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

(WT/DS291, 292, and 293)

Executive Summary of the Oral Statement of the United States at the First Substantive Meeting with the Panel

June 17, 2004

GENERAL COMMENTS ON EC SUBMISSION

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

2. 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.

3. 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.

4. 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, the EC measures in this case are plainly included within the scope of the SPS Agreement.

5. 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.

GENERAL MORATORIUM VIOLATES THE SPS AGREEMENT

6. 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 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.

7. 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.

8. 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."

9. The statements of Commission and member State officials confirm the existence of a moratorium. For example, 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 summary of the meeting notes the following EC response: "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." The EC representative's statement that there were proposals to *restart* biotech authorization procedures is plainly an acknowledgment that those procedures had been suspended.

10. Commission documents also confirm the existence of the moratorium. Most recently, in an official Background document to the Agriculture and Fisheries Council of Ministers held on April 26, 2004, 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."

11. The EC first submission in fact goes quite a long way toward conceding the existence of the moratorium. 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." 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.

12. Turning to the EC's arguments as to why there was no general moratorium, the EC first 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.

13. The EC's second response is to submit application histories for each of the products covered by the moratorium. This information, however, 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.

14. Second, we would like to point out a few applications in which even the EC's own exhibits show quite clearly how the moratorium operates. The EC submission writes that the two oilseed rape products were approved for cultivation, import, and marketing under the 90/220 Directive at "Community level."

However, 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.

15. We would also like to refer to the example of Bt Cotton. 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. However, in February 1999, the regulatory committee did not approve the application by a qualified majority vote. 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 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, are not provided for under the EC's regulations. The chronology is then blank until July of 2001. We would submit that "Inter-Service Consultation" is just another word for the moratorium.

16. Finally, we would like to address the application under the Novel Foods regulation for Bt-11 sweet corn. 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. The United States would like to make very clear that 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. Also, 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.

17. We 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, the EC Council itself acknowledges the existence of the "moratorium" – it uses this very word – in a statement concerning the scheduled Bt-11 approval.

18. 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. The EC notes that its Deliberate Release directive repeatedly uses the word "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 are elements of environmental protection.

19. 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. The EC's argument is based on two panel reports that considered the status under the Anti-dumping and Subsidies Agreements of investigating authorities' so-called "practices". But, 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.

PRODUCT-SPECIFIC MORATORIA VIOLATE THE SPS AGREEMENT

20. 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 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." Nonetheless, contrary to the EC's assertions, its own exhibits show that applications stalled in its approval system without justification.

21. Earlier in this statement, we noted the examples of how Bt Cotton and two oilseed rape products had stalled in the approval process. We would also like to point out the example of Roundup Ready Cotton. 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 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.

22. 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 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 committee 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.

MEMBER STATE MEASURES VIOLATE THE SPS AGREEMENT

23. Like the moratoria (general and product-specific), the member State measures are SPS measures which affect international trade. Each of the six member States t have imposed bans on approved biotech products, but none of the member States put forth a "risk assessment" as defined in Annex A, paragraph 4. These measures are thus not "based on" "risk assessment[s]" as required by Article 5.1 of the SPS Agreement.

24. 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.

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

26. 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.

27. 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 information submitted by the Members States did not justify their bans." 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."

28. 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.