Trade in Biotechnology Food Products

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The United States is the world's largest producer and exporter of modern biotechnology food products. Without generally accepted standards for evaluating the safety of biotechnology food products, sharply different views have emerged—as between the United States and the European Union–on the need to trace biotechnology components used in the food production chain as well as on the need for mandatory labels designating biotechnology food products. Many countries are aligning their biotechnology policies either with those of the United States or the European Union. This article highlights key recent developments in global trade in biotechnology food products, and discusses trade-related biotechnology policy developments in a number of key trading countries, as the Codex Alimentarius, the United Nations-based food standards setting body, is set to consider in June 2003 the first global guidelines for biotechnology food products.

Biotechnology refers to a collection of scientific techniques used to create, improve, or modify plants, animals, and microorganisms for the development of products such as foods, enzymes, drugs, and vaccines.[2] This article focuses on international trade in food products developed through modern agricultural biotechnology—i.e., through the use of genetic engineering—because the principal biotechnology products marketed to date have been genetically engineered field crops such as corn, cotton,[3] and soybeans.[4]

Conventional agricultural biotechnology techniques, such as selective breeding and crossbreeding of related species, have been used for hundreds of years to produce crops with specific traits; however, such techniques can be time-consuming because they may require breeding several generations to obtain a desired trait and breed out unwanted characteristics. Modern biotechnology uses various scientific techniques, most notably genetic engineering, to modify plants, animals, or microorganisms by introducing into their genetic makeup genes for specific desired traits (the biotechnology component), including genes from unrelated species. Genetic engineering allows faster development of new food products and increases the range of traits available for developing new crop varieties. Biotechnology crops have been developed to resist insect damage, resist viral infections, tolerate certain herbicides, and provide enhanced nutritional content.[5]

Global Biotechnology Crop Production

The United States is the world's largest producer of biotechnology crops. More than 88 million acres of U.S. farmland were planted with biotechnology crops in 2001, accounting for 68 percent of total 2001 global acreage planted in biotechnology crops. Argentina ranks as the second largest producer, accounting for 22 percent of 2001 global biotechnology crop acreage, followed by Canada (6 percent) and China (3 percent). South Africa, Australia, Mexico, Bulgaria, Uruguay,

[1] The views expressed in this article are those of the author. They are not the views of the U.S. International Trade Commission (USITC) as a whole or of any individual Commissioner.

[2] In its broadest sense, biotechnology also includes processes that humans have used for thousands of years to ferment foods such as beer, wine, bread, and cheese, to alter raw food products to produce more stable foods. Donna U. Vogt and Mickey Parish, Congressional Research Service (CRS), *Food Biotechnology in the United States: Science, Regulation, and Issues*, Jan. 19, 2001, p. 2.

[3] Cottonseed oil, extracted from cotton seeds, is used in many food products and is a commonly used cooking oil.

[4] Biotechnology (bioengineered, or transgenic) food products also are identified in the literature as genetically-modified (GM) food products or as food products containing genetically-modified organisms (GMOs).

[5] U.S. Department of Agriculture (USDA), Food and Drug Administration (FDA); and World Health Organization (WHO), "20 Questions on Genetically Modified (GM) Foods," found at http://www.who.int/fsf/GMfood/q&a.pdf, retrieved Nov. 6, 2002;U.S. General Accounting Office (GAO), *Concerns Over Biotechnology Challenge U.S. Agricultural Exports*, GAO-01-727, June 2000; Ronald Bailey, "The Looming Trade War Over Plant Biotechnology, CATO Institute, *Trade Policy Analysis*, No. 18, Aug. 1, 2002; and Jorge Fernandez-Cornejo and William D. McBride, USDA, Economic Research Service (ERS), "Adoption of Bioengineered Crops," *Agricultural Economic Report*, No. 810, May 2002.

Romania, Spain, Indonesia, Germany, and France, among others, each accounted for less than 1 percent of global biotechnology crop acreage in 2001.[6]

Current trends indicate that the use of biotechnology crops in the United States continues to increase. When surveyed about their prospective crop planting for the upcoming crop growing season, farmers reported their intentions to plant 26 percent of total U.S. corn acreage with biotechnology varieties in 2001, rising to 32 percent in 2002; 69 percent of cotton acreage to be planted with biotechnology varieties in 2001, rising to 71 percent in 2002; and 68 percent of soybean acreage to be planted with biotechnology varieties in 2001, rising to 74 percent in 2002.[7]

U.S. Biotechnology Policies

Biotechnology products approved for human and animal consumption have been commercially available in the United States since 1995.[8] Genes derived from a soilborne bacterium, *Bacillus thuringiensis* (Bt), were introduced into certain crops to develop Bt corn, Bt cotton, Bt potato, Bt rice, and Bt tomato, conferring to the crops resistance to certain insects. Glyphosate-tolerant (known commercially as "Round-Up Ready®") soybeans contain a gene that protect soybeans from the herbicide glyphosate, thereby allowing the soybeans and any weeds to be sprayed with the herbicide to kill the weeds but leave the soybeans unaffected. There are also approved herbicide-resistant varieties of canola, cotton, corn, radicchio, rice, and sugar beet. There are virus-resistant varieties of papaya, potato, and squash. Biotechnology varieties of tomato and cantaloupe contain a gene that slows the ripening process to allow fruit to ripen longer on the vine.[9]

In the United States, regulation of biotechnology food products does not differ fundamentally from regulation of conventional food products.[10] The United States applies existing food safety and environmental protection laws and regulations to biotechnology products, and approves their use for consumption based on the characteristics of the products rather than whether the products are derived from genetic engineering. Among the factors considered in decisions to approve a biotechnology food product for human consumption are: its expected nutritional value; its ability to be rapidly digested to minimize the likelihood that it will become allergenic; and the extent to which the biotechnology component is substantially the same as other proteins commonly present in food.[11]

