

The “EC Biotech Products” Ruling at the WTO and the Cartagena Protocol on Biosafety

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Summary: A recent dispute panel decision at the World Trade Organization (WTO) on the European Commission’s (EC) regulation of genetically modified organisms (GMOs) raises some important questions about a United Nations treaty - the Cartagena Protocol on Biosafety. The EC defended its regulatory regime with reference to its Protocol commitments, which take a precautionary approach to regulating GMOs. The WTO panel rejected the precautionary defense of the EC, and ruled that the Cartagena Protocol is not relevant if disputants are not party to the agreement. By confining the analysis of the environmental regulation of GMOs to a jurisdictional framework, the Panel has reinforced the schism between the WTO and the United Nations system. The modes of “cooperation” of the WTO with UN agencies have arguably reduced part of their functions to be technical support agencies for the WTO’s global economic decision-making.

According to the Compliance Committee of the Cartagena Protocol on Biosafety, the Parties are having technical and financial difficulties in implementing the Protocol.¹ For example, only 44 Parties, about one third of the membership, submitted interim national reports on the status of development of risk assessment and risk management measures for regulating genetically modified organisms (GMOs), in accord with Protocol Article 15-16.² A Secretariat report noted, “Many developing countries seem to be at a stage where they have developed a draft framework for biosafety but are not yet at a stage of implementation.”³

The Parties, other governments and non-governmental observers will gather on March 13 in Curitiba, Brazil to discuss the Protocol’s implementation. Despite the need to reduce these difficulties and further negotiate the Protocol terms of implementation, Protocol participants may be distracted by the “EC Biotech

¹ “Report of the Second Meeting of the Compliance Committee under the Cartagena Protocol on Biosafety,” Convention on Biological Diversity, UNEP/CBD/BS/COP-MOP/3/2 (February 8, 2006).

² “Risk Assessment and Risk Management (Article 15-16),” Convention on Biological Diversity, UNEP/CBD/BS/COP-MOP/3/9 (January 17, 2006), paragraphs 8-9.

³ *ibid.*, paragraph 10d)

Products” interim ruling announced on February 7 by the WTO.⁴ The ruling raises the issue of the relation of the Protocol to the WTO. The European Communities’ (EC) defended its regulatory regime with reference to its Protocol commitments. This analysis attempts to summarize the ruling and what the WTO dispute settlement panel stated about the EC’s defense referring to its Biosafety Protocol commitments.

Background

The Biosafety Protocol is appended to the larger United Nations Convention on Biological Diversity (CBD). Whether fulfillment of the obligations of the CBD is compatible with the WTO agreement on intellectual property (TRIPS) has been a subject of intense debate. Bilateral investment agreements that define corporate control over access to genetic resources as intellectual property and investment have raised further impediments against achieving compatibility.⁵ A statement presented by a representative of the United Nations Environmental Program (UNEP) at the beginning of the CBD Ad Hoc Open-Ended Working Group on Access and Benefit Sharing in the use of genetic resources pointed out conflicts between CBD objectives and TRIPS.

The UNEP representative noted that, “Private monopoly can only begin where national or community sovereignty has been effectively suspended. Therefore, under the TRIPS Agreement, the very genetic resources which nations and communities are supposed to control access to will be under the control of intellectual property rights holders.”⁶ Developed countries strongly protested that there was no incompatibility between TRIPS and CBD objectives. Nevertheless, the WTO has minimized its cooperation with the CBD’s initiatives to carry out its sustainable development objectives. Although the CBD Secretariat is an accredited observer to meetings of the WTO Committee on Trade and Environment, the Secretariat’s application to be an observer to the Committees on Sanitary and Phytosanitary Measures and Technical Barriers to Trade, issues of central importance to the Protocol, remains blocked by some WTO members.⁷

The EC Biotech Products Interim Ruling: An Overview

Argentina, Canada and the United States charged the EC with violating its WTO commitments under four agreements: the Agreement on Agriculture, the General

⁴ “European Communities - Measures Affecting the Approval and Marketing of Biotech Products,” Interim Reports of the Panel, WT/DS291-293/Interim (7 February 2006), World Trade Organization at <http://www.tradeobservatory.org>

⁵ Carlos M. Correa, “Bilateral Investment Agreements: Agents of new global standards for the protection of intellectual property rights?” *GRAIN* (August 2004), 22 at <http://www.grain.org>

⁶ “Intellectual Property and Development,” South Centre and CIEL IP Quarterly Update: First Quarter 2005, 14-15 at <http://www.southcentre.org>

⁷ “Cooperation With Other Organizations, Conventions and Initiatives,” Convention on Biological Diversity, UNEP/CBD/BS/COP-MOP/3/6 (January 25, 2006), paragraph 4.

