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Agricultural Biotechnology: The U.S.-EU Dispute

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Summary

The United States, Canada, and Argentina in May 2003 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 effect since 1998. The moratorium reportedly has cost U.S. corn growers some $300 million in exports to the EU annually. U.S. growers plant genetically engineered (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, has 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 deemed to be inherently different than their conventional counterparts and should be more closely regulated. This report will be updated if events warrant.

Issue[1]

On May 13, 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. U.S. agricultural interests contend that these policies not only have blocked their exports to the EU, their fourth-largest foreign market, but also have fueled unwarranted concerns about the safety of agricultural biotechnology throughout the world. EU officials say they have been moving as quickly as possible to reinstate biotechnology approvals while trying to reassure their consumers regarding safety issues. For example, they are implementing new labeling and tracing rules for genetically engineered (GE) crops and foods. The

[1] Sources include USTR, *2003 National Trade Estimates Report on Foreign Trade Barriers;* Pew Initiative on Food and Biotechnology, *U.S. vs. EU: An Examination of the Trade Issues Surrounding Genetically Modified Food*, updated August 2003; *Biotechnology Regulations and the WTO*, International Agricultural Trade Research Consortium, Working Paper #02-2, 1/02; and various EU documents.

WTO case is one of several high-profile trade disputes between the United States and the EU, which share two-way agricultural trade valued at approximately $15 billion annually.

Background

The United States accounted for 63% of the 167 million acres planted to GE crops in 2003, according to the International Service for the Acquisition of Agri-biotech Applications (ISAAA), a group supportive of the technology. In 2003, 81% of all U.S. soybean, 73% of U.S. cotton, and 40% of U.S. corn acres were planted with GE seed varieties, designed mainly to control pests (weeds and insects).[2] 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 have approved no products of agricultural biotechnology since 1998, even though they have an elaborate approval process in place and, in October 2002, began implementing revisions to that process aimed at reassuring the states and the public about the safety of the EU regulatory system. 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-wide legislation for approvals until new, stricter regulations for labeling and tracing GE-containing products also take effect. These new regulations are being implemented in 2004; see "Labeling and Traceability," below.[3]

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. Since then, they have 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, other approved varieties also are being grown in the United States. Thus, U.S. export of any corn to the EU is impractical because of the difficulty of segregating EU-approved from EU-unapproved varieties.

The WTO Case

The U.S.-led case began with a request for 60 days of formal consultations with the EU to resolve the dispute. Several other countries expressed support by joining as third parties or indicating their intent to do so. The consultations were not successful, so the United States announced on August 7, 2003, that it was asking the WTO to establish a dispute settlement panel. Settlement procedures typically take about 18 months, according to USDA.

The United States and its allies argue that the EU moratorium violates the WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures. The SPS

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

[3] Before the moratorium, the EU had approved the commercial release of 18 genetically modified organisms (GMOs), including "Roundup-Ready" soybeans.

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 the Technical Barriers to Trade Agreement, the General Agreement on Tariffs and Trade, and the Agreement on Agriculture.

The United States has argued that the moratorium has not only impacted 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 food aid, and Zambia refused all GE shipments because of unspecified environmental and food safety concerns. U.S. officials argue that these actions are directly linked to the EU policy. (Some African producers may fear that the EU will refuse their agricultural exports to the EU if GE crops are widely introduced in Africa.)

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. On January 28, 2004, the European Commission (EC), the EU's executive body, took steps that could lead to the approval within several months of two varieties of GE corn. More specifically, two separate EU policy committees failed to approved either variety — Syngenta Bt11 corn in a December 2003 meeting, and Monsanto NK603 corn in a February 2003 meeting. However, the EC forwarded the Bt11 application to the European Council of Ministers in late January. If the Council fails to act within three months, the EC can (and is expected to) adopt it by default, which would be viewed by most observers as an effective end to the moratorium.[4]

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 what has been called the precautionary approach, which says 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.

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[4] For other details, see Commission of the European Communities, *Communication to the Commission ... for an orientation debate on Genetically Modified Organisms and related issues*, at [http://europa.eu.int/comm/food/food/biotechnology/gmfood/gmo_comm_en.pdf].

