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U.S. Agricultural Biotechnology in Global Markets: An Introduction

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Summary

U.S. farmers have been rapidly adopting genetically engineered (GE) crops — mainly corn, soybean, and cotton varieties — to lower production costs and improve management. However, the U.S. agricultural economy is highly dependent upon exports, at a time when many foreign consumers are wary of the products of agricultural biotechnology. As a result, U.S. exporters often have encountered barriers to trade in these markets.

Among the most controversial barriers is in the European Union (EU). The EU, the fourth-largest foreign market for U.S. agricultural products, since 1998 has maintained a de facto moratorium on approvals of new GE crop varieties. In May 2003, the United States launched a formal challenge of the EU policy, contending that it both violates international trade agreements and causes unwarranted concerns about the safety of agricultural biotechnology throughout the world.

The EU and other important U.S. trading partners around the world have adopted widely divergent approaches to regulating biotechnology. The wide range of approaches to GE product regulation is in part due to the fact that an international consensus on how to regulate agricultural biotechnology is still evolving. U.S. officials say they are active globally to ensure that national and international standards for genetically modified organisms (GMOs) are consistent, transparent, based on scientific principles, and compliant with international trade rules (e.g., those administered through the World Trade Organization). For example, they have been working to ensure that the so-called Cartagena Biosafety Protocol, a multilateral agreement on the safe handling, transfer, and transboundary movement of living modified organisms, does not present new obstacles to U.S. exports of such products.

Another issue involves recent difficulties in moving U.S. food aid to certain African countries due to what U.S. officials said were unwarranted, EU-provoked concerns that such aid's possible GE content could pose safety problems for recipients. Debate also revolves around the potential benefits and problems of introducing GE crops to developing countries.

Congress continues to follow these issues closely. For example, a number of leading lawmakers pressed hard for the Administration to aggressively challenge the EU moratorium. Following the Administration's decision to do so, the Senate and House passed resolutions (S.Res. 154; H.Res. 252) in support of the action. Several House hearings have been held to review barriers to the adoption of, and trade in, GE agricultural products; and to review challenges and opportunities for plant biotechnology development in Africa. Additional hearings are possible. Whether the 108th Congress will consider other legislation affecting agricultural biotechnology was uncertain in June 2003. This report will be updated if events warrant.

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U.S. Agricultural Biotechnology in Global Markets: An Introduction

Overview

U.S. farmers are widely adopting biotechnology, growing genetically engineered (GE) crops — mainly corn, soybean, and cotton varieties — to lower production costs and reduce labor requirements.¹ In 2002, 66% of an estimated 145 million acres planted to GE crops worldwide were in the United States, according to the International Service for the Acquisition of Agri-biotech Applications (ISAAA).²

U.S. crops where GE varieties are common are highly dependent upon export markets. According to USDA, approximately 40% of all U.S. soybeans, 20% of all corn, and 45% of all upland cotton production is exported. These crops and their major products accounted for more than a fourth (\$13.3 billion) of the total annual average annual value of \$52.6 billion for all U.S. agricultural exports during calendar years (CY) 2000 to 2002. Not all of these soy, corn, and cotton exports were GE varieties, but the U.S. marketing and regulatory systems do not distinguish between (approved) GE and non-GE varieties. Commingling bulk commodity shipments provides an important cost competitive advantage for U.S. handlers in domestic and world markets, according to industry analysts.

These analysts observe that U.S. adoption of agricultural biotechnology has been facilitated by the current U.S. regulatory system. 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 (OSTP). 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 product 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 a GE food is substantially different

¹For data and details on U.S. plantings of GE crops, see CRS Report RS21381, *Adoption of Genetically Modified Agricultural Products*.

