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**Summary of the WTO Interim Report
in *EC-Biotech***

by

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This article summarizes the Interim Report (“Report”) of the Dispute Settlement Panel (“Panel”) of the World Trade Organization (“WTO”) in the matter of *Europe Communities – Measures Affecting the Approval and Marketing of Biotech Products* (“EC – Biotech”). The Report was released confidentially to the parties on February 7, 2006, but Friends of the Earth-Europe published a leaked copy on its website. According to news reports, the Appellate Body adopted the Report as its final ruling on May 10, 2006.

In May 2003, the United States, Canada and Argentina requested consultations with the EC regarding a moratorium on the approval of biotech products imposed since October 1998 by the EC and its member states. The parties asserted that the moratorium restricted imports of agricultural and food products from the complaining parties. In addition, the parties asserted that a number of EC member states maintain national marketing and import bans on biotech products even though those products have already been approved by the EC for import and marketing in the EC. It is estimated that the final reports will be circulated to Members no later than the end of September 2006.

Background of the Dispute

In this case, three nations that produce and export genetically modified seed products (“GMOs”) – the United States (WT/DS291), Canada (WT/DS292), and Argentina (WT/DS293)(the “complaining parties”) – challenged two EC directives and an EC regulation establishing a pre-marketing approval process for GMOs in the EC. The directives, Directive 90/220/EEC and Directive 2001/18 (which repealed Directive 90/220/EEC on October 17, 2002), provided a multi-step process involving member state and community officials for approval, of GMOs before they could be imported or marketed in the EU. EC Regulation 258/97 provides approval procedures relating to “novel foods and novel food ingredients.” The Panel reviewed this process in detail in its Report at ¶¶ 7.103-7.146.

The parties did not dispute that, from October 1998 until the establishment of the Panel in August 2003, the EC did not approve any biotech product applications. The complaining parties pointed to statements by several EC officials declaring a “moratorium” on the approval of applications until the EC had updated its labeling and traceability regulations. The complaining parties alleged that this moratorium, both in general and as applied to specific product approval applications, constituted a sanitary or phytosanitary (“SPS”) measure that failed to observe the following requirements for SPS measures under the Agreement on Sanitary and Phytosanitary Measures (“SPS Agreement”):

- Article 2.2 – permitting SPS measures only based on “sufficient scientific evidence;”
- Article 2.3 – prohibiting discrimination between WTO members through SPS measures;
- Article 5.1 – requiring that SPS measures be based on risk assessments;
- Article 5.5 – prohibiting “arbitrary or unjustifiable distinctions in the levels” of SPS measures in different situations;

- Article 5.6 – requiring Members to employ the least restrictive means to achieve the desired SPS protections;
- Article 7 – requiring Members provide notification of changes in SPS measures in accordance with Annex B;
- Annex B(1) – requiring publication of SPS measures;
- Article 8 – requiring Members to observe the requirements of Annex C in the operation of control, inspection and approval procedures;
- Annex C(1)(a) – requiring that Members undertake procedures related to SPS measures “without undue delay”;
- Annex C(1)(B) – requiring that Members publish SPS procedures and communicate with applicants promptly and openly based on certain guidelines;
- Article 10.1 – requiring that Members “take account of the special needs of developing country Members” in establishment of SPS measures.

In addition to challenging the moratorium, the complaining parties also challenged the “safeguard measures” instituted by six EC member states – Austria, France, Germany, Greece, Italy, and Luxembourg. Under the safeguard measures, permitted by EC regulations, the EC member states limited the importation or marketing of certain biotech products already approved by the EC.

The Panel held that the EC did in fact institute a moratorium on deciding GMO applications from October 1998 until August 2003. The Panel found especially persuasive a June 1999 declaration of the “Group of Five countries” – Denmark, Italy, France, Greece, and Luxembourg – that stated an intent by those countries not to concede to the approval of any further GMO applications until the EC updated its regulations pertaining to labeling and traceability of GMOs. The Panel held that the Commission, while not necessarily in favor of the Group of Five countries’ declaration, did in fact fail to take steps necessary to move applications through the approval process, perhaps due to an awareness of the lack of political support for such approvals. ¶ 7.1273.