Agreement on Trade and Tariffs 1994, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade. In its conclusions, the Dispute Settlement Panel effectively dismisses (“did not need to rule”) the charges, except those brought under the SPS Agreement. Prior to official publication of the ruling, the Plaintiffs very likely will try to persuade the Panel to increase the findings of violated Agreements and Articles. All Parties will almost certainly appeal the ruling to the WTO’s Appellate Body, which is expected to issue its report in 2007.

The Panel’s conclusions (pp. 1030-1059) focus on three issues:

1. “Undue delay” in approving biotech products for commercial use (Article 8 and Annex C, paragraph 1a);
2. the requirement for a scientifically based risk assessment as the basis for a trade related SPS “measure” (regulation, law, recommendation, judicial ruling etc.) per Article 5.1 and Annex A(4); and
3. the application of provisional SPS measures when there is insufficient scientific information about a product on which to base a risk assessment (Article 5.7).

The Panel ruled that the EC violated the SPS Agreement with respect to three kinds of SPS measures: 1) an alleged general EC moratorium of approving biotech products for commercialization; 2) product specific SPS measures; and 3) EC member State safeguard measures against biotech products. The Panel found that between June 1999 and August 29, 2003 - when the Panel was established - the EC maintained an unjustified de facto moratorium on 24 of 27 biotech product approvals for which the EC’s scientific committee had given its affirmative risk assessment, but which had not moved to final approval because of a wide variety member state objections, many pertaining to environmental protection (p. 1031).

Panel findings on EC member state justifications for their safeguard measures

The Panel ruled that none of these objections exempted EC member states from the Article 5.1 requirement to justify an SPS measure, such as a product ban, with a risk assessment that would convince the EC’s scientific committee to reverse its positive risk assessment in favor of commercialization. Furthermore, the Panel determined that in no case did the member states demonstrate that “the relevant scientific evidence was insufficient to perform a risk assessment, such that the member State might have had recourse to a provisional measure under Article 5.7 of the SPS Agreement” (p. 1032).

For example, the Panel determined that the scientific information presented by Austria to an EC scientific committee to justify maintaining a biotech-product free planting zone did not meet the SPS Agreement’s definition of a risk assessment, and therefore, Austria was in violation of Article 5.1 (pp. 927-936). The Panel,

presumably with the benefit of expert opinion, makes some judgments about scientific information presented by Austria to justify its SPS measures, e.g. dismissing a study of the impact of genetically modified Bt toxins on butterflies because the butterflies were fed liquid Bt toxin, rather than evaluating “the potential for adverse effects associated with insects eating MON 810 maize plants” (para. 7.3089, p. 942). Questions from the Panel to scientific experts and the experts’ answers will form an annex that will be available on-line with the official ruling and shed more light on how the Panel used the expert opinion that it requested (p. 255).

The Panel rejects the EC precautionary principle defense

Though the plaintiffs did not file charges under Article 5.7 of the SPS Agreement, the EC tied part of the defense of its regulatory regime to its right to have recourse to Article 5.7. The EC argued, “[i]n cases where relevant scientific information is insufficient” to perform a risk assessment, the member should be able to apply a provisional measure until sufficient evidence is available to perform a “more objective risk assessment” to review the need for the provisional SPS measure. The Panel rejected the EC argument that it had the right to recourse to Article 5.7, which the EC argued was “an expression of the precautionary principle” (p. 97) whose prudent application was a sufficient defense against the plaintiffs’ charges of “undue delay” in approving biotech products for commercialization.

The Panel judged the precautionary principle to be too controversial and unsettled in international public law to serve as a basis for Panel rulings (pp. 303-307). Citing the Appellate Body report of the EC Hormones ruling as its authority, the Panel stated that “even if a Member follows a precautionary approach, its SPS measures need to be ‘based on’ (i.e. ‘sufficiently warranted’ or ‘reasonably supported’ by a risk assessment” (para. 7.3057, p. 934). The Panel disallows the risk management option of taking a precautionary approach to regulating GMOs if a risk management decision is not based on a risk assessment as defined by the SPS Agreement.

