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Agricultural Biotechnology: The U.S.-EU Dispute

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Summary

In May 2003, the United States, Canada, and Argentina initiated a formal challenge before the World Trade Organization (WTO) of the European Union's (EU's) de facto moratorium on approving new agricultural biotechnology products, in place since 1998. Although the EU effectively lifted the moratorium in May 2004 by approving a genetically engineered (GE) corn variety, the three countries are pursuing the case, in part because a number of EU member states continue to block approved biotech products. Because of delays, the WTO is expected to decide the case by December 2005. The moratorium reportedly cost U.S. corn growers some \$300 million in exports to the EU annually. U.S. growers plant GE varieties mainly for weed and pest control. 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. The EU moratorium, U.S. officials contend, threatened other agricultural exports not only to the EU, but also to other parts of the world where the EU approach to regulating agricultural biotechnology is taking hold. The EU approach presumes that the products of biotechnology are inherently different than their conventional counterparts and should be more closely regulated. This report will be updated.

Issue

In May 2003, the United States, Canada, and Argentina announced their intent to challenge in the World Trade Organization (WTO) the European Union's (EU's) de facto moratorium (since 1998) on approving new agricultural biotechnology products.¹ U.S. agricultural interests contend that these policies not only blocked their exports to the EU, their fourth-largest foreign market, but also fueled unwarranted concerns about the safety

¹ Background on the dispute is in USTR, *2005 National Trade Estimates Report*, [http://www.ustr.gov/assets/Document_Library/Reports_Publications/2005/2005_NTE_Report/asset_upload_file446_7468.pdf]; and in *Dispute DS291: European Union — Measures Affecting the Approval and Marketing of Biotech Products*, at [http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm].

of agricultural biotechnology throughout the world. EU officials say they moved as quickly as possible to reinstate biotechnology approvals while trying to reassure their consumers regarding safety issues. The EU effectively ended its moratorium with its May 2004 approval of a GE corn variety for human consumption. However, a number of EU member states continue to block dissemination of approved biotech varieties. The EU has also implemented new labeling and tracing rules for genetically engineered (GE) crops and foods.²

The U.S., Canada, and Argentina are pursuing the case, with U.S. agricultural interests contending that despite the recent approvals the EU process is unpredictable and not transparent.³ In August 2004, the WTO announced that it would establish a panel of expert scientists from the Codex Alimentarius Commission⁴ 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. Most recently, the panel chairman announced that, because of voluminous submissions by the parties, the panel would delay issuing its judgment until December 2005, some 28 months after the decision to establish a panel. Ordinarily, WTO dispute settlement takes about 18 months.

Background

The United States accounted for 59% of the 200 million acres planted globally to GE crops in 2004, according to the International Service for the Acquisition of Agri-biotech Applications (ISAAA), a group supportive of the technology.⁵ In 2004, 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).⁶ 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 agricultural biotechnology products between 1998 and 2004. As of January 2004, 22 GE products or crops were awaiting approval. A block of EU states had effectively halted the release of any new GE crops into the environment, saying that they would not implement the EU-

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 Food Chemical News, August 2, 2004.

⁴ 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.

⁵ See *ISAAA Briefs 32-2004: Preview: Global Status of Commercialized Biotech/GM Crops: 2004*, [[http://www.isaaa.org/kc/CBTNews/press_release/briefs32/ESummary/Executive%20Summary%20\(English\).pdf](http://www.isaaa.org/kc/CBTNews/press_release/briefs32/ESummary/Executive%20Summary%20(English).pdf)]

⁶ USDA, Economic Research Service website, *Adoption of Genetically Engineered Crops in the U.S.*, at [<http://www.ers.usda.gov/data/BiotechCrops/>].

wide legislation for approvals until new, stricter regulations for labeling and tracing GE-containing products (discussed below) took effect.⁷

In the three years before the de facto ban, U.S. corn exports to the EU averaged about \$300 million annually (Spain and Portugal were the largest EU importers), according to USDA data. 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 EU-approved from EU-unapproved varieties.

The WTO Case

The United States and its co-complainants argue 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 GM-derived 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 has argued that the moratorium has 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 agricultural productivity and feeding growing populations. U.S. officials cite the 2003 famine in six sub-Saharan countries. A number of these countries imposed conditions on the use of GE corn in U.S. food aid, and Zambia refused all GE shipments 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. On July 15, 2003, the EU announced that it was taking 11 of its 15 member states to the European Court of Justice for failing to implement the GM approval legislation. 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.