² ISAAA, *Global Status of Commercialized Transgenic Crops: 2002*. ISAAA is a private organization that promotes agricultural biotechnology. Argentina grew 22% of world acreage, following by Canada and China at 6% and 4%, respectively. Twelve other countries also grew some GE crops on a limited number of acres, ISAAA reported. Although no GE crops are approved for commercial use in Brazil, an estimated 20-30% of its 40-42 million acres of soybeans were believed to be GE varieties in 2002, according to various USDA and private analysts.

(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. The framework maintains that new biotechnology products are regulated under existing federal statutory authorities, all of which were conceived and enacted before the advent of commercial agricultural biotechnology.³

The problem for U.S. agriculture is that many countries remain wary of agricultural biotechnology, including those in the European Union (EU), where consumer and environmental organizations have been vocal in expressing concerns about the safety of GE crops and animals. The EU and other important U.S. trading partners have adopted widely divergent approaches to regulating biotechnology. As a result, U.S. exporters are encountering barriers to their products in these markets.

For example, since 1998, the EU, the fourth largest foreign market for U.S. agricultural products, has maintained a de facto moratorium on approvals of new GE crop varieties. In May 2003, the United States, Canada, and Argentina began a formal challenge of the EU policy in the World Trade Organization (WTO), contending that it violates international trade agreements and also has fueled unwarranted concerns about the safety of agricultural biotechnology throughout the world (see page 7). The EU counters that it must protect its consumers by exercising the so-called 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 — which is also being emulated somewhat in other important U.S. markets such as Japan and South Korea, for example — the products of biotechnology are deemed to be inherently different than their conventional counterparts.

Even some countries that grow GE crops are imposing their own approval and labeling regulations for GMOs. For example, China is planting its own GE cotton and other crops, but has imposed a temporary GMO import regime while it develops permanent new rules for approval and labeling of GMO farm products. This has created uncertainty about continuing access to this important U.S. export market.

Some U.S. producers, who otherwise generally have supported biotechnology, have expressed trepidation about expansion to more GE varieties due to such foreign market uncertainties. Their concerns have been evident as biotechnology companies work toward government approvals of GE wheat. Although some growers are eager to plant the new varieties when they become available, others do not want commercialization approvals until there is wider global acceptance.⁴ Wheat growers, too, depend heavily on exports; USDA reports that 56% of production is exported.

³For details see: CRS Report RL30198, *Food Biotechnology in the United States: Science, Regulation, and Issues*.

⁴GAO; Pew Initiative on Food and Biotechnology. *USDA May Set Strict Rules for Biotech Wheat*, March 17, 2003. Also, "USDA Seeks to Avoid Disruption in Wheat Exports After First GMO Approval," *Inside U.S. Trade*, March 21, 2003.

The average annual value of U.S. wheat exports was \$3.6 billion (7% of all agricultural exports) in CY2000-2002.

International Oversight of Agricultural Biotechnology

National Regulation⁵

Around the world, countries have taken widely divergent approaches to regulating the products of agricultural biotechnology. Critics have noted that many, particularly in the developing world, have adopted no coherent policy at all.⁶ Among those that do, each has its own system. Although multilateral attempts to harmonize GMO regulation have been under way for several years, internationally recognized standards still are evolving.

The disparity of national regulatory responses has been characterized as a “renationalization” of agri-food safety regulation, and “a sharp break from the international food safety system that evolved over the past 100 years, where importers tended to accept the food and environmental safety judgments of regulators from those countries developing and exporting the products.”⁷ Others argue that scientific knowledge about biotechnology’s effects on food and environmental safety is still incomplete. In the meantime, they argue, countries have a right and obligation to take the “precautionary approach” to regulation. Various countries’ national biotechnology regulation is occurring within two broad categories:

Approval to commercialize new products of agricultural biotechnology. The United States, Canada, Japan, Mexico, Argentina, and South Africa are among the countries where developers seeking approvals of new GE products have found a relatively flexible regulatory environment. To this list might be added India and China, where considerable research has been conducted on agricultural biotechnology and domestic approvals appear to be increasing, but where, nonetheless, imports of GE crops may face obstacles.⁸ In Australia, the EU, and New Zealand, approvals