The United States does not require biotechnology food products to be so labeled (although voluntary labeling as to biotechnology content is permitted), largely because these products are seen as substantially equivalent to conventional food products and because there is no scientific basis to presuppose that biotechnology food products are more risky or substantially different from other food products.[12] Nevertheless, concern about biotechnology food products appears to be increasing. Frito-Lay, McDonald's, and Proctor & Gamble have stated that they will not accept biotechnology corn and potatoes from U.S. growers for their french fries and corn/potato chip products.[13] A number of U.S. states and cities have had legislative activity to label biotechnology food products. Most recently, Oregon voters rejected a November 2002 ballot initiative that would have required labeling of biotechnology food products. At the federal level, in May 2002, Rep. Dennis J. Kucinich (D-OH) introduced H.R. 4814, "The Genetically Engineered Food Right to Know Act" (H.R. 4814), which would require biotechnology food products to be so labeled.

One key trade concern for U.S. producers is the fact that U.S. farm, grain storage, and transportation

[6] Biotechnology Industry Organization (BIO), "Guide to Biotechnology: Agricultural Production," found at *http://www.bio.org/er/agriculture.asp*, retrieved Nov. 6, 2002.

[7] USDA, National Agricultural Statistical Service, *Prospective Plantings*, CrPpr2–4 (3-02), pp. 20-21.

[8] The FDA approved the first biotechnology food product for the U.S. market in 1990. That approval was for a biotechnology-derived food processing enzyme, chymosin, produced by genetically-modified bacteria. Chymosin is the active enzyme in rennet, a milk-clotting agent used to make cheese; traditionally rennet was obtained from calf stomach linings. FDA, "Safety Assurance of Foods Derived by Modern Biotechnology in the United States," July 1996, found at *http://www.cfsan.fda.gov/~lrd/biojap96.html,* retrieved Nov. 16, 2002.

[9] USDA, FDA, "The FDA List of Completed Consultations on Bioengineered Foods." *http://www.cfsan.fda.gov/~lrd/biocon.html*, retrieved Nov. 6, 2002.

[10] U.S. regulatory oversight in biotechnology is provided primarily by USDA and its agencies, which regulate and monitor the use of biotechnology for agriculture; the Environmental Protection Agency (EPA), which approves new pesticidal and herbicidal substances; and FDA which, among other things, has legal authority with respect to food safety and labeling.

[11] U.S. Department of State, "Food Safety: Regulating Plant Agricultural Biotechnology in the United States," found at *http://usinfo.state.gov/products/pubs/biotech/*, retrieved Nov. 12, 2002.

[12] GAO, *Concerns Over Biotechnology Challenge U.S. Agricultural Exports*, GAO-01-727, June 2001, and Vogt and Parish, CRS, *Food Biotechnology in the United States*; USDA, Agricultural Biotechnology website, found at *http://www.usda.gov/agencies/biotech/*.

[13] American Corn Growers Association, press release, Apr. 28, 2000, found at *http://www.acga.org/news/2000/043000.htm*, retrieved Nov. 12, 2002.

systems are not designed to segregate bulk, untagged, biotechnology agricultural products, on a large scale and with precision, from conventional varieties. Such segregation, which would require duplication in storage and transportation infrastructure, would impose added costs to the U.S. farm sector. There are also the concerns of unintended cross-contamination—that biotechnology crops will crossbreed with other plants resulting in unintended harmful breeds, and that a small number of biotechnology crops will undermine biological diversity. Moreover, the U.S. Government "does not have the authority to force farmers to market their crop in one channel or another. Therefore, the U.S. Government can not certify that certain varieties are completely absent from export channels."[14]

International Harmonization

There are currently no globally accepted standards for evaluating the safety of biotechnology food products. Some question whether separate regulations for trade in biotechnology products are needed at all, and "trade lawyers differ over the need for sui generis rules and disciplines for bioengineered products in international trade versus other approaches such as interpreting or clarifying existing agreements to take them into account."[15] Efforts to develop generally accepted standards for biotechnology products are being conducted by United Nations (UN) agencies and by the Organization for Economic Cooperation and Development (OECD). Biotechnology also has been addressed in other trade-related fora not reviewed in this article, such as the Asia Pacific Economic Cooperation (APEC) forum.

Codex Alimentarius Commission

The Codex Alimentarius Commission (Codex) is an international standard setting body for food safety jointly administered by two UN agencies–the Food Agriculture Organization (FAO) and the World Health Organization (WHO)–to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Program. The purposes of this program are to protect consumer health, to ensure fair food trade practices, and to promote coordination of all food standards work undertaken by international governmental and non-governmental organizations. The United States has participated in Codex since it was formed in 1962.

The standard-setting role of Codex is explicitly recognized in the World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement refers WTO members to the standards, guidelines, and recommendations established by Codex. Other international trade agreements also reference Codex. For example, the North American Free Trade Agreement cites Codex standards as basic requirements to be met by the United States, Canada, and Mexico in terms of the health and safety aspects of food products.[16] APEC and the European Union (EU) also refer to Codex as the basis for their requirements.

