biotech products – the procedures under that system must be undertaken and completed "without undue delay." It is hard to think of a situation that involves "undue delay" more than a moratorium on approvals. Many of the products caught up in the EC moratorium have been positively assessed by the EC's own scientific committees. In this case, the EC can present no scientific basis for its moratorium on approvals. In short, having established a biotech approval regime, the European Communities is obligated to apply those procedures fairly and transparently, and without undue delay.

5. In addition to the moratorium on the approval of biotech products, six EC member States have adopted marketing or import bans on biotech products that previously have been approved by the European Communities. These product-specific bans, like the moratorium, are not based on science and are thus inconsistent with the EC's obligations under the WTO Agreement.

6. In challenging the EC's moratorium under the DSU, the United States is simply calling on the EC to allow its own approval procedures to run their course.

GENERAL COMMENTS ON EC SUBMISSION

7. I would now like to make some general comments on the EC submission.

8. First, much of the EC submission addresses issues that have little, if any, connection to the legal questions in dispute in this proceeding.

9. The EC submission stresses the EC's view that biotechnology involves complexity. However, the EC does not claim, and indeed could not claim, that any of the scientific issues discussed in its background section justified either a general moratorium or the product-specific moratoria. Instead, the EC claims that there was no moratorium at all. To make this claim, the EC asks us to believe that the EC's own highest officials misunderstand the EC approval system, and that the failure to approve any biotech products between October 1998 and August 2003 was mere coincidence.

10. Moreover, if the EC has scientific questions about biotechnology, those questions can be and should be addressed within the context of the EC's own approval system, and in a manner consistent with its WTO obligations. Indeed, this is just how the EC approached scientific and technical issues for the biotech products that the EC approved prior to October 1998.

11. Similarly, the EC does not claim, and could not claim, that any proceedings in other international fora absolve the EC from complying with its WTO obligations regarding biotech

products. Most notably, the EC discusses the Biosafety Protocol at length. The EC itself, however, acknowledges that the Protocol explicitly provides that parties may not disregard their existing international obligations in their implementation of the Biosafety Protocol. Furthermore, the Biosafety Protocol foresees a functioning regulatory system in each Party country; it does not provide an excuse for refusing to make prompt, transparent decisions.

12. So what then is the connection between the EC's discussion of biotech-related proceedings in other fora and the legal merits of this dispute? The answer, again, is none of the proceedings in those other fora excuse the EC of its WTO obligations.

13. In short, the EC's brief presents a cloud of information unrelated to the merits of this dispute, apparently with the hope that it might somehow justify EC measures that the EC claims don't in fact exist. This type of argumentation mirrors the EC measures themselves. The EC's biotech moratorium, like the EC submission in support of the moratorium, is nontransparent and based on vague and shifting rationales.

14. The second general comment regarding the EC submission concerns its arguments on the applicability of the SPS Agreement. In this discussion, the EC argues at length, and in the hypothetical, that the EC might adopt measures that are not covered within the scope of the SPS Agreement. But, once again, the EC does not link its discussion to the legal issues in this dispute. The pertinent question is whether the measures that the EC has actually adopted, and that are covered in this dispute's terms of reference, are within the scope of the SPS Agreement.

And, as discussed in the First U.S. Submission, and summarized below, the EC measures in this case are plainly included within the scope of the SPS Agreement.

15. The third general comment is that the EC has attempted to de-emphasize the general moratorium. The United States wishes to reemphasize, as made clear in its opening submission, that the general moratorium is at the core of this dispute. The United States brought this dispute because the EC at the highest levels announced a general moratorium on biotech approvals, and followed through on those pronouncements by failing to approve any biotech products for over 5 years. This type of broad-brush measure, imposed nontransparently, without scientific basis, and in clear contravention of the EC's WTO obligations, poses a severe threat to the principles underlying the WTO Agreement.

