



CRS Report for Congress

Agricultural Biotechnology: The U.S.-EU Dispute

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Summary

In May 2003, the United States, Canada, and Argentina initiated a dispute with the European Union concerning the EU's *de facto* moratorium on biotechnology product approvals, in place since 1998. Although the EU effectively lifted the moratorium in May 2004 by approving a genetically engineered (GE) corn variety, the three complainants pursued the case, in part because a number of EU member states continue to block already approved biotech products. The moratorium reportedly costs U.S. corn growers some \$300 million in exports to the EU annually. U.S. officials also contend that the EU moratorium threatens U.S. agricultural exports to other parts of the world where the EU approach to regulating agricultural biotechnology is taking hold. On November 21, 2006, the WTO's Dispute Settlement Body (DSB) adopted the dispute panel's report, which ruled that a moratorium had existed, that bans on EU-approved GE crops in six EU member countries violated WTO rules, and that the EU failed to ensure that its approval procedures were conducted without "undue delay." The EU has announced it will not appeal the ruling and has asked for a reasonable period of time in which to implement the ruling. This report will be updated.

The Dispute Panel's Ruling

The dispute panel found that the EU had maintained a moratorium on approvals of genetically engineered crops between June 1999 and the beginning of panel deliberations in August 2003. The EU had claimed that there were no measures imposing a moratorium. The panel agreed with the United States and the co-complainants that marketing or import prohibitions on GE products in six EU countries (Austria, France, Germany, Greece, Italy, and Luxembourg) violated the WTO's Agreement on Sanitary and Phytosanitary (SPS) Measures, which requires such measures to be based on science and risk assessment. The panel upheld the complainants' charge that the EU also violated the SPS agreement by not ensuring that approvals for 24 of 27 genetically modified (GM) products in the approval pipeline were carried out without "undue delay."

The dispute panel's ruling dismissed several other U.S. and co-complainant claims, including claims that EU approval procedures were not based on appropriate risk

assessment; that the EU unfairly applied different risk assessment standards for GE processing agents; and that the EU had unjustifiably discriminated between WTO members. The panel made no recommendations as to how the EU should bring its practices in line with WTO rules, nor did the ruling require the EU to change its regulatory framework for approving GE products. The panel did not address such sensitive issues as whether GE products are safe or whether an EU moratorium on GE approvals continued to exist.

The EU announced on December 19, 2006, that it will not appeal the panel's ruling in the case. However, it has asked for a reasonable period of time (ordinarily not longer than 15 months in WTO practice) in which to implement the decision. Time may be required to reach an internal political agreement among EU member countries to lift the prohibitions on already approved GE products. Time may also be required if the Commission of the EU resorts to court challenges to require member countries to lift the prohibitions on GE products.¹

Background

In May 2003, the United States, Canada, and Argentina requested consultations, the first step in WTO dispute settlement, with the EU concerning the latter's *de facto* moratorium (since 1998) on approving new GE products. U.S. agricultural interests contended that these policies not only blocked their exports to the EU, but also fueled unwarranted concerns about the safety of agricultural biotechnology throughout the world. Although the EU recommenced approvals in May 2004 with the approval of a GE corn variety for human consumption, a number of EU member states continue to block dissemination of approved biotech varieties. The EU restarted its approval process following implementation of new labeling and traceability rules for GE crops and foods.²

In August 2004, the WTO announced that it would establish a panel of expert scientists from the Codex Alimentarius Commission³ to advise on scientific issues raised by the dispute, as requested by the EU, delaying its decision from September 2004 to March 2005. The United States opposed involvement of Codex because, it maintained, the safety of GE products was not at issue.

The United States accounted for 54% of the 252 million acres (102 million hectares) planted globally with GE crops in 2006.⁴ In 2005, 85% of all U.S. soybean, 76% of U.S.

¹ See "EU Council Rejects Proposals to Lift Bans on GMO Products" in *Inside U.S. Trade*, December 22, 2006, at [http://www.insidetrade.com/secure/dsply_nl_txt.asp?f=wto2002.ask&dh=70507021&q=gmo].

² The EU's labeling and traceability regulation is at [http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf].

³ The Codex Alimentarius Commission, often referred to simply as Codex, drafts nonbinding standards for food additives, veterinary drugs, pesticide residues, and other substances that affect consumer food safety. Codex, which is explicitly cited in the WTO Agreement on Sanitary and Phytosanitary Measures, can play an important advisory role when issues of food health and safety arise in WTO dispute settlement.

⁴ Data are from ISAAA Brief 35-2006, *Global Status of Commercialized Biotech/GM Crops*: (continued...)

cotton, and 45% of U.S. corn acres were planted with GE varieties, designed mainly to control pests (weeds and insects).⁵ They do not segregate them from non-GE varieties, because the U.S. regulatory system recognizes them (once approved for commercialization) as substantially equivalent to non-GE varieties. Gaining market acceptance of GE crops within the United States has been easier than overseas, however, where, in markets like the EU, consumers and their governments have been more wary of biotechnology.