⁷ Before the moratorium, the EU had approved the commercial release of 18 genetically modified organisms (GMOs), including “Roundup-Ready” soybeans.

Differing Regulatory Approaches

The United States has embraced the concept of substantial equivalence with regard to a GE food or agricultural product. That is, as long as such a product is substantially the same as its conventional counterpart, it should be regulated no differently (except for products marketed as “organic,” where genetic engineering is prohibited). 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 than their conventional counterparts.

United States. The basic federal guidance for regulating biotechnology products is the **Coordinated Framework for Regulation of Biotechnology** (51 *Fed. Reg.* 23302), published in 1986 by the White House Office of Science and Technology Policy. One of its key principles is that genetically engineered products should continue to 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 (GMOs), except to the extent that a GE food is substantially different (e.g., contains an allergen or has a changed nutritional content). Based on substantial equivalence of GM products, the framework regulates new biotechnology products under existing federal statutory authorities.⁸

European Union. The EU has established separate structures specifically for approving biotechnology crops and also for labeling products derived from them. Currently, the key measure is Council Directive 2001/18 (as amended in July 2003),⁹ which spells out steps for assessing human health and environmental risks before any GMO or GMO-containing 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 conducts all scientific risk assessments and communicates risks to the public. Then, the EU Council of Ministers decides whether or not to approve a GM product for the EU market. EU regulations empower the Commission to approve applications by default if the Council of Ministers fails to act on them within three months.

⁸ Jurisdiction over GE products is shared by USDA’s Animal and Plant Health Inspection Service, the Food and Drug Administration, and the Environmental Protection Agency. See CRS Report RL30198, *Food Biotechnology in the United States: Science, Regulation, and Issues*.

⁹ [http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf]

Labeling and Traceability

The WTO case does not involve new, stricter EU labeling and traceability regulations, which, U.S. agricultural interests argue, have continued to discriminate against U.S. exports even after the GMO approval moratorium was lifted. The labeling and traceability regulation, adopted in July 2003, requires that most foods, ingredients, and (for the first time) animal feeds from GMOs 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-GMO 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 GM. Products like meat, milk, and eggs from animals fed or treated with GM materials will not have to be labeled, however. Traceability provisions now require all firms that produce, store, move, or process GM 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.¹⁰

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 GMOs, 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.¹¹

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

¹⁰ Personal communication with Economic Research Service, January 21, 2005.

¹¹ Details on these surveys can be found at ERS, *Economic Issues in Agricultural Biotechnology* (Information Bulletin No. 762), February 2001, pp. 28-30. In November 2004, Pew 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. GM foods. Survey results can be found at [<http://pewagbiotech.org/research/2004update/>].

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,” Pew concluded. “Although these crises have not been caused by GE food, GE food has been caught up in the general suspicion about food safety.” Vocal environmental groups in the EU also have raised concerns about environmental impacts.

Outlook

It is unclear how a WTO dispute panel might rule on the U.S.-EU case. If the U.S. case succeeds, it would validate the basic principles of the SPS agreement and could discourage other countries from emulating the EU regulations. The United States has pointed out that even many EU farmers would like to be planting and selling GE crops. However, U.S. success might open EU markets to few if any significant GE imports (at least partly because of the labeling and traceability regulation). The United States might simply have to settle for some form of alternate compensation. Within the EU, some member states have taken unilateral actions to block or slow adoption of GE crops and foods even while other members push for their acceptance. Some analysts have suggested that a U.S. win also could create a backlash among the European public and governments who view the United States as forcing biotechnology on unwilling consumers.

For several years, Members of Congress representing agricultural interests had urged the United States to challenge the EU ban formally, 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. All are expected to monitor developments closely.

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, by unanimous consent, a resolution (S.Res. 154) supporting the U.S. action against the EU; a similar House measure (H.Res. 252) was passed on June 10, 2003, by a suspension vote, 339-80. Also, the conference report to accompany the Consolidated Appropriations Act for FY2005 (H.Rept. 108-792; H.R. 4818) notes that \$3.3 million is provided to USDA for “cross-cutting trade negotiations and biotechnology resources.” The Conference Report to accompany FY2006 agriculture appropriations (H.Rept. 109-255, P.L. 109-97) continues funding to the U.S. Department of Agriculture for “cross-cutting trade negotiations and biotechnology research.” S. 600, the Foreign Affairs Authorization Act, Fiscal Years 2006 and 2007, provides 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).