GENERAL MORATORIUM VIOLATES THE SPS AGREEMENT

16. With that in mind, I will now turn to the EC's general moratorium on biotech approvals. The EC's discussion of the general moratorium is remarkable in that it is concerned solely with whether or not the general moratorium qualifies as a "measure" under the SPS Agreement. Should the Panel find, as the complainants all submit, that the general moratorium is indeed a measure under the SPS Agreement, the EC has <u>not</u> contested that the general moratorium is inconsistent with the EC's obligations under the WTO Agreement. In particular, the EC has not contested that the general moratorium:

- results in "undue delay" in breach of Article 8 and Annex C;

- is inconsistent with its obligations under Article 7 and Annex B to publish measures promptly;

- is inconsistent with its obligations under Article 8 and Annex C(1)(B) to keep applicants informed of the progress of applications;

- is not based on a risk assessment as required under Article 5.1; and

- results in arbitrary or unjustifiable distinctions in the levels of protection in breach of Article 5.5.

The EC's decision, at least in its first submission, not to contest these central issues illustrates precisely why the United States, Argentina, and Canada brought this dispute in the first place. In short, the complainants believe that a general moratorium on all biotech products is indefensible under the WTO Agreement, and is causing harm to the complainants.

17. The evidence that the general moratorium exists is overwhelming. To summarize the facts in the first U.S. submission: Up to October 1998, the EC had approved at least ten biotech products. But between October 1998 and August 2003, the EC failed to approve a single biotech

product under its novel foods or deliberate release legislation, even though many of those products had been favorably assessed by the EC's own scientific committees.

18. The moratorium became widely known no later than June 1999, when it was announced by Environment Ministers of five member States. In particular, at a Council Meeting of EC Environment Ministers in June 1999, Environment Ministers of Denmark, Greece, France, Italy and Luxembourg issued a Declaration stating: "in exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms… they will take steps to have any new authorisations for growing and placing on the market suspended."

19. The statements of Commission and member State officials confirm the existence of a moratorium. For example, as early as July 2000, European Environment Commissioner Margot Wallström publicly admitted the existence of a "moratorium," calling it "illegal and not justified." This sentiment was reiterated at a press conference in October 2001 following a meeting of the Council of Environment Ministers when Commissioner Wallström reportedly "admitt[ed] that no end was in sight for the moratorium, which she said was an illegal, illogical, and otherwise arbitrary line in the sand."

20. European Commissioner for Health and Consumer Protection, David Byrne, stated in June 2000 that the reluctance of member States to approve the placing on the market of biotech products "has resulted in a complete standstill in the current authorisations and a de facto moratorium on the commercial release of GMOs." Commissioner Byrne again acknowledged

the existence of the moratorium in February 2003 when he implored member States that "we must lift the moratorium."

21. And, the EC's official representative to the SPS Committee acknowledged the existence of the moratorium. At the meeting of the SPS Committee held on October 31-November 1, 2001, the United States and Canada expressed concerns about the EC's adoption of the moratorium. The summary of the meeting[1] notes the following EC response:

> "The representative of the European Communities reaffirmed the European Commission's interest and positive actions aimed at allowing the authorization procedures to continue. The recent meeting of the European Environmental Council had started a very important discussion on proposals presented by the Commission to *restart* the authorization procedure."[2]

The EC representative's statement that there were proposals to *restart* biotech authorization procedures is plainly an acknowledgment that those procedures had been suspended.

22. Commission documents also confirm the existence of the moratorium. A Commission Working Document dated November 2000 states "the current authorization procedure for commercial release of GMOs, including those that may end up in the food chain, has ground to a standstill." A Commission Press Release dated July 2001 states that the adoption of new legislative proposals "will contribute towards the lifting of the de facto moratorium on the commercial release of GMOs." An October 2001 internal Commission working paper states that

[1] Committee on Sanitary and Phytosanitary Measures, Summary of the Meeting Held on 31 October-1 November 2001, Note by the Secretariat, para. 105 (G/SPS/R/25) (18 January 2002).

[2] Emphasis added.

"[t]his reluctance to go forward with authorizations of GMOs has resulted in a de facto moratorium on the marketing of new GMOs and impacted on product approvals under the sector-based legislation." In July 2003, a Commission fact sheet on GMO regulation stated that "[t]he revised Directive [2001/18] and the two proposals for Regulations are expected to pave the way for a resumption of GM authorizations in the European Union." A document issued by the General Secretariat of the Council of the European Union stated that the proposed rules on traceability and labeling of biotech products could "possibly lead to the lifting of the current moratorium." Most recently, in a document that Canada referred to today, an official Background document to the Agriculture and Fisheries Council of Ministers held on April 26, 2004, during which the Council of Ministers considered a Council Decision to authorize the placing on the market of Bt-11 sweet corn, the following statement appears: "The adoption of a decision to authorize Bt-11 would bring an end to the current *moratorium* on genetically modified food and feed in Europe."[3]

23. The EC's first submission provides two responses to this overwhelming evidence. Before addressing these two issues, however, I would like to note that the EC first submission in fact goes quite a long way toward conceding the existence of the moratorium.