⁵Sources for this section include: International Food Policy Research Institute (IFPRI), *Policy, National Regulation, and International Standards for GM Foods*, by Peter W. B. Phillips, professor of agricultural economics, University of Saskatchewan, January 2003 (hereinafter cited as IFPRI/Phillips); World Health Organization, *Twenty Questions on Genetically Modified (GM) Foods*, 2002; and General Accounting Office (GAO), *International Trade: Concerns Over Biotechnology Challenge U.S. Agricultural Exports* (GAO-01-727), June 2001.

⁶See for example the testimony of John Kilama, President, Global Bioscience Development Institute, before the House Committee on Agriculture, March 26, 2003.

⁷IFPRI/Phillips.

⁸Reports by USDA’s Foreign Agricultural Service (FAS) and by other trade officials suggest that India’s seeming reluctance to accept imports of GE soybean oil, and China’s imposition of additional testing requirements for imported GE crop varieties, may have more to do with
(continued...)

have slowed. A total of nearly 30 countries reportedly have developed relatively coherent (although in the case of some countries, either somewhat ambivalent or not necessarily fully transparent) policies with regard to GE approvals.

Systems for labeling and traceability. In Argentina, Canada, Hong Kong, and the United States, labeling products as to whether or not they are from GE-derived crops generally is voluntary. However, the EU and more than 20 countries have either adopted, or announced plans for, mandatory labeling of GMO products. A number of them, for example, Australia, Brazil, China, Indonesia, Japan, New Zealand, Saudi Arabia, South Korea, and the United Kingdom (an EU member), have formally implemented their mandatory labeling regimes. Many others, however, have not fully outlined their proposals or indicated when they might take effect; some also apparently lack implementing structures.⁹ Generally, mandatory labeling also necessitates accompanying traceability requirements, meaning that the marketing system must have documentable ability to trace the presence or absence of GMOs through each step from farm to point of sale (see also page 9).

Multinational Oversight

The wide range of national approaches to GMO regulation is in part due to the fact that an international consensus on how to regulate agricultural biotechnology is still evolving. Agricultural biotechnology and trade policy analysts throughout the world generally agree that an international consensus on how best to regulate agricultural biotechnology is not only desirable but necessary. Attempts have been under way for some years in a variety of multinational institutions to develop more harmonized standards for ensuring the safety of GE crops and foods, and to establish ground rules for testing, enforcement, and dispute resolution. It is not yet clear which of these international bodies will have the greatest influence in resolving these questions, although it appears likely that most, if not all, will have some role.

The IFPRI/Phillips paper (see footnote 5) observed that “Despite the substantial effort being undertaken, there is no common view on the goal of international regulation. While most agree that safety is the bottom line, few can agree on what that means, whose opinions should hold the most weight (scientists’ or citizens’), or how to handle nonsafety issues such as social, economic, or ethical concerns.”

A wide array of multinational bodies has, or claims, a role in some facet of biotechnology regulation and standard-setting (see **Table 1**). Several are longstanding and largely science-based organizations, including the U.N. World Health Organization (WHO), the U.N. Food and Agriculture Organization (FAO), the food standards-focused Codex Alimentarius Commission, the International Plant Protection Convention (IPPC), and the International Epizootics Organization (OIE). The WTO and the Organization for Economic Cooperation and Development

⁸(...continued)

trade protectionist tendencies than with food and environmental safety concerns.

⁹IFPRI/Phillips. Also see: Sheldon, Ian, Ohio State University, and Tim Josling, Stanford University, *Biotechnology Regulations and the WTO*, International Agricultural Trade Research Consortium Working Paper 02-2, January 2002.

(OECD) are primarily (although not necessarily exclusively) concerned about free trade.