With minor exceptions, the EU and its member states approved no GE products between 1998 and 2004. As of January 2004, 22 GE products or crops were awaiting approval. A bloc of EU states had effectively halted the release of any new GE crops into the environment, saying that they would not implement the EU-wide legislation for approvals until new, stricter regulations for labeling and tracing GE-containing products (discussed below) took effect.⁶

In the three years before the *de facto* ban, U.S. corn exports to the EU averaged about \$300 million annually, according to USDA data (Spain and Portugal were the largest EU importers). During the ban, they declined to less than one-tenth of that value annually — the result, according to analysts, of the EU’s moratorium on the approval of new corn varieties already approved in the United States. Although one variety of biotech corn was approved by the EU prior to the moratorium, the United States grew other varieties. Thus, U.S. export of any corn to the EU was impractical because of the difficulty of segregating approved from unapproved varieties.

The WTO Case

The United States and co-complainants argued that the EU moratorium violated the WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures. The SPS agreement permits countries to regulate crops and food products to protect health and the environment, but their rules must be scientifically justified, and approval procedures must occur without undue delay. U.S. interests contend that there is no scientific evidence that GE food and feed crops are substantially different from, or any less safe than, conventional varieties, a conclusion they say even European scientific authorities have reached. The United States contends that EU biotechnology measures also are inconsistent with provisions of other WTO agreements, namely the Technical Barriers to Trade Agreement (TBT), the General Agreement on Tariffs and Trade (GATT), and the Agreement on Agriculture.

The United States maintained that the EU moratorium not only affected U.S. exports to the EU, but also caused other countries — particularly in the developing world — to shun biotechnology, which the U.S. asserts holds great promise for vastly improving

⁴ (...continued)
2005, at [<http://www.isaaa.org>].

⁵ USDA, Economic Research Service website, *Adoption of Genetically Engineered Crops in the U.S.*, at [<http://www.ers.usda.gov/data/BiotechCrops/>].

⁶ Before the moratorium, the EU had approved the commercial release of 18 genetically modified organisms (GMOs), including “Roundup-Ready” soybeans.

agricultural productivity and feeding growing populations. U.S. officials point to conditions placed on deliveries of U.S. food aid that contained GE corn by six famine-affected countries in sub-Saharan Africa because of unspecified environmental and food safety concerns.

EU officials counter that their cautious approach to regulating biotechnology is necessary to cultivate trust among European consumers. At the same time, they also assert that they have shown good faith in moving quickly to restart the approval process. In May 2004, the EU effectively ended the moratorium by approving a GE corn variety (Syngenta Bt-11) for human consumption. Since then, the EU has approved GE corn varieties (Monsanto's NK603) for both human and animal consumption, Pioneer's 1570 corn for feed use, and 17 strains of GE corn seed (all derived from the MON 810 strain approved in 1998) for commercial use.

Differing Regulatory Approaches

The United States has embraced the concept of substantial equivalence with regard to GE products: if a GE product is substantially the same as its conventional counterpart, it should be regulated no differently than the conventional product. The EU, on the other hand, takes a "precautionary approach," which means that if scientific evidence is insufficient or inconclusive regarding a practice's or product's potential dangers to human or environmental health, it should be more vigorously regulated or even prohibited if there are reasonable grounds for concern, thus providing a safeguard against future unforeseen problems. Under this approach, the products of biotechnology are deemed to be inherently different from their conventional counterparts and to require a separate regulatory regime.

United States. The basic federal guidance for regulating biotechnology products is the **Coordinated Framework for Regulation of Biotechnology** (51 *Fed. Reg.* 23302). One of its key principles is that GE products should be regulated according to their characteristics and unique features — not according to their method of production. Once approved, food products do not have to be labeled as to whether or not they contain any genetically modified organisms, except to the extent that a GE food is substantially different (e.g., contains an allergen or has a changed nutritional content). Because they are deemed substantially equivalent, GE products are regulated under existing federal statutory authorities.⁷

European Union. The EU has established separate structures specifically for approving GE products and for labeling products derived from them. Currently, the key measure is Council Directive 2001/18 (as amended in July 2003),⁸ which spells out steps for assessing human health and environmental risks before any GE product can be released into the environment or marketed. Prior to the 2003 amendments, the competent authority in the EU member state where the product was to be released was responsible for assessing its safety and, if approved, notifying other member states, opening the way for marketing throughout the EU (with EU-level intervention if one member state

⁷ See [<http://heinonline.org/HOL/Page?handle=hein.fedreg/051123&id=96&collection=fedreg>].

⁸ [http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf].

disagreed with another's decision). The amended directive provides for a "one-door-one-key" approach, whereby the European Food Safety Authority (EFSA) conducts all scientific risk assessments and communicates risks to the public. Then, the EU Council of Ministers decides whether or not to approve a GE product for the EU market. EU regulations empower the European Commission to approve applications by default if the Council of Ministers fails to act on them within three months.