Codex is currently developing draft principles for human health risk analysis of biotechnology food products, and plans to consider formally adopting these principles in July 2003. These principles are to be based on pre-market assessment, performed on a case-by-case basis including an evaluation of both direct effects from the biotechnology component and any unintended effects. Although these Codex principles would not have a binding effect on national legislation, they could "be used as a reference in case of trade disputes."[17]

UN Convention on Biological Diversity and Biosafety Protocol

The UN Convention on Biological Diversity (CBD) was adopted at the 1992 so-called Earth Summit in Rio de Janeiro. The pact sets out broad commitments for conservation and sustainable use of the world's biodiversity, and for sharing the benefits arising from the commercial and other utilization of genetic resources in a fair and equitable way. The United States, one of 168 signatories of the CBD, signed the agreement in 1993 but has not ratified it.

Parties to the CBD completed a supplementary agreement, known as the Cartagena Protocol on Biosafety (Biosafety Protocol), in January 2000. Because it had not ratified the CBD, the United States participated in the Biosafety Protocol negotiations only as an observer. If it enters into force, the Biosafety Protocol would be a legally binding environmental treaty that seeks to protect biological diversity from the potential risks posed by crossborder movements of certain biotechnology food products that are capable of transferring or replicating their genetic material.[18]

[14] U.S. Department of State, "Frequently Asked Questions About Biotechnology," fact sheet, Jan. 22, 2001, found at *http://www.state.gov/e/eb/rls/fs/1142pf.hm,* retrieved Nov. 6, 2002.

[15] Charles E. Hanrahan, CRS, *U.S.–European Agricultural Trade: Food Safety and Biotechnology Issues*, 98-8611, Jan. 17, 2001, p. 2.

[16] Codex, "Understanding the Codex Alimentarius," found at *http://www.codexalimentarius.net/*, retrieved Nov. 6, 2002.

[17] WHO, "20 Questions on Genetically Modified (GM) Foods."

[18] As of August 2002, the Biosafety Protocol has been signed by 103 countries, and has been ratified by 37 countries. It must be ratified by 50 countries before it enters into effect 90 days later. Convention on Biological Diversity, found at *http://www.biodiv.org/world/parties.asp,* retrieved Nov. 5, 2002.

The cornerstone of the Biosafety Protocol is a mandatory requirement that exporters seek consent from the competent national authority in importing countries before shipping certain biotechnology products intended for release into the environment. Such advanced notification and consent would not apply to shipments of biotechnology food products intended for direct use as food, feed, or processing (although additional restrictions and mandatory requirements could be added later),[19] but would apply to shipments of such products as seeds for planting and fish for field release. Although excluded from the mandatory advanced reporting requirement, shipments of biotechnology food products intended for food, feed, or processing would be required to be accompanied by documentation stating that such shipments "may contain" biotechnology components and that the products are "not intended for intentional introduction into the environment."[20]

Although it was not drafted to be subordinate to any other international agreement, the Biosafety Protocol preserves countries' rights under other international agreements, including the WTO. The Protocol recognizes that trade and environment agreements should be mutually supportive. However, according to its framers, the Biosafety Protocol would offer benefits beyond those afforded by the WTO because, "the WTO is ... less inclined to take into account socio-economic concerns, such as the risk that exports of genetically engineered crops may replace traditional ones and undermine local cultures and traditions in importing countries; however, under the Protocol these socio-economic considerations may be taken into account."[21]

The Biosafety Protocol would require that regulatory decisions under the Protocol be based on risk assessments "carried out in a scientifically sound manner" and "taking into account recognized risk assessment techniques." However, the Protocol reaffirms the use of the so-called precautionary principle advocated by the EU, which is also a key element of the CBD. The precautionary principle authorizes countries to deny entry to undesired biotechnology imports—even in cases of insufficient scientific data, analysis, or information to support the denial. This differs from the provisions of the WTO SPS Agreement and the Technical Barriers to Trade (TBT) Agreement. Although the SPS Agreement authorizes WTO members to "provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information," the SPS Agreement provides that members adopting such measures to "seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time," and sets forth a mechanism for WTO members whose exports are constrained by such provisional measures to seek an explanation for them. The TBT Agreement requires WTO members to avoid technical regulations that create obstacles to trade.[22]

OECD

The OECD established the Internal Coordination Group on Biotechnology in 1993 to facilitate international coordination in the areas of agriculture, technology, and trade. As a biotechnology clearinghouse for its members, the OECD BioTrack provides information related to major legislative developments in OECD member countries, and an online database of biotechnology products and field trials. The main focus of the work is on international harmonization of regulatory oversight in biotechnology to ensure that the environmental health and safety aspects are properly evaluated.

This OECD effort seeks to promote international harmonization in the safety assessment and regulation of biotechnology food products, so as to avoid divergent standards that could arise from different approaches to risk management and possible measures taken to mitigate such risks. Under active discussion, food labeling practices and requirements–particularly concerning ingredients modified through biotechnology–are one such subject where different approaches have the potential to impede international trade in food products and so become nontariff trade barriers.

The OECD maintains a collection of consensus documents on biotechnology that are intended to establish a set of mutually acceptable standards and practices member countries. One set of consensus documents comprises technical information for use during the regulatory assessment of biotechnology products. Consensus documents on food and feed safety are being published concerning nutrients,

[19] CRS, *Biosafety Protocol for Genetically Modified Organisms: Overview*, Jan. 18, 2001, RL30594, found at *http://www.cnie.org/NLE/CRSreports/Agriculture/ag-93.pdf*, retrieved Nov. 5, 2002, and WHO, "20 Questions on Genetically Modified Foods."

[20] Article 18 of the Biosafety Protocol. For additional information, see UN Environment Program, Secretariat of the Convention on Biological Diversity, "Frequently Asked Questions," found at *http://www.biodiv.org/biosafety/faqs.asp#lmo,* retrieved Nov. 8, 2002.

