U.S. vs. EC Biotech Products Case

WTO Dispute Backgrounder

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Introduction

By the end of October 2005, the World Trade Organization dispute panel hearing the "European Communities Measure Affecting the Approval and Marketing of Biotech Products" (EC Biotech Products) case is scheduled to issue its ruling, first to the parties to the dispute, followed by publication of the ruling about a month later. The date of the ruling's issue has been postponed twice due to "several import new is-sues raised by the parties" and by "a vast amount of material" that requires review as a result of consultation with experts.1 An interim ruling could come out as early as September with a final ruling handed down in October.2 The panel and ruling combine the cases of the United States (DS 291/17), Canada (DS 292/17) and Argentina (DS 293/17) against the European Communities. This short analysis reviews the main issues drawn from available U.S. and EC submissions plus related documents.

Overview: Four central questions in the case

1. Will the EC and other WTO members be able to develop and maintain a regulatory system for GMOs that allows for the use of precautionary measures (see "The precautionary principle," below) to protect consumer, animal and/or plant health when there is insufficient scientific evidence to assess the risks of a biotech product presented to governments for commercialization approval?

2. Will the panel agree with the EC that some of its regulatory objectives for GMOs fall outside of the competence of WTO agreements and are covered by other international agreements (e.g. the objective to preserve biodiversity against plant species invasion by GM varieties)?

3. How will the panel document its use of expert opinion in determining the factual matters that pertain to the main legal issues of the dispute?

4. How will the panel use previous WTO dispute panel and appellate body rulings on "scientific uncertainty" to justify its ruling?

The precautionary principle

Since the EC has taken a number of steps to revise its regulatory system to commercialize GMOs, the U.S. objectives in bringing the dispute are not entirely clear. One underlying objective is to get a dispute panel and/or appellate body ruling that there is no basis in the WTO agreements to support EC's argument "that states have the right to adopt a precautionary approach when dealing with GMOs."12 In support of this argument, the EC cites articles 10(6) and 11(8) of the Cartagena Protocol on Biosafety, an international public law agreement to which none of the plaintiffs are parties.

The "precautionary approach" derives from German air pollution legislation in 1968 as a result of suggestive but not conclusive evidence that industrial air pollution was damaging the environment. In addition to justifying the government's authority to take preventative action against environmental damage, the legislation required that the regulatory actions be "proportional" to the potential for harm and that there be an assessment of the costs and benefits of action and inaction.13 Subsequent formulations of the precautionary principle, including those applied to the risk analysis of GMOs, have specified the relation between scientific evidence and a typology of scientific uncertainty, and the need to shift the burden of proof to the technology developer to demonstrate the safety of a new technology ("harmful until proven safe").14

An EC Communication describes precaution as a risk management tool which is part of a risk analysis framework rather than the overall guide to its (i.e., the framework's) implementation. According to this argument, precautionary action should only be taken after experts prepare an "objective" quantitative risk assessment. Precaution is seen as a temporary measure pending further risk assessment."15 The commission's interpretation of the precautionary principle is clearly an attempt to make its application conform with the provisions of the SPS agreement. A great deal of the commission's work has been to analyze the application of precautionary approaches to government regulation over a wide range of products and over a time frame much longer than the decade since the commercialization of the first GM crops.16

U.S. corporations have taken a strong stand against a precautionary approach to the regulation of new goods and services.17 Additionally, the current head of the U.S. Office of Information and Regulatory Affairs in the president's Office of Management Budget has sought to pervert the precautionary principle by assuming that new products are safe until proven otherwise and putting a prohibitive cost-benefit analysis against most regulation. Given the antipathy of the White House and major U.S. corporations to the precautionary approach, most regulatory applications of precautionary approaches have occurred at the sub-federal level.

17. E.g. Lawrence Kogan, "EU Regulation, Standardization and the Precautionary Principle: The Art of Crafting a Three-Dimensional Trade Strategy That Ignores Sound Science," THE NATIONAL FOREIGN TRADE COUNCIL INC. (August 2003).