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Agricultural Biotechnology: The U.S.-EU Dispute

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Abstract. 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 (MON810), the three complainants pursued the case, in part because a number of EU member states continue to block already approved biotech products. Industry estimates are that the moratorium 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. The United States and EU agreed on November 21, 2007 (subsequently extended to January 11, 2008), as a deadline for EU implementation of the panel report. On January 11, the U.S. Trade Representative announced that, while it was reserving its rights to retaliate, it would hold off seeking a compliance ruling while the United States sought to normalize trade in biotechnology products with the EU. In a related development, France, citing environmental concerns, announced a ban on cultivation of MON810. The EU Commission would act within 60 days to either uphold or revoke the French ban.



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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 (MON810), the three complainants pursued the case, in part because a number of EU member states continue to block already approved biotech products. Industry estimates are that the moratorium 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. The United States and EU agreed on November 21, 2007 (subsequently extended to January 11, 2008), as a deadline for EU implementation of the panel report. On January 11, the U.S. Trade Representative announced that, while it was reserving its rights to retaliate, it would hold off seeking a compliance ruling while the United States sought to normalize trade in biotechnology products with the EU. In a related development, France, citing environmental concerns, announced a ban on cultivation of MON810. The EU Commission would act within 60 days to either uphold or revoke the French ban.

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 EU announced on December 19, 2006, that it would not appeal the panel's ruling in the case. The United States and EU agreed that a reasonable period of time would be until November 21, 2007, a deadline subsequently extended by mutual agreement until January 11, 2008. Time would likely be required to reach intra-EU agreement to lift the prohibitions on already approved GE products or to launch court challenges to require member countries to lift their 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 adoption of new labeling and traceability rules for GE crops and foods in 2003.²

The United States accounted for 54% of the 252 million acres (102 million hectares) planted globally with GE crops in 2006.³ In 2005, 85% of all U.S. soybean, 76% of U.S. cotton, and 45% of U.S. corn acres were planted with GE varieties, designed mainly to control pests (weeds and insects).⁴ GE production is not segregated from production from traditional varieties because the U.S. regulatory system recognizes GE crops (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,

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 Data are from ISAAA Brief 35-2006, *Global Status of Commercialized Biotech/GM Crops: 2005*, at [<http://www.isaaa.org>].

⁴ USDA, Economic Research Service website, *Adoption of Genetically Engineered Crops in the U.S.*, at [<http://www.ers.usda.gov/data/BiotechCrops/>].

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.⁵

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.

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.

⁵ Before the moratorium, the EU had approved the commercial release of 18 genetically modified organisms (GMOs), including MON810 and “Roundup-Ready” soybeans.

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.⁶

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),⁷ 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 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

⁶ See [<http://heinonline.org/HOL/Page?handle=hein.fedreg/051123&id=96&collection=fedreg>].

⁷ [http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf].

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.⁸

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.⁹

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.

⁸ Personal communication with Economic Research Service, January 21, 2005.

⁹ Details on these surveys can be found at ERS, *Economic Issues in Agricultural Biotechnology* (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>].

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 and Friends of the Earth, also have raised concerns about environmental impacts.

Recently, concerns have been voiced by European grain and feedstuffs traders and compound feed manufacturers about EU regulations and attitudes about GE corn and soybeans.¹⁰ They point to short supplies and high prices for feedstuffs and call for changes in the EU regulations that impose strict limits on adventitious presence and that have helped create a shortage of feed supplies in the EU. COCERAL, the association of EU feedstuffs traders, has pointed out that neither Argentina nor Brazil, who along with the United States supply the bulk of annual EU feed supplies, could guarantee that its corn and soybean shipments contain only EU-approved GMOs.

Congressional Interest

In the 110th Congress, Members representing agricultural interests have urged the United States to take an aggressive stance with respect to EU biotechnology regulations. Senator Grassley, the Ranking Member of the Senate Finance Committee, has expressed hope that the EU would soon come into compliance with the WTO ruling in the biotechnology case. He noted that, although he would have preferred the U.S. Trade Representative to take a harder line in the case, he recognized that a “hard approach” of seeking retaliation might not be successful.¹¹ At the same time, many lawmakers are well aware of the risks involved in escalating U.S.-EU trade tensions to new heights.

Pending House and Senate versions of a new farm bill (H.R. 2419) to replace the expiring 2002 farm statute contain provisions relating to agricultural biotechnology. The House bill authorizes the appropriation of funds for U.S. representation in the Codex Alimentarius Commission and other international standard-setting entities. Codex, of which the United States is a member, and whose role is to formulate and recommend (non-binding) food safety standards to its member countries, is in the process of developing guidelines for handling trace amounts of non-approved GE products that have been approved in other countries. Both the House and Senate farm bills also reauthorize a program of competitive grants to develop agricultural biotechnology for developing countries. The Senate version of the farm bill reauthorizes a biotechnology and trade program that targets nontariff barriers to U.S. exports of U.S. agricultural commodities produced through biotechnology.

¹⁰ “GMO zero tolerance devastating for EU feed industry,” from *AgBioWorld*, July 19, 2007, viewed at [http://www.agbioworld.org/newsletter_wm/index.php?caseid=archive&newsid=2747].

¹¹ “U.S. To Hold Off on GMO Retaliation Against EU, France Bans GMO Corn, *Inside U.S. Trade*, January 18, 2008, viewed at [http://www.insidetrade.com/secure/dsply_nl_txt.asp?f=wto2002.ask&dh=107026683&q=].