Labeling and Traceability

The WTO case does not involve new, stricter EU labeling and traceability regulations, which, U.S. agricultural interests argue, continued to discriminate against U.S. exports even after the GE product approval moratorium was lifted. The labeling and traceability regulations, adopted in July 2003, require that most foods, ingredients, and (for the first time) animal feeds from GE products be labeled, even if they no longer contain detectable traces. The regulations (1830/2003 on the Traceability and Labeling of GMOs and 1829/2003 on Genetically Modified (GM) Food and Feed) were implemented in April 2004.

Under the regulations, a tolerance level for non-GE foods, feeds, and processed products of 0.9% is set for allowable "adventitious presence" (AP) — that is, unintended, low-level presence — of an EU-approved GE substance. All products with more than 0.9% must be labeled as containing GE products. Products like meat, milk, and eggs from animals fed or treated with GE materials will not have to be labeled, however. Traceability provisions now require all firms that produce, store, move, or process GE products to track and keep records on them from farm to consumer. Compliance with the EU labeling rule requires segregation of GE crops and foods derived from them from the time they are planted all the way through the processing and marketing chain. This entails prevention of pollen drift from GE to non-GE fields; and difficult and costly handling procedures such as using separate equipment, storage, and shipping containers, or at least painstakingly cleaning them. U.S. interests argue that food companies forced to label accurately all GE products face huge risks and liabilities. All of these problems discriminate against U.S. shipments — even though they are as safe as "conventional" shipments, they contend. In practice, many U.S. manufacturers have opted not to market GE products in the EU, in part due to the EU's stricter GE regulations.⁹

Differing Public Attitudes?

Differing U.S. and EU perspectives may reflect the fact that U.S. consumers apparently have been not only less fearful of GE foods than their European counterparts, but also more confident in their food safety regulators. According to USDA's Economic Research Service (ERS), surveys of consumer attitudes toward GE products, conducted both here and overseas, have yielded mixed results. Still, "U.S. consumers have voiced little objection to genetically modified foods, while EU consumers have been vocal in their disapproval," ERS observed.¹⁰

⁹ Personal communication with Economic Research Service, January 21, 2005.

¹⁰ Details on these surveys can be found at ERS, *Economic Issues in Agricultural Biotechnology* (continued...)

Europeans may be much more wary of changes in how their food is produced due to a series of recent food safety crises. During the 1990s, bovine spongiform encephalopathy (BSE, or “mad cow disease”) emerged in the United Kingdom and spread to other parts of Europe. U.K. food safety authorities first insisted that the disease could not be transmitted to humans eating meat from BSE-infected animals. By 1996 scientific evidence indicated there was a link between some cases of a similar human disease and consumption of BSE-contaminated beef. In 1999, high levels of dioxin were found in meat products and eggs originating in Belgium. Also, foot-and-mouth disease (FMD) outbreaks in Europe added to consumer concerns and to their “waning faith in regulatory agencies,” according to the Pew Charitable Trust’s Initiative on Food and Biotechnology. Pew is careful to point out that these crises have not been caused by GE food, but that GE food has been caught up in the general suspicion about food safety. Environmental groups in the EU, such as Greenpeace or Friends of the Earth, also have raised concerns about environmental impacts.

Congressional Interest

Members of Congress representing agricultural interests had urged the United States to challenge the EU moratorium in the WTO, in the belief that U.S. producers have been adversely impacted there, and will face further barriers if more countries take the EU approach to regulating the products of biotechnology. At the same time, many lawmakers are well aware of the risks involved in escalating U.S.-EU trade tensions to new heights.

The House Agriculture Committee held hearings on March 26 and on June 17, 2003, on the EU moratorium and related biotechnology issues. The Senate on May 23, 2003, passed S.Res. 154 supporting the U.S. action against the EU; a similar House measure (H.Res. 252) was passed on June 10, 2003. Also, the conference report accompanying the Consolidated Appropriations Act for FY2005 (H.Rept. 108-792; H.R. 4818) provided \$3.3 million to USDA for “cross-cutting trade negotiations and biotechnology resources.” The conference report accompanying FY2006 agriculture appropriations (H.Rept. 109-255, P.L. 109-97) continues funding to USDA for biotechnology research. S. 600 (109th Congress), the Foreign Affairs Reauthorization Act for FY2006 and FY2007, provided for grants to the State Department to help ensure that foreign governments’ views of biotechnology reflect scientific findings about such technology (S.Rept. 109-35). Conversely, legislation (H.R. 5266, H.R. 5267, H.R. 5270, and H.R. 5271) was also introduced in the 109th Congress that would have subjected GE products to greater regulation.

¹⁰ (...continued)

(Information Bulletin No. 762), February 2001, pp. 28-30. In December 2006, the Pew Initiative on Food and Biotechnology released a new survey of U.S. attitudes on GM foods which, Pew said, determined that Americans’ knowledge of them remains low, that their opposition to such foods has softened somewhat since 2001 (from 58% to 48%), and support remains stable at 27%.. Survey results can be found at [<http://pewagbiotech.org/research/2006update/2.php>].