[21] UN Environment Program, Secretariat of the Convention on Biological Diversity, "Frequently Asked Questions."

[22] Preamble and articles 10 and 15 of the Biosafety Protocol. See also article 5 of the SPS Agreement and article 2 of the TBT Agreement.

toxicants, usage, and other relevant information on biotechnology food products.[23]

Global Biotechnology Policies in Practice

Biotechnology food products are being used for human consumption all over the world. Most industrialized countries and many developing countries have indigenous biotechnology crop research and development programs. However, differences in consumer attitudes toward risk and government approaches to food safety have slowed the acceptance of biotechnology products in many countries. In the absence of broadly accepted standards, many countries have adopted their own safety standards with respect to biotechnology food products. While national standards and procedures can help exporters, they also can reduce international competition, distort markets, and prevent foreign firms from entering markets. Widely different national standards and approval procedures increasingly have resulted in international trade friction. Highlights of recent biotechnology policy developments in selected U.S. export markets follow.

European Union

The EU is one of the most important trading partners and competitors of the United States in world agricultural markets. Total U.S. farm product exports to the EU were valued at $6.4 billion in 2001, making the EU the fourth largest single market for U.S. farm products (behind Japan, Canada, and Mexico). The EU ranked as the largest single market for U.S. soybean exports, with U.S. exports valued at $1.1 billion in 2001, down from $2.3 billion in 1997.[24]

EU policies with respect to biotechnology were long determined by Directive 90/220/EEC, which entered into force in October 1991. That directive applied to biotechnology food safety, animal feed, seeds, and environmental safety. In May 1997, the EU adopted the Novel Foods Regulation (Regulation 258/97)[25] to specifically address biotechnology food safety and labeling. Among other things, the regulation requires all food products containing, consisting of, or produced from biotechnology components to be so labeled. Other significant regulations include Regulation 1139/98 concerning biotechnology corn and soybean approved before the Novel Foods Regulations entered into force, Regulation 50/2000 concerning labeling of additives and flavorings containing biotechnology components, and Regulation 49/2000 concerning labeling requirements in cases of unintended contamination of biotechnology material in non-biotechnology food. Currently under consideration are regulations to specifically address biotechnology seeds and feed.

Based on the precautionary principle, the European Commission (EC) does not approve new biotechnology products if there is insufficient, inconclusive, or uncertain scientific data regarding potential risks. EU consumer experiences vastly differ from those in the United States. Recent food contamination events in the EU, including outbreaks of bovine spongiform encephalopathy (commonly known as "mad cow disease") and its human equivalent Creutzfeldt-Jacob disease that began in the late 1990s as well as incidents of food contamination such as the 1999 contamination of Coca-Cola products in Belgium and France "have undermined the confidence of public opinion and consumers because of decisions or absence of decisions were not supported by full scientific evidence."[26] The precautionary principle is viewed as providing a basis for action when science is unable to give a clear basis.

The EC approved the commercial release of 18 biotechnology food products under Directive 90/220/EEC, including Round-Up Ready® soybeans and Bt corn, into the European market. However, no further authorizations have been granted, and a de facto moratorium on further approvals has been in place since June 1999. There are currently 13 applications pending approval. Moreover, some EU member states have invoked the safeguard clause of Directive 90/220/EEC to temporarily ban the placing on the market of biotechnology corn and canola products in their territories, including Austria, Luxembourg, France, Greece, Germany, and the United Kingdom.

[23] OECD, "About Biosafety: BioTrack," found at *http://www.oecd.org/EN/about/0,,EN-about-528-14-no-no-no-0,00.html*, retrieved Nov. 12, 2002.

[24] USDA, FAS "U.S. Exports of Soybeans, CY 1997-2001," found at *http://www.fas.usda.gov/scriptsw/bico/bico.asp?Entry=lout&doc=640*, and USDA, FAS, "U.S. Exports of Agricultural Products CY 1997 - 2001 and Year-to-Date Comparisons," found at *http://www.fas.usda.gov/scriptsw/bico/bico.asp?Entry=lout&doc=595*, retrieved Nov. 13, 2002.

[25] Novel foods and novel foods ingredients are defined as food and food ingredients that have not been on the EU market to a significant degree before May 1997, including biotechnology foods and food ingredients. European Commission (EC), Health and Consumer Protection Directorate-General, "Novel Foods Regulation," found at *http://europa.eu.int/comm/food/fs/novel_food/nf_regulation_en.html*, retrieved Nov. 12, 2002.

[26] EC Health and Consumer Protection Directorate-General, "Commission Adopts Communication on Precautionary Principle," press release, Feb. 2, 2000.

However, these safeguard cases have been examined by the EU Scientific Committee on Plants, "which in all cases deemed that the information submitted by Member States did not justify their bans."[27]

Directive 2001/18/EC, which replaced Directive 90/220/EEC, entered into force in October 2002. EU sources report that this new directive strengthened the previous legislation by requiring more detailed pre-market risk assessments, mandatory post-market monitoring and surveillance, and mandatory labeling and traceability requirements. Thus, "[t]he Commission considers that it has fulfilled its commitment to create the conditions to re-start the authorization procedure" for biotechnology products.[28]

The EU approved enhanced labeling requirements for biotechnology food and feed in November 2002. The new requirements add to existing EU rules by requiring all biotechnology food products to be labeled irrespective of whether the biotechnology component is present in the final product, effectively extending labeling requirements to highly refined products like corn and soybean oil produced from biotechnology crop varieties and food ingredients made from biotechnology products, even though the products may have no detectable traces of the biotechnology component. For the first time, biotechnology feed products also must be labeled. For non-biotechnology food products, the EU reduced the threshold of allowable biotechnology material below which labeling is not required from 1 percent to no higher than 0.9 percent. For products unintentionally contaminated with biotechnology material, such as bulk commodity shipments, the EU moved its allowable tolerance from zero to 0.5 percent. The United States Government had delivered a demarche to the EU in September 2002 outlining U.S. concerns about the pending traceability and labeling regulations and their likely adverse impact on U.S. bulk shipments.[29]

U.S. officials have stated that the United States continues to have profound problems with EU biotechnology policy, and have expressed the concern that the EU approach to biotechnology and antipathy to biotechnology food products will spread to other countries.[30] U.S. farm groups have urged the United States to seek formal WTO dispute settlement consultations on the EU moratorium on new biotechnology approvals.