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. Thus, if a food produced through biotechnology is determined to be substantially equivalent to one produced by more conventional means, that food is subject to no additional (or no different) regulatory processes. 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). However, marketers are free to make such claims, one way or the other, so long as the labeling is truthful. Assuming the essential equivalence of GM products, the framework regulates new biotechnology products under existing federal statutory authorities, all of which were conceived and enacted before the advent of commercial agricultural biotechnology.[5]

European Union.[6] In contrast to the United States, the EU has established separate structures specifically for approving biotechnology crops and also for labeling products from them. Currently, the key measure is Council Directive 2001/18, which came into force on October 17, 2002, but was amended in July 2003. Generally replacing several earlier GM directives, 2001/18 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 Council of Ministers decides whether or not to approve a GM product for the EU market. This directive also mandates new GMO labeling and traceability requirements (see below).

Labeling and Traceability

The WTO case does not involve this new, stricter EU labeling and traceability regulation, which, U.S. agricultural interests argue, will continue to discriminate against U.S. exports even after the GMO approval moratorium is lifted. The labeling and traceability regulation also was adopted in July 2003, and requires that most foods, ingredients, and (for the first time) animal feeds from GMOs be labeled, even if they no

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[5] The three lead agencies are USDA's Animal and Plant Health Inspection Service, which regulates the import, interstate movement, and field testing of GE plants; the Food and Drug Administration, which regulates food and animal feed additives, including those derived from biotechnology, to ensure that they pose no human health risks; and the Environmental Protection Agency, which regulates pesticides, including those genetically engineered into plants. See CRS Report RL30198, *Food Biotechnology in the United States: Science, Regulation, and Issues*.

[6] Sources for this section include USDA Office of Agricultural Affairs, U.S. Mission to the European Union, *Genetically Modified Food and Feed*, updated March 11, 2003; Pew Initiative on Food and Biotechnology, *U.S. vs. EU: An Examination of the Trade Issues Surrounding Genetically Modified Food*, 2002 and 2003; and various European Commission materials.

longer contain detectable traces. The regulation (1830/2003) was published formally on October 18, 2003, and is being implemented this year.

Under the regulation, 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. The allowable level for unapproved GE varieties that received a positive EU risk assessment during the moratorium is 0.5% for three years, after which it drops to 0%. Previously, only products with detectable GM material had to be so labeled. Products like meat, milk, and eggs from animals fed or treated with GM materials will not have to be labeled, however. In addition, 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.[7]

U.S. interests contend that the U.S. grain system is competitive largely because of its high-volume, commingled nature. 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.

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. "In the United States, only a few protests have been heard and few major food manufacturers have reacted."[8]

ERS, the Pew Initiative on Food and Biotechnology, and others suggest that many Europeans may believe that food-related biotechnology is unnecessary, frivolous, or even dangerous. 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

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[7] For a description of the new rules, see the July 2, 2003, Commission press release at [http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/03/935|0|RAPID&lg=EN&display=]. The Commission also published "co-existence" guidelines, on July 23, 2003, on the planting of GM crops next to non-GM varieties.

[8] Details on these surveys can be found at ERS, *Economic Issues in Agricultural Biotechnology* (Information Bulletin No. 762), February 2001, pp. 28-30. Pew released on September 18, 2003, 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 in the last two years but opinions about safety remain split." Survey results can be found at [http://pewagbiotech.org/research/2003update/].

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," 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."[9] 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, in part because agricultural GMOs are not explicitly recognized in the Uruguay Round trade agreements, concluded before the advent of widespread agricultural biotechnology. 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 appear to be taking unilateral actions to block or slow adoption of GE crops and foods even while other members attempt to 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. Another concern has been that the United States is now subject to the gradual imposition of approximately $4 billion worth of WTO-sanctioned retaliatory tariffs on its exports to the EU, due to its failure so far to comply with a WTO ruling to make its favorable tax treatment of U.S. Foreign Sales Corporations compliant with trade rules. Pressing ahead with the WTO case has complicated efforts to resolve this dispute (and perhaps others), some analysts believe.

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 FY2004 (H.Rept. 108-401; P.L. 108-199) notes that $3.3 million is provided to USDA for "cross-cutting trade negotiations and biotechnology resources."

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[9] Pew Initiative. Unlike BSE, scientists have not linked FMD to human health concerns, although it is a serious animal health problem.