Codex, for example, was created in 1963 by FAO and WHO to develop internationally recognized, science-based food standards and guidelines and related materials. Its main objectives are to protect consumer health, ensure fair trade, and promote coordination of food standards work undertaken by governmental and non-governmental organizations. Codex standards are used to evaluate national food regulations and to settle sanitary and phytosanitary (SPS) related trade disputes in the WTO.

In 1999, the Codex established the ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. The task force was charged with considering health and nutritional implications, and with developing standards, guidelines or recommendations, as appropriate, for such foods. The task force held its fourth and final meeting in March 2003, when it completed work on the last of three framework documents, *Draft Principles for the Risk Analysis of Foods Derived from Recombinant-DNA Microorganisms*. The task force's documents were to be presented for approval by the full Commission at its July 2003 meeting.

U.S. officials expressed satisfaction with the outcome of the final session, although deliberations over the guidelines often were contentious. At the last meeting, for example, an open discussion was held on rules for traceability of GE products. The EU led by France was advocating that they encompass rules for full traceability of GE products. The United States was arguing that traceability is acceptable only for food safety/public health purposes, not merely to preserve the identity of specific products, including those resulting from biotechnology. The U.S. view is that these types of questions should be considered in other Codex committees because they are not unique to biotechnology.¹⁰

The 2000 Cartagena Biosafety Protocol is a newer, environmentally-focused effort devoted to the safe transfer, handling and use of bio-engineered products crossing international borders. The United States is not a party to the Protocol but is participating to ensure that its provisions do not undermine such trade in GM-derived products (see page 10).

¹⁰For details see: USDA, Food Safety and Inspection Service. *Report of the United States Delegate, Fourth Session, Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology*, Yokohama, Japan, March 11-14, 2003, which can be viewed at: http://www.fsis.usda.gov/OA/codex/rep_bt03.htm.

Table 1. Multinational Institutions Involved in Biotechnology

Institution (No. of members)	Purpose/Activity	Lead U.S. Agency
(Cartagena) Biosafety Protocol (50)	January 2000 agreement, under the U.N. Convention on Biological Diversity, on movement and use of living modified organisms. 50 countries, the required number for entry into force, have ratified the treaty. U.S. is not a party to the Convention or Protocol, but is working with ratifiers, and others, to ensure implementation does not harm U.S. exports.	State
Codex Alimentarius (165)	Sets science-based international food safety standards recognized by WTO [in the Sanitary & Phytosanitary (SPS) Agreement]. A Codex task force has devised guidelines for assessing risks; final Codex approval is anticipated.	FDA
Food & Agriculture Organization of U.N. (183)	Interested in food security benefits of biotechnology vs. potential safety risks. FAO Commission on Genetic Resources for Food & Agriculture advises on availability and use of genetic resources for food and agriculture; equitable sharing of benefits — goals of the FAO Treaty on Plant Genetic Resources for Food and Agriculture. The U.S. signed it in November 2002; wants to ensure U.S. agriculture and biotechnology are not adversely affected.	USDA
International Plant Protection Convention (120)	Prevents spread of plant pests & pathogens; its standards are recognized by the SPS Agreement.	APHIS
International Epizootics Organization (162)	Prevents spread of animal pests & pathogens; its standards are recognized by the SPS Agreement.	APHIS
Organization for Economic Cooperation & Development (30)	Composed of developed democracies; fosters market economies, free trade. Promotes international harmonization of biotechnology regulations through development of consensus documents and information, and through outreach.	Depends on issue
World Health Organization (192)	Has main responsibility for health, safety aspects of Codex, including biotechnology. Commissioned an “evidence based” study of human health aspects of GMOs; comments on draft were due in March 2003.	HHS
World Trade Organization (145)	Oversees world trade rules now governed by the 1994 Uruguay Round (UR) Agreements, including trade dispute settlement. The UR predates most agricultural biotechnology, but the U.S. believes such issues can be resolved through the UR SPS and TBT Agreements. WTO also is the forum for the current trade negotiations under the Doha Development Agenda, where agriculture, including, potentially, biotechnology, is on the table.	USTR
(Bilateral Efforts)	The U.S. increasingly works with individual countries to harmonize regulations, educate policymakers and consumers, and eliminate barriers to trade related to biotechnology (see text).	Depends on issue

Sources: IFPRI; USDA.