Argentina

An estimated 90 percent of Argentina's soybean crop and 20 percent of its corn crop is planted in biotechnology varieties. Argentina's high adoption rates of biotechnology crops have been in large part due to the cost savings these crops afford. Argentina, which lacks sufficient storage and handling facilities to segregate bulk biotechnology commodities, joined with the United States, Canada, and other countries opposed to increasing traceability and labeling requirements for bulk commodities in the Biosafety Protocol negotiations.[31] Argentina has participated as an observer in bilateral U.S.-Canadian discussions on harmonization of the regulatory review process of biotechnology food products.[32]

Argentina approved the use of 5 biotechnology crops during 1996-98, but halted new commercial approvals in 1998 as a result of human health and environmental concerns. Approvals resumed in April 2001 when Argentina approved the commercial use of Round-Up Ready® cotton.[33]

Argentina and its Southern Common Market (Mercosur) partners Brazil, Paraguay, and Uruguay, have not agreed on common biotechnology regulations. Mercosur's Food Commission has recommended a range of Codex standards for adoption by member countries, and is using other Codex standards as points of reference in continuing deliberations. Moreover, the Mercosur partners have agreed to wait until international policies are developed by Codex.[34]

Brazil

Brazil is the world's second largest producer of soybeans and ranks as one of the world's leading producers of biotechnology-free crops. As a major

[27] Charles E. Hanrahan, CRS, *U.S.–European Agricultural Trade*, and EU, "Questions and Answers on the Regulation of GMOs in the EU," press release, Oct. 15, 2002, MEMO/02/160.

[28] EU, "New GMO Directive taking effect today provides more transparent and effective system for authorisation of GMOs, says European Commission," press release, IP/02/1513, Brussels, Oct. 17, 2002.

[29] "U.S. Demarche Highlights Priority Changes to EU Biotech Rules," *Inside U.S. Trade*, Oct. 11, 2002.

[30] Alan P. Larson, Under Secretary for Economic, Business, and Agricultural Affairs, U.S. Department of State, "Remarks before the CATO Institute," Sept. 5, 2002.

[31] Randall D. Schnepf, Erik Dohlman, and Christine Bolling, USDA, ERS, *Agriculture in Brazil and Argentina: Developments and Prospects for Major Field Crops*, Agriculture and Trade Report No. WRS013, December 2001.

[32] Government of Argentina National Advisory Committee on Agricultural Biotechnology, "2001 Annual Report," found at http://www.sagpya.mecon.gov.ar/0-0/, retrieved Nov. 18, 2002.

[33] USDA, FAS, *Argentina: Biotechnology, New Biotech Crop Approved in Argentina, 2001*, GAIN Report AR1029, Nov. 5, 2001.

[34] U.S. Department of Commerce, International Trade Administration, "Mercosur Holds Off on GMO Regulation," *International Market Insight*, Oct. 28, 2000, and Codex, "Codex and the International Food Trade," found at *http://www.fao.org/docrep/w9114e/W9114e06.htm#TopOfPage,* retrieved Nov. 13, 2002.

producer of biotechnology-free crops, Brazil has become a leading supplier to the EU market, which prefers non-biotechnology food products. Commercial distribution and trade of biotechnology products in Brazil officially remain prohibited pending a judicial resolution to a longstanding court battle over a request to import Round-Up Ready® soybeans into Brazil, as well as ongoing debate in the Brazilian Congress and in civil society on biotechnology. However, U.S. industry sources estimate that 60 percent or more of soybeans grown in Brazil are biotechnology varieties. Reports are that growers, especially in southern Brazil, are planting unregistered biotechnology crops from neighboring Argentina.[35]

Brazil's 1995 Biosafety Law, as updated, establishes rules and procedures with respect to the development, import, use, and commercialization of biotechnology food products. That law also created the Brazilian Technical Commission on Biosafety (CTNBIO), the national regulatory agency for biotechnology policy. Entry of biotechnology products into Brazil is prohibited without CTNBIO prior approval. CTNBIO approved a request to import Round-Up Ready® soybeans in 1998, but that approval subsequently was withdrawn in response to an injunction issued by a Brazilian federal judge in June 1999. The request for this injunction was filed by a Brazilian consumer protection advocacy group, a Brazilian government agency, and Greenpeace[36] citing the need for local environmental impact studies of the biotechnology soybeans.[37] In June 2000, during an appeal of the case, a federal judge ruled that CTNBIO did not have the authority to waive the requirement for local environmental impact studies and reports. In December 2000, the Brazilian President issued a provisional measure to formally grant CTNBIO the authority to evaluate and authorize the production and sale of biotechnology products in Brazil; however, the provisional measure has not yet been approved by the Brazilian Congress.[38]