Panel: a Protocol based defense cannot be used at the WTO if disputants are not Protocol Parties

The EC maintained that protection of the environment is not covered by the Annex A definitions of the SPS Agreement. It further argued that some of the EC’s environmental regulations are based in commitments to the Protocol.⁸ Canada argued that since none of the plaintiffs were Parties to the Protocol, “the Protocol should not be taken into account in the interpretation of the obligations under the WTO Agreement” (pp. 113). The Panel agreed with this argument, noting that the Protocol became legally effective two weeks after the establishment of the Panel. The panel further noted “we do not consider that the rules of the Biosafety Protocol

⁸ “First Written Submission by the European Communities,” paragraphs 416-417 and 112 at <http://www.foceurope.org/biteback>

can be deemed to apply to the United States merely because it participates in the Protocol's Clearing House Mechanism" (for exchange of information on biotech product regulation) (paragraph 7.75, p. 302). Therefore, "the *Biosafety Protocol* is not 'applicable' in the relations with these WTO members (the plaintiffs) and all other WTO Members" and the Panel does not have to take into account obligations to the Protocol or defenses made on the basis of the Protocol (p. 302).

In effect, the Panel makes domestic measures based on the Protocol, including the Protocol's Articles on risk assessment and risk management, indefensible if they are challenged by a non-Party or free rider to the Protocol under the definition of risk assessment in the WTO SPS Agreement. Not becoming a Party to the Protocol, while intervening to prevent its implementation, as the United States, Canada and Argentina do through their participation in the so-called Miami Group at the Protocol negotiations,⁹ is apparently a bullet proof litigation strategy against any attempt by WTO Members who are also Protocol Parties to defend their environmental regulation of GMOs with reference to fulfilling their Protocol commitments.

Non-membership in the Protocol also allows non-Parties to avoid having to inform Protocol Parties of the lamentable state of environmental regulation of GMOs, as is underscored in a recent U.S. Department of Agriculture inspector's general report.¹⁰ A NGO amicus brief sought to bring the impoverished scientific basis of GMO approvals to the attention of the Panel,¹¹ but the Panel chose not to take amicus briefs into account (p. 250). By disregarding evidence of the weak regulation of GMOs, the Panel's jurisdictional based ruling on the Protocol defense of environmental regulation of GMOs would annul any benefits of Protocol implementation in the event that Protocol consistent modes of compliance conflict with WTO Agreements, particularly the SPS Agreement.

Conclusion

The Panel cannot be accused of not having taken its duties seriously, but it can be faulted for a lack of legal imagination. Although the EC evoked the Protocol in the defense of its environmental protection regulations, the Panel did not need to confine its ruling to jurisdictional issues. Instead, it could have declined to rule given the lack of consensus about risk assessment and risk management options in

⁹ e.g. Lim Li Lin and Lim Li Ching, "No Agreement at Biosafety Protocol experts' meeting," Third World Network Biosafety Information Service, March 18, 2005 at <http://biosafety-info.net>

¹⁰ "Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits," Office of Inspector General, Southwest Region, Audit 50601-8-Te (December 2005) at http://biosafety-info.net/file_dir/144379085943d064abd6d99.pdf

¹¹ "European Communities -- Measures Affecting the Approval and Marketing of Biotech Product: Amicus Curiae Brief," Center for International Environmental Law et al. at http://www.ciel.org/Publications/ECBiotech_AmicusBrief_2June04.pdf

multilateral agreements. Hopefully, the Appellate Body will find that the Panel had no need to rule as it did on the Protocol-based EC defense.

By confining the analysis of the environmental regulation of GMOs to a jurisdictional framework, the Panel has reinforced the schism between the WTO and the United Nations system. This profound breach in the multilateral system was created with the founding of the WTO in 1995 as a *sui generis* institution disjunct from the United Nations and with no obligations to its Conventions, agreements or agencies. Disjoining the WTO from the UN System allows the WTO to avoid the requirement of Article 103 of the UN Charter, which obliges UN Members to heed the Charter in the event of a conflict between it and another international agreement.¹² The modes of “cooperation” of the WTO with UN agencies have arguably reduced part of their functions to be technical support agencies for the WTO’s global economic decision-making.¹³ Efforts to overcome this breach are nascent and partially based on a hierarchy of values that underlie multilateral institutional relations.¹⁴

¹² Kristin Dawkins, “The hierarchy of international law: a hierarchy of values?” Institute for Agriculture and Trade Policy (March 30, 2005) at <http://www.tradeobservatory.org/library.cfm?RefID=70110>

¹³ Peter Sutherland et al., “The Future of the WTO: Addressing institutional challenges in the new millenium,” World Trade Organization (2004), 35, and *What U.N. For the 21st Century? A New North-South Divide*, (Geneva: South Centre, 2005).

¹⁴ Dawkins, “The hierarchy of international law: a hierarchy of values?”