24. In this regard, I would like to point the Panel's attention to paragraph 157 of the EC First Submission. This section of the EC submission provides background regarding the EC's modification of its Deliberate Release directive, effective October 2002, by which directive

[3] *See* Exhibit US-109.

2001/18 replaced directive 90/220. In describing the reasons for adopting a modified directive, the EC submission states:

> These issues [meaning issues relating to alleged scientific uncertainty] affected some of the pending applications as **a number of Member States made it clear that they were not in a position to vote in favor of granting market authorizations** for individual products without these issues being addressed first.[4]

From where we stand, this statement is quite close to a confirmation of the basic point that the complainants are making in this dispute: namely, that at a certain point in time, certain member States decided that they simply were not going to vote for new product approvals. Under the EC's rules of qualified majority voting, a minority of member States can block EC action. Blocks by qualified majority in the regulatory committee may be overridden by a simple majority vote in the Commission. But, as the record here shows, the EC has decided not to submit final decisions for a majority vote by the Commission. In addition, if one of those "number of member States" that are unwilling to grant market authorizations were the original recipient of the application, then that single member State may block a Deliberate Release application all by itself. The EC in paragraph 157 does not go so far as to agree with the complainants that the moratorium still exists, or that the moratorium affected the Novel Foods regulation. Nonetheless, the EC's statement that "a number of member States made it clear that they were not in a position to vote in favor of granting market authorizations" confirms that there was in fact a moratorium as to approvals under 90/220, the first version of the Deliberate Release directive.

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[4] EC First Submission, para. 157 (emphasis added).

25. I will now turn to the EC's arguments in its first submission as to why this Panel should nonetheless find that there is no general moratorium. First, the EC argues that it cannot be "legally affected" by "casual statements of any of its numerous representatives". But the complainants are not relying on "casual statements of numerous representatives"; the statements cited by complainants are statements made by the EC's highest officials, by its member States, and by its official bodies. Moreover, the EC itself concedes, as it must, that such statements can be considered as evidence of the existence of a measure.

26. The EC's second response is to submit application histories for each of the products covered by the moratorium. The EC claims[5] that this information shows that "none has been stalled and none has been subject to a general suspension of the approval process." This assertion, however, is unsupported and baseless. To the contrary, the information submitted by the EC is entirely consistent with the EC's imposition of a general moratorium. First, the information submitted by the EC confirms that there were in fact no approvals of biotech products between October 1998 and the establishment of the Panel's terms of reference in August 2003.

27. We will address the EC's product histories at greater length in our second submission. At this time, however, I would like to point out a few applications in which even the EC's own exhibits show quite clearly how the moratorium operates.

[5] EC First Submssion, para. 485.

28. First, I would refer the Panel's attention to two oilseed rape products discussed in Paragraph 298 and Exhibits 89 and 90 of the EC Submission. The U.S. submission noted that these two products were subject to the general moratorium. The EC submission, however, writes to the contrary that these two products were approved for cultivation, import, and marketing under the 90/220 Directive at "Community level" The key phrase here, however, is "Community level." The EC submission entirely fails to note that under Directive 90/220, the "Community level" approval is not effective unless and until the member State that initially received the application takes a final step of placing the product on the market. In this case, that member State, which was France, never allowed the product to be placed on the market. Thus, these products in fact were never approved for cultivation, import, and marketing in the EC. This is an example, as I noted before, of how in certain circumstances a single member State can block a product approval. And, more importantly, it is an example of how the EC's own submission does not contradict, and in many cases supports, the existence of the general moratorium.