The lack of a policy resolution on biotechnology imports has led to a number of policy contradictions in Brazil. In 2000, concern with the low domestic supply of corn feed for the Brazilian poultry and pork industry led CTNBIO to approve imports of Bt corn from Argentina, conflicting with an earlier court decision prohibiting the imports. The presence of traces of biotechnology ingredients in domestic and imported food products for sale in 2000 led to certain food products being removed from grocery shelves in major Brazilian cities because some provincial labeling regulations are more restrictive than federal regulations. A July 2001 Presidential decree established a labeling requirement for packaged food products containing more than 4 percent of detectable biotechnology products, but the Brazilian Congress continues to debate the issue and has not yet developed implementing regulation.[39]

Canada

Total U.S. farm exports to Canada were valued at $8.1 billion in 2001, making Canada the second leading destination of U.S. farm exports after Japan. Canada ranked as the 10th largest market for U.S. soybeans, with U.S. exports valued at $130 million in 2001. U.S.-Canadian cooperation on biotechnology dates to a July 1998 meeting between USDA APHIS and the Canadian Food Inspection Agency and Health Canada to compare and harmonize where possible the regulatory review process for biotechnology food products. One result of this meeting was an agreement on harmonized guidelines for the molecular genetic characterization of biotechnology plants, with the goal of facilitating the safe commercialization of biotechnology plants.[40]

The Canadian government has approved a total of 51 novel foods for human consumption, most of which are biotechnology food products, including varieties of

[35] G.L. Cromwell et al., "Genetically Modified Soybeans," reproduced on the Iowa Soybean Association website, *http://www.soymeal.org/worldlitarticles/cromwellandcoworkers2001*, retrieved Oct. 29, 2002, and Reuters, "Brazil Drags Heels on Green Light for GM Soybeans," Nov. 6, 2001.

[36] Despite the fact that Brazil's Ministry of the Environment approved the sale of the biotechnology soybeans, a subordinate agency of that ministry, the Brazilian Institute for the Environment and Natural Resources, was a co-petitioner in filing for the injunction.

[37] At the time of the original approval request, CTNBIO waived the requirement for an environmental impact study in Brazil because Monsanto, which produces the soybean, had presented as evidence studies conducted in the United States. The injunction obliged Monsanto and its local Brazilian subsidiary, Monsoy, to prepare an environmental impact report specifically for Brazil.

[38] USDA, FAS, *Brazil: Biotechnology Update of Biotech Issues in Brazil, 2000*, GAIN Report BR1623, Nov. 7, 2001, and *Food and Agricultural Import Regulations and Standards, Country Report 2002*, GAIN Report BR2609, July 26, 2002.

[39] USDA, FAS, *Brazil: Food and Agricultural Imports Regulations and Standards, State of Biotechnology in Brazil, 2001*, GAIN Report BR1601, Jan. 17, 2001, and *Brazil: Biotechnology Update of Biotech Issues in Brazil, 2000*, GAIN Report BR1623, Nov. 7, 2001.

[40] Health Canada, "Canada and the United States Bilateral Agreement on Biotechnology," found at *http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_canada_and_united_states_bilat.html*, retrieved Nov. 22, 2002.

corn, canola, potato, tomato, squash, soybean, flax, and sugar beet. Canada's Novel Foods Regulation requires that prior notification be made before marketing or advertising a novel food in Canada. In addition, the Canadian Government conducts a safety assessment of all biotechnology-derived foods to demonstrate that the food is safe before it is allowed into the Canadian market. Like the United States, Canada does not have a mandatory labeling requirement for biotechnology products, and supports labeling on a case-by-case basis consistent with Canadian policy with respect to all foods. Canadian legislation currently authorizes voluntary labeling of biotechnology food products.[41] In late 2001, the Canadian legislature defeated a bill that would have required mandatory labeling of biotechnology food products.[42]

Mexico

Total U.S. farm exports to Mexico were valued at $7.4 billion in 2001, making Mexico the third leading market for U.S. farm exports after Japan and Canada. Mexico ranked as the second largest market for U.S. corn, with U.S. exports valued at $567 million in 2001, and the second largest market for U.S. soybeans, with U.S. exports valued at $770 million in 2001.

Like the United States, Mexico applies its existing food safety laws and regulations to biotechnology food products. However, the Mexican government is considering a number of legislative initiatives that would establish a separate biotechnology approval regime. Biotechnology products intended for human consumption must receive prior approval before the products can be introduced into the Mexican market. Biotechnology varieties of canola, corn, cotton, potato, rice, and soybeans have been approved for human consumption in Mexico. Mexico also continues to engage in biotechnology research and development efforts, and has conducted crop studies on biotechnology varieties of alfalfa, cantaloupe, papaya, pineapple, tobacco, tomato, and wheat.[43]

[41] Canadian Food Inspection Agency, Office of Biotechnology, "Frequently Asked Questions on Biotechnology-Derived Food;" "How Many Genetically Modified Food Products are Permitted in Canada?" "Labeling of Genetically Engineered Foods in Canada," and "Regulation of Biotechnology in Canada," found at *http://www.inspection.gc.ca/english/toce.shtml*, retrieved Nov. 12, 2002.

[42] USDA, FAS, *Canada: Biotechnology, Mandatory GM Labeling Bill C-287 Defeated 126-91, 2001*, GAIN Report CA1149, Oct. 24, 2001.

[43] Mexican Intersecretarial Commission on Biosafety and Genetically Modified Organisms website, found at *http://www.cibiogem.gob.mx/html, and Mexican Secretary of Health website*, found at *http://www.ssa.gob.mx/unidades/dirgcsbs/informacion/biotec.htm*, retrieved Nov. 18, 2002.