Agricultural biotechnology was not a major element of international trade during the last comprehensive round of multilateral trade negotiations and therefore is not directly addressed in the 1994 Uruguay Round (UR) agreements. However, the U.S. position has long been that the UR Agreement on Agriculture, the Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures, and the Technical Barriers to Trade (TBT) Agreement provide adequate guidance for dealing with trade in GMOs. Taken together, these agreements seek to reduce or eliminate all unnecessary or arbitrary barriers to trade, and ensure that SPS or technical measures (e.g., GMO labeling) are transparent, scientifically defensible, and based on accepted international standards.¹¹ The U.S. proposal in the current Doha round of negotiations in the WTO is silent on biotechnology itself but presumes a continuation of this position.

Selected U.S. Concerns

U.S. officials say they are actively engaged multilaterally and bilaterally to ensure that any national or international standards are consistent, transparent, based on scientific principles, and compliant with international trade rules (e.g., those administered through the WTO). However, they face difficulties in reconciling the current U.S. approach with the opposing perspectives of other influential countries like those in the EU and elsewhere. Following are discussions of selected issues in the international arena which have challenged U.S. supporters of agricultural biotechnology.

The EU's De Facto Moratorium on GMO Approvals¹²

On May 13, 2003, the U.S. Trade Representative (USTR) and the U.S. Secretary of Agriculture announced that the United States, Canada, Argentina, and Egypt were filing a case before the World Trade Organization against the EU's de facto 5-year moratorium on approving new agricultural biotechnology products. (Egypt subsequently decided against filing with the United States.) The Administration was under increasing pressure from key Members of Congress and farm groups to launch such a case. U.S. agricultural interests contend that not only have these policies blocked their exports to the EU, but also 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. There is concern among some policymakers that the filing of a WTO case

¹¹See also ERS, "Biotechnology in Agriculture Confronts Agreements in the WTO," in *Agriculture in the WTO* (WRS-98-4), December 1998.

¹²Sources 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*, 2002; European Commission, *Questions and Answers on the regulation of GMOs in the EU*, March 4, 2003; and Sheldon, Ian, and Tim Josling, *Biotechnology Regulations and the WTO*, International Agricultural Trade Research Consortium, Working Paper #02-2, January 2002.

will only escalate trade tensions between the United States and the EU, where the value of two-way agricultural trade amounts to more than \$14 billion annually.

Background. With minor exceptions, the EU has approved no agricultural biotechnology products since 1998, even though it has an elaborate approval process in place, and, in October 2002, implemented revisions to that process aimed at reassuring its member states and the public about the safety of its regulatory system. Approximately 13 products in early 2003 were awaiting approval, some for as long as 6 years. A majority of EU states has effectively blocked the release of any new GE crops into the environment. These states — France, Belgium, Luxembourg, the Netherlands, Germany, Austria, Italy, Ireland, Greece, Spain, Portugal, and Finland — say they will not implement the EU-wide legislation for approvals until new, stricter, regulations for labeling and tracing GM-containing products also are adopted. Although the European Commission first approved these separate proposals in July 2001, the lengthy EU decision-making and implementation process make it unlikely that these proposals will come into force any earlier than some time in 2004.

In the 3 years before the de facto ban, U.S. corn exports to the EU averaged approximately \$300 million annually (Spain and Portugal were the largest EU importers). 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 are being grown in the United States, making exports of any U.S. corn (which is not separated as to GM or non-GM varieties) to the EU impractical. U.S. soybean exports to the EU have declined, too, from an average value of approximately \$2.2 billion in the 3 years before the ban to about \$1.2 billion annually (2000-2002), according to USDA data. Unlike