29. The second example I would like to refer to is Bt Cotton, addressed in paragraphs 222 to 228 and Exhibit 65 of the EC First Submission. In particular, I would like to refer to the chronology provided as the first page of Exhibit 65. Spain, the member State that initially received the application, forwarded it with a positive opinion to the EC in November 1997. The EC's Scientific Committee on Plants made a favorable assessment in July 1998. The application, like many others, then ran into trouble with the qualified majority voting rules of the EC's regulatory committee. In February 1999 the regulatory committee did not approve the application by a qualified majority vote. Like for all regulatory committee decisions, the EC

did not provide the applicant with any reason for the regulatory committee's failure to achieve a qualified majority of votes in favor of the application. Moreover, under the EC's own rules, an application that fails to achieve a qualified majority of votes in the regulatory committee must be submitted to the EC Council for an additional vote, and such submission must be made, to quote Article 21 of the EC Directive, "without delay." But what happened in this case?

30. The EC's own chronology states that the next action is nearly three months later, in May 1999. And the action taken is not, as required under EC legislation, the submission of the application to the EC Council. Instead, the chronology states: "Launching of Inter-Service Consultation on draft Council Decision." To our knowledge, this term, and this step, is not provided for under the EC's regulations. Moreover, there is no indication that this step is notified or explained to the applicant. The chronology is then blank until July of 2001. So what then is this over two-year gap, described only by the cryptic phrase "Inter-Service Consultation" in the EC's chronology for Bt Cotton? We would submit that "Inter-Service Consultation" is just another word for the moratorium, and that in contrast to the EC's claims, the EC product-specific chronologies support the existence of the moratorium.

31. Finally, I would like to address the application under the Novel Foods regulation for Bt-11 sweet corn, described in paragraphs 305-309 and Exhibit 92 of the EC First Submission. This product received a favorable opinion from the EC's Scientific Committee on Food over two years ago, in April 2002. The EC submission states that the Commission was finally ready on May 19 of this year to accept a proposal allowing the use of Bt-11 sweet corn for food use. We

understand that this did occur, and that the EC may finally allow the sale of this product for food use – although not for planting – once the decision is published in the EC's official journal.

32. In order to anticipate a possible question of the Panel, the United States would like to make very clear that when and if Bt-11 sweet corn is finally allowed to be sold in the EC, the approval will have no effect on our request that this Panel find that the EC adopted a general moratorium on approvals of biotech products and that this moratorium is inconsistent with the EC's WTO obligations. The measure that we are requesting that the Panel examine is the measure in existence at the time when the Panel and its terms of reference were established, which is the measure in effect as of August 29, 2003. To be clear, the United States would not view an approval of Bt-11 as a lifting of the EC's moratorium or as an indication that the EU will begin to meet its WTO obligations by making decisions on all other pending applications without undue delay. But any issues relating to whether or not steps taken by the EC after August 2003 have brought the EC into compliance with its WTO obligations are not before the Panel.

33. I would also note that the Bt-11 approval, should it occur, is entirely consistent with, and in fact supports, the existence of the general moratorium. As noted above, both the European Commission and the Council have stated that the entry into force of the EC's new traceability and labeling rules for biotech products might finally allow for the lifting of the moratorium. Those new rules went into effect on April 19, 2004. The fact that the Commission then approved Bt-11 just one month later is, at least in our view, certainly no mere coincidence. To the contrary, this timing indicates that, as the EC itself has acknowledged everywhere but in its First

Submission, the EC approval system was held up not by any problems with particular applications, but by events outside the scope of its approval legislation. Moreover, as I noted above, the EC Council itself acknowledges the existence of the "moratorium" – it uses this very word – in a statement concerning the scheduled Bt-11 approval.

34. As discussed in the first U.S. Submission, the EC approval regime, including that part of the regime modified by the general moratorium, is plainly a "sanitary or phytosanitary" measure. However, in light of the EC's hypothetical discussion of the types of risks covered by its Deliberate Release legislation, the United States would like to make the following points.

35. First, the EC notes that its Deliberate Release directive repeatedly uses the word "environment." The EC asserts that the SPS Agreement was not intended to address the protection of risks to the environment. The idea, however, that all environmental issues are outside the scope of the SPS agreement is plainly wrong. Article 5.2 of the Agreement explicitly requires the consideration of relevant ecological and environmental conditions in an assessment of SPS risks. In addition, the SPS Agreement's definition of an SPS measure includes "Any measure applied to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests." The agreement explicitly provides that animal includes "wild fauna", and that "plant" includes "forests and wild flora." Certainly, the protection of wild fauna, forests, and wild flora – matters explicitly covered by the SPS Agreement – are elements of environmental protection. Thus, the EC has no basis for arguing

that environmental issues are automatically covered by the TBT Agreement as opposed to the SPS Agreement.