The EU Approval Procedures Fall Within the Scope of the SPS Agreement

As a preliminary matter, the Panel considered whether the EC approval procedures themselves constituted SPS measures, thus triggering the application of the SPS Agreement. That agreement, in Annex A(1), defines an SPS measure as:

Any measure applied:

- (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests, or
- (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

The EC argued its approval procedures were SPS measures only in part. For example, the EC argued that GM seeds intended to be planted in the ground were not “foods, beverages or feedstuffs” under Annex A(1)(b), and that GMOs were not “diseases” or “pests” as defined by Annex A(1). The EC also argued that one of the express purposes of Directives 90/229 and 2001/18 was

protection of “the environment,” which they argued was distinct from protection of human, animal and plant life defined by the SPS. ¶ 7.198. The Panel rejected these arguments, giving a broad reading to the definition of an SPS measure and thus a broad applicability to the scientific-justification requirements of the SPS agreement. This type of reading is unique among WTO agreements.

The General and Product-Specific Moratoria Are Not SPS Measures But Caused “Undue Delay” in Application of SPS Measures

While the Panel’s decision that the EC approval procedures are SPS measures required that the Panel analyze the complaints under the SPS Agreement, the impact of that agreement was limited. The complaining parties did not challenge the EC approval procedures themselves, but the EC moratorium on approval of applications and the Member State safeguard measures.

The Panel held that the moratoria (both general and product-specific), unlike the approval procedures themselves, were not SPS measures subject to the requirements of the SPS agreement. The Panel held that the moratorium was not a “requirement” or “procedure,” as identified by Article 5.1 and Annex A (1), because they were procedural decisions that neither approved nor rejected applications. As a result, the requirements of risk assessment and scientific basis for SPS measures did not apply to the moratorium. ¶ 7.1335.

However, the Panel held that the moratoria did constitute “procedures to check and ensure the fulfillment of sanitary or phytosanitary measures,” as identified in Annex C(1)(A), which provides that such measures must be undertaken “without undue delay.” The Panel held that neither the perceived inadequacies of the EC regulatory system on GMOs nor the evolving science and application of a precautionary approach justified the lengthy delay in approval of applications in the EC from 1998 to 2003. According to the Panel, Annex C(1)(A), together with Article 8, were intended to prevent Members from using procedural delays to avoid establishing or revising substantive SPS rules indefinitely. ¶ 7.1510. The Panel also held that a Member could take a precautionary approach in compliance with Annex C(1)(A) by adopting substantive rules that provided for provisional approvals or approvals subject to other conditions. ¶ 7.1520.

The Panel observed that not all moratoria would necessarily violate the “undue delay” standard of Annex C(1)(A). For instance, a general delay might be justifiable if new scientific evidence were brought to light that conflicted with available scientific evidence and affected the approval of all applications. ¶ 7.1525.

The Member State Safeguard Measures Are Invalid SPS Measures Not Based on Risk Assessment

The Panel held that the member state safeguard measures were SPS measures subject to the substantive requirements of the SPS Agreement. While Article 5.7 permits Members to adopt SPS measures “where relevant scientific evidence is insufficient,” the Panel held that the EC member states imposing the safeguard measures had not conducted separate risk assessments, and the risk assessments conducted by the EC did not support the imposition of SPS measures. Notably, the Panel held that the decision in the *EC – Hormones* case (WT/DS26/AB/R), which permitted the imposition of SPS measures based on divergent scientific views, applied only to cases where the divergent views were expressed within the same risk assessment. ¶ 7.3050.