China

China currently ranks as the world's largest importer of soybeans and as the second largest importer of soybeans from the United States after the EU. China's imports of U.S. soybeans were valued at $1 billion in 2001, almost one-fifth of total U.S. sales. China also is developing indigenous biotechnology capabilities.[44]

In June 2001, the Chinese government issued rules requiring safety certification, registration, and labeling of biotechnology food and feed products and some products derived from them—essentially subjecting U.S. soybean and other processed food and agricultural shipments to an approval process that could take up to 270 days, and effectively halting U.S. soybean exports to that country. U.S. officials expressed the concerns that the Chinese government had not provided sufficient time for compliance before the scheduled implementation date, and that China had provided insufficient guidelines on the new approval and labeling requirements. During that period, China replaced U.S. soybean imports with imports from Argentina and Brazil—the other two main global soybean suppliers.[45] The United States reached an initial agreement with China on the matter in October 2001, allowing U.S. exports to resume in large quantities, and a formal interim resolution was announced in December 2001.[46]

China issued implementing regulations for its new biotechnology certification, registration, and labeling policy in January 2002. The United States stated that these new regulations threatened U.S. soybeans, corn, and cotton exports, and that China had not presented any science-based evidence to support the regulations. The United States further requested China to allow for procedures that would enable a smooth transition during implementation of the regulations to avoid trade disruptions.[47] U.S. soybean exports to China were effectively blocked for three months, from January to March 2002, while U.S. and Chinese officials met to discuss these issues in an attempt to ensure that trade would resume. After further bilateral consultations,

[44] Alan P. Larson, U.S. Department of State, "Remarks before the CATO Institute."

[45] USDA, FAS, *China: Oilseeds and Products, MOA Assesses Impact of Biotech Regulation*, GAIN Report CH1028, June 27, 2001.

[46] Office of the U.S. Trade Representative (USTR), "United States Announces Interim Resolution of Soybean Dispute with China," press release 01-104, Dec. 3, 2001.

[47] USTR, "Joint Statement of U.S. Agriculture Secretary Ann M. Veneman and U.S. Trade Representative Robert B. Zoellick Regarding China's Biotechnology Regulations, Feb. 7, 2002," press release 02-15, Feb. 7, 2002, found at *http://www.ustr.gov/releases/2001/12/01-104.pdf,* retrieved Nov. 14, 2002.

China issued interim provisions regulating biotechnology food imports and, in March 2002, issued temporary certificates good through December 152002, thereby allowing U.S. soybean exports to resume while China completed its safety evaluation of biotech products. On October 18, 2002, China officially published new measures providing an additional nine-month extension of interim provisions regulating biotechnology agriculture imports.[48]

India

Reversing a longstanding policy of prohibiting the commercial release of biotechnology crops, the Indian government in March 2002 approved three Bt cotton seed varieties resistant to insect damage for commercial use in southern India (a biotechnology cotton variety adapted for northern India was denied clearance because of inadequate test data). India's Genetic Engineering Approval Committee (GEAC) reportedly approved the Bt cotton following a year of unusually heavy infestation of boll worms and illegal planting of unapproved Bt cotton varieties. India has a significant biotechnology research and development program despite the country's former policy prohibiting the commercial release of biotechnology crops. Indian scientists are working on biotechnology varieties of rice, mustard, tomato, potato, and other crops. GEAC has not yet established labeling requirements for biotechnology cottonseed oil and other biotechnology food products.[49]

Japan

Total U.S. farm product exports to Japan were valued at nearly $8.9 billion in 2001, making Japan the top destination for U.S. farm exports. In 2001, Japan ranked as the top country destination of U.S. corn, with U.S. exports valued at $1.3 billion, and the third leading destination (after China and Mexico) of U.S. soybeans, with U.S. exports valued at $730 million.[50]

The Japanese government has approved 37 biotechnology products for human consumption. In April 2001, new legislation entered into force making it illegal to import into Japan biotechnology food products which are not yet approved in Japan. That legislation also requires labels for biotechnology food products if biotechnology components are in the top 3 ingredients and account for 5 percent or more of the total weight; exceptions from the labeling requirement include alcoholic beverages and processed food products in which the biotechnology component has been removed through processing. A total of 24 of the 37 approved biotechnology products are subject to mandatory labeling. The Japanese government monitors and randomly tests imports of those 24 food products (including soybeans, tofu, and corn grits), and requires that they conform to a verifiable system for segregation of the biotechnology-containing products.[51]

In September 2000, a small amount of corn under the commercial name StarLink™ [52] was found in the U.S. food supply and, in October 2001, a consumer group detected StarLink™ in certain Japanese snack foods and in animal feed. Neither the United States nor Japan have approved StarLink™ corn for human consumption.[53] The Japanese Government eventually developed an inspection plan to assure that no commingled corn was shipped to Japan. In February 2001, the United States and Japan agreed to strengthen testing of feed and food corn exports to Japan for the presence of StarLink™, enhancing a November 2000 U.S.-Japan protocol on feed and food corn to prevent StarLink™ corn exports to Japan. The reported

[48] USTR, "United States Says New China Regulations Should Free Up Soybean," press release 02-98, Oct. 18, 2002, found at *http://www.ustr.gov/releases/2002/10/02-98.htm,* retrieved Nov. 5, 2002, and USDA *China*, GAIN Report CH2011, Mar. 13, 2002.

[49] USDA, FAS, *India: Biotechnology, India Enters the GMO Era, 2002*, GAIN Report IN2023, Apr. 24, 2002.