36. Second, it bears repeating that the EC's enumeration of various risks is, as noted, entirely hypothetical. The EC has not claimed that a single measure in this dispute - be it the general moratorium, one of the product-specific moratoria, or any of the member State measures – has been adopted solely to address risks purportedly outside the scope of the SPS Agreement.

37. The EC's last defense is to argue that even if the EC, as a matter of fact, adopted a general moratorium on approvals of biotech products, such a moratorium is legally precluded from qualifying as a "measure" under the SPS Agreement. This defense, too, is without any merit.

38. Approval procedures are listed in the definition of SPS measure in Annex A as a specific example of an SPS measure. The fact that the moratorium on approvals is not embodied in a single written document does not alter its status as a measure. Certainly, if the EC had acted transparently and amended its novel food and deliberate release regulations to provide for an indefinite suspension of approval procedures, the amendment would be a "law," "decree," or "regulation" and fall within the scope of an SPS "measure". The fact that the EC has adopted the moratorium in a nontransparent way, without official publication, in no way changes that result.

39. Moreover, the SPS Agreement includes in its definition of "measure" the terms "requirement" and "procedure", which are not necessarily in written form. For example, the *New Shorter Oxford English Dictionary* defines the term "procedure"as a "particular mode or course of action" or a "set of instructions for performing a specific task which may be invoked in the course of a program." Under the ordinary meaning of the term "procedure," a suspension by the EC of the consideration of applications for, or granting of, approval of biotech products is an unwritten procedure covered under the SPS Agreement.

40. In addition, the list of measures subject to the SPS Agreement is not exhaustive. Paragraph 1 of Annex A states, in relevant part, that "[s]anitary or phytosanitary measures *include* all relevant laws, decrees, regulations, requirements and procedures." The use of the word "include" indicates that the Agreement covers more than just the identified types of measures, and should be read to include other measures that may not fit squarely within the illustrative list. As the Appellate Body explained in *Japan Sunset:*

> "[I]n GATT and WTO dispute settlement practice, panels have frequently examined measures consisting not only of particular acts applied only to a specific situation, but also of acts setting forth rules or norms that are intended to have general and prospective application."

41. Finally, the object and purpose of the SPS Agreement, and more broadly the WTO Agreement, supports the fact that the EU moratorium constitutes a "measure." The preamble of

the Agreement provides that one object and purpose of the SPS Agreement is to "minimize [the] negative effects [of SPS measures] on trade." If a WTO Member could avoid its SPS obligations by adopting a nontransparent, unwritten SPS measure that has a negative effect on trade, an object and purpose of the SPS Agreement would not be fully realized.

42. The EC's only argument to the contrary is to invoke two panel reports that considered the status under the Anti-dumping and Subsidies Agreements of investigating authorities' so-called "practices".[6] But, as we will elaborate further in our rebuttal submission, the conclusions in those reports are not applicable to the determination of whether an actual moratorium on approvals (as opposed to a "practice") is a measure. Unlike the complaining parties in those disputes, the co-complainants here are not saying that a pattern of decisions itself *constitutes* a measure. Instead, the co-complainants have pointed to an unbroken pattern of decisions (or rather, to an unbroken pattern of lack of decision) as the inevitable *result* of the moratorium, which is itself an independent measure. As we explained in our opening submission, the EC in this dispute cannot be permitted to profit rhetorically from the lack of transparency in its moratorium. Had the decision to suspend approvals been published in a single document, the EC would have been unable to deny that its unbroken history of lack of action was anything other than the necessary consequence of the contents of that decision. The EC, however, chose not to publish the moratorium in writing (while at the same time ensuring that the entire world knew that it existed). That choice does not change the legal analysis, however: the moratorium itself,

[6] *US – Export Restraints* and *US – Steel Plate*.

and not the history of non-decisions that resulted from the moratorium, is the measure at issue in this dispute.