Further, the Panel distinguished a statement in the *Japan – Apples* case (WT/DS245/AB/R) that SPS measures may be imposed when there is insufficient scientific evidence to perform an “adequate”

assessment of risks. The Panel instead held that a risk assessment is “adequate” if it meets the definition of a risk assessment in Annex A(4), which only requires an “evaluation” of likelihood of entry of a pest or disease and its potential adverse effects without reference to any qualitative standard determined by the Member. ¶ 7.3226.

Other Legal Issues Decided By the Panel

Multilateral Environmental Agreements Not Ratified By All Parties Need Not Be Taken Into Account By WTO Panels

The Panel also rejected an argument by the EC that it should consider rules of international environmental law established by the 1992 Convention on Biological Diversity (CBD) (ratified by the EC, Argentina and Canada, and signed by the U.S.) and the supplement 2000 Cartagena Protocol on Biosafety (Biosafety Protocol)(ratified by the EC and signed by Argentina and Canada). The Panel held that the Vienna Convention on the Law of Treaties(VCLT), which governs the force to be given to other international agreements, did indicate that international law rules should be taken into account in WTO rulings but that the rule was limited to treaties “applicable in the relations between the parties.” Because the CBD and the Biosafety Protocol did not have the force of law in all member countries to the dispute, the Panel held that it could, but was not required to, take those treaties into account. With little explanation, the Panel held it was not necessary or appropriate to rely on these treaties in the present case. ¶ 7.95.

The EC also argued that the precautionary principle should be taken into account because it was a “general principle of international law.” The Panel construed this to mean that the principle was either a rule of customary law or the general principle of law recognized by States. Noting that it was unclear whether the Members had widely accepted the precautionary principle, the Panel declined to decide whether this was a principle of international law and did not rely on it in its Report. ¶ 7.87.

Needs of Exporting Developing Nations Need Not Be Weighed More Heavily Than Environmental Priorities of Importing Developed Nations

Argentina argued that the moratoria related to Argentine product applications violated Article 10.1 relating to the consideration of developing countries in establishing SPS measures. The Panel rejected this argument, stating that nothing in Article 10.1 requires Members to weigh the export levels of developing countries more heavily than domestic concerns such as protection of its own consumers or the environment. ¶ 7.1614.

The Practical Effect of the Panel Report Is Limited

In its recommendations, the Panel did not require any action on the general moratorium since it held that the moratorium had already been lifted in 2003. The Panel recommended the product-specific moratoria be lifted, effectively recommending that the approval process be completed for any pending applications. The Panel also recommended that the member state bans be brought into conformity with WTO law, either by revoking them or by justifying them based on an SPS-compliant risk assessment.

The Report does not, however, take any position or effect any decision with respect to numerous controversial issues in the case and with respect to GMO import regulation generally. First, the Panel did not take a position on whether GMOs are safe. Second, the complaining parties did not challenge, and therefore the Panel did not decide, whether the EC pre-marketing approval measures are compliant with WTO rules. Third, the Panel did not conclude that the moratorium itself should

have been based on a scientific risk assessment. Finally, the Panel observed that Members might still block GMO imports, specifically or generally, by justifying them with adequate risk assessments, by granting time-limited or conditional approvals pending further scientific assessment, or by delaying decisions for some period in the event of new scientific evidence that conflicted with existing evidence.

The Panel decision also included several decisions favorable to the complaining parties and future GMO exporters. First, the Panel held that it was not required to (and did not) consider the international environmental norms embodied in the CBD or the Biosafety Protocol. Second, the Panel held that a Member could not unduly delay a substantive decision on pre-marketing approval applications of GMOs by means of procedural roadblocks. Third, the Panel somewhat restricted the ability of Members to impose SPS measures based on a perceived inadequacy of the scientific evidence available, thus limiting the precautionary principle to cases where the scientific evidence in a particular risk assessment is internally inconsistent or where there is insufficient evidence even to conduct a risk assessment as defined in Annex A(4).