[50] USDA, "U.S. Proposals for Global Agricultural Trade Reform: What's at Stake for Corn," found at *http://www.fas.usda.gov/info/factsheets/WTO/commodities2002/Corn2.pdf*; and "U.S. Proposals for Global Agricultural Trade Reform: What's at Stake for Soybeans," found at *http://www.fas.usda.gov/info/factsheets/WTO/commodities2002/Soybeans3.pdf*, retrieved Nov. 13, 2002.

[51] USDA, FAS, *Japan: Biotechnology*, GAIN Report JA1080, Aug. 29, 2001.

[52] StarLink™ was developed in the United States by Aventis CropScience and its predecessor companies. The corn is modified to contain "stacked genes" (i.e., more than one commercially desirable transgenic trait) including both an insecticidal protein, Bt Cry9C, and genes to make StarLink™ tolerant to a commonly used broad-spectrum herbicide. Alejandro C. Segarra and Jean M. Rawson, CRS, *StarLink Corn Controversy: Background*, Jan. 10, 2001, RS20732.

[53] The EPA approved Cry9C only for corn destined for animal feed and industrial uses. The agency did not approve the protein for human consumption due to concerns about the potential of Cry9C to cause allergic reactions. Although health safety tests had found that Cry9C did not resemble any known allergens, results from other tests did not allow experts to completely rule out the potential for allergenicity. Two particular concerns were that the Cry9C protein could survive cooking or processing, and that Cry9C is hard to digest. Under Japanese regulations, StarLink™ was not approved for any use and there was a zero tolerance threshold for StarLink™ in corn imports. In October 2000, Aventis voluntarily withdrew the registration of StarLink™ corn to provide further assurance that no StarLink™ corn was sold or grown in the future, although remaining StarLink™ corn can be used for domestic animal feed or industrial uses until existing stocks are depleted. Segarra and Rawson, CRS, *StarLink Corn Controversy: Background*; Raymond Formanek Jr., "Proposed Rules Issued for Bioengineered Foods, *FDA Consumer Magazine*, March-April 2001; and StarLink™ Information Center website, found at *http://www.starlink-corn.com/History/What%20Happened.htm*, retrieved Nov. 15, 2002.

detection of StarLink™ in the U.S. corn crop has continued to decline since mid-2001. As a result of the StarLink™ exports, Japanese imports of U.S. corn declined by 1.3 million metric tons (8 percent in volume terms) in 2001, although both countries pledged to work to reverse that trend. The Japanese Government now requires that unapproved biotechnology food and feed ingredients be segregated from the export channel; however, Japan also has established a 1-percent tolerance for the unintended presence of such unapproved products with the condition that they are approved in other countries under consensus standards set within the OECD.[54]

South Africa and the Southern Africa Region

South Africa applies its existing agricultural and health safety laws and regulations to biotechnology food products. Shipments of biotechnology food products containing more than 1 percent of biotechnology components must receive prior approval for import, distribution, use, and commercial release within South Africa pursuant to the country's 1997 GMO Act. South Africa currently does not require biotechnology food products to be labeled, but in May 2001 proposed labeling requirements were published for public comment. The proposed regulations are similar to those of the United States, and would require labeling for biotechnology food products if their composition or nutritional value differs significantly from non-biotechnology food and if there is a potential for allergic reaction. The South African regulations also would require labeling if human or animal genes are used in plants. Four biotechnology crops have been approved for commercial release in South Africa, including varieties of cotton, corn, and soybeans. South Africa's longstanding biotechnology research and development program has developed local biotechnology varieties of corn, potatoes, sorghum, strawberries, and sugar cane.[55]

South Africa remains one of the few African countries that has approved the commercial release of biotechnology crops for human consumption, although a number of African countries have field tested biotechnology crops. Despite ongoing famine conditions, Zambia has refused U.S. emergency food aid because of its biotechnology components. The Zambian government reportedly seeks to prevent imported biotechnology food products from contaminating the country's domestic crops and jeopardizing its biotechnology-free food exports to the EU market (Zambia recently agreed to accept U.S. corn for distribution only to foreign refugees in that country). Zimbabwe, Mozambique, and Malawi also are concerned about seeds from biotechnology-derived food aid contaminating domestic crops and jeopardizing exports to the EU; however, those countries accept biotechnology corn that is quarantined and milled before distribution.[56]

The U.S. Agency for International Development (USAID) launched the Southern African Regional Program on Biotechnology to promote awareness and training programs on biotechnology among sub-Saharan southern African countries. USAID has established a partnership with seven Southern African Development Community (SADC) countries–Malawi, Mauritius, Mozambique, Namibia, South Africa, Zambia, and Zimbabwe–to provide technical training in biosafety regulatory implementation. This program has as its goal to strengthen science-based regulation of biotechnology in the SADC region, as well as to promote conformity with the science-based standards set forth in the WTO.[57]

[54] U.S. Embassy, Tokyo, Japan, "U.S. and Japan Agree To Improve Testing of Food Corn for Starlink," Feb. 21, 2001, found at *http://www.fas.usda.gov/starlink.html, retrieved* Nov. 12, 2002, and USDA, FAS, *Japan*, GAIN Report JA 2011.

[55] AfricaBio, "South African Biotechnology," found at *http://www.africabio.com/policies/biotechsa.shtml, and USDA, FAS, South Africa: Food and Agricultural Import Regulations and Standards, GAIN Report SF2021*, Aug. 5, 2001.

[56] USAID, "Southern Africa: Complex Food Security Crisis, Situation Report No. 3, Nov. 1, 2002," found at *http://www.usaid.gov/htm_response/ofda/southernafrica_sr3_fy03.html*, retrieved Nov. 18, 2002.

[57] Ibid.