PRODUCT-SPECIFIC MORATORIA VIOLATE THE SPS AGREEMENT

43. Turning to the EC's product-specific moratoria, whether one views them as separate measures or simply as undue delay in the approval process of these individual products, the EC once again asserts that no such measures ever existed and that no application faced any undue delays. The EC makes this assertion even though, as explained above, no biotech products were approved between October 1998 and the establishment of the Panel's terms of reference in August 2003, and even though EC officials, official bodies, and member States acknowledged the existence of a moratorium. The primary basis for the EC's denial of the product-specific moratoria is the vague statement that "what has happened in many of these applications is that, at different stages of the procedure, requests for additional information have been put to applicants."[7] Nonetheless, contrary to the EC's assertions, its own exhibits show that applications stalled in its approval system without justification. I will point out some examples here, and the United States will address the EC's product chronologies more fully in our second submission.

44. Earlier in this statement, I noted the examples of how Bt Cotton and two oilseed rape products had stalled in the approval process. Bt Cotton stalled for more than two years, after the

[7] EC First Submission, para. 486 (emphasis added).

European Commission failed to forward a proposal to the EC Council, as required by the EC legislation. The oilseed rape products stalled when France, the member State that had originally received the application, refused to take the final step and place the product on the market. In none of these instances were the delays caused, as the EC claims, by additional requests for information to the applicants.

45. I would like to point out one further example of how many delays in the EC biotech approval process were clearly not attributable to pending requests for information. This example is Roundup Ready Cotton, addressed in paragraphs 229 to 234 and Exhibit 66 of the EC First Submission. Spain, the member State that initially received the application, forwarded it with a positive opinion to the EC in November 1997. The EC's Scientific Committee on Plants made a favorable assessment in July 1998. In February 1999, the Roundup Ready cotton application, like Bt cotton, did not receive a qualified majority vote in the regulatory committee. Like for Bt cotton, the next step in the EC chronology is the "Launching of Inter-Service Consultation on draft Council Decision" in May 1999. There is no further entry in the chronology until January 2003, which is more than 2 and ½ years later. Again, this is another example of a major delay that was not caused, as the EC claims, by a pending request to the applicant for additional information.

46. These specific application chronologies – Bt cotton, Roundup Ready Cotton, and the two oilseed rape products – exemplify how the product-specific moratoria resulted in undue delay in the EC's approval process. In each of these cases, the approvals were stalled for at least two and

one half years, without the EC setting forth any problems with the particular product applications. To the contrary, each of these products had received favorable scientific assessments by the EC's own scientific committees.

47. These chronologies also highlight how the product-specific moratoria are inconsistent with the related procedural obligations in Annex C(1)(b) of the SPS Agreement. In particular, paragraphs 2 and 3 require that:

> (2) "when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies":
>
> (3) "the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary".

48. In the Bt Cotton, Roundup Ready Cotton, and oilseed rape applications, the applicant is not informed in a precise and complete manner of all deficiencies, or of the results of the approval procedure. To the contrary, when the regulatory commitee fails to approve an application by a qualified majority vote, or when the EC Commission enters into "Inter-Service Consultations" rather than sending an application on to the Council, the applicant is given no explanation, and thus no opportunity to correct any deficiencies. The same is true when, as for the oilseed rape products, the member State that originally received the application fails to take the final step of placing a product on the market. In short, when the EC subjects product applications to moratoria in which products are never submitted for final decision, the EC is not in compliance with its transparency obligations under Article C(1)(b).

49. Finally, for completeness I should note that the EC product-specific moratoria, like its general moratorium on all biotech products and for the same reasons, are inconsistent with the EC's obligations under Article 7 and Annex B to publish measures promptly; not based on a risk assessment as required under Article 5.1; and result in arbitrary or unjustifiable distinctions in the levels of protection in violation of Article 5.5.

MEMBER STATE MEASURES VIOLATE THE SPS AGREEMENT

50. Like the moratoria (general and product-specific), the member State measures are sanitary or phytosanitary measures which affect international trade. The purpose of the member State measures are indicated by the text of the EC legislation that the member States invoked when they enacted their import or marketing bans. In particular, Article 16 of Directive 90/220 allows member States provisionally to "restrict or prohibit the use and/or sale of [an approved] product" if the "Member State has justifiable reasons to consider that [the] product . . . constitutes a risk to *human health or the environment.*" Similarly, Article 12 of Regulation 258/97 allows Members to "temporarily restrict or suspend the trade in and use of" an approved product if it has information that the approved product "endangers *human health or the environment.*" As each of the member States enacted their measures pursuant to Article 16 of Directive 90/220 or Article 12 of Regulation 258/97, all of the measures were enacted for the purpose of protecting human health or the environment.

51. The nine measures imposed by six member States are sanitary or phytosanitary measures which are not "based on" "risk assessment[s]" as required by Article 5.1 of the SPS Agreement. Although each of the six member States that have imposed bans on approved biotech products offered reasons for their measures – though unjustified according to the EC scientific committees – none of the member States put forth a "risk assessment" as defined in Annex A, paragraph 4. Rather, the justifications offered by the member States typically expressed concerns about adverse effects of the banned products, or biotech products in general, but did not include risk assessments of the banned products.

52. In fact, the only risk assessments put forth for the banned products are the positive scientific assessments rendered by member States to which the products were submitted, and then by the EC's own scientific committees. In the case of each member State ban, these favorable assessments were reaffirmed when the scientific committees considered and rejected the information provided by the member States. Thus, the member State measures do not bear a "rational relationship" to the EC's positive risks assessment, and are not "based on" a risk assessment, in violation of Article 5.1.

53. The EC puts forth a number of defenses of the member State measures – each is without merit.

54. First, the EC makes the vague and cryptic argument that "It results from that analysis [of Sections II.A.4, III.B.3 and II.D.4 of its submission] that each of the member State measures was

adopted for some reasons that fall within the scope of the SPS Agreement, and some reasons that do not fall within the SPS Agreement."[8] The United States is not able to discern from this assertion what reasons the EC is referring to that it considers outside the scope of the SPS Agreement. But no matter. The important point is that the EC does not dispute, and in fact agrees, that each of the member States measures was adopted for "some reasons" that fall within the scope of the SPS Agreement.

55. Second, the EC argues that each of the measures fall within the scope of Article 5.7 of the SPS Agreement. But the EC does not specify how Article 5.7 might apply. Its only argument is that under the terms of the EC legislation, the member State measures are labeled as provisional. The mere label of a measure, however, is most certainly not sufficient to bring it within the scope of Article 5.7.

56. To the contrary, as the Appellate Body has found, a measure must meet four requirements to fall within the scope of Article 5.7. Each of the member State measures, however, fails to meet any of these four requirements. First, the measures were not imposed because scientific information is "insufficient." To the contrary, the European Communities and its scientific committees found sufficient information to evaluate and render positive assessment for each of the banned products. Second, the measures were not based on "available pertinent information." To the contrary, as the European Commission stated in a memo, the member State measures "have been examined by the Scientific Committee on Plants, which in all cases deemed that the

[8] EC First Submission, para 578.

information submitted by the Members States did not justify their bans."[9] Third, there is no evidence that the member States have sought to "obtain additional information" concerning the banned products in order to make a "more objective assessment of the risk." In this regard, we note that all the member State measures were adopted in the period 1997 to 2000, in other words more than four years ago. Finally, by failing to seek and obtain additional information, the member States have also failed to review the measure in light of such information "within a reasonable period of time."

57. Third, the EC argues that even if the member State measures fall outside the scope of Article 5.7, that the measures are nonetheless consistent with Article 5.1 because they are based on a risk assessment. The EC's only support for this position, however, is the conclusory statement that the "member States may have drawn their own conclusions from the relevant risk assessments." The only "relevant risk assessments" of which the United States is aware, however, are those by the EC scientific committees providing positive assessments of the banned products. The EC has failed to identify any other "relevant risk assessments", nor to explain how the member State marketing or import bans could be based on such assessments. In short, the EC's argument that the member State measures are consistent with Article 5.1 is without merit.

[9] Questions and Answers on the Regulation of GMOs in the EU, MEMO/02/160, March 4, 2003 (Exhibit US-107), at 4.

CONCLUSION

58. Mr. Chairman, members of the Panel, this concludes the U.S. opening statement. The United States would be pleased to respond to any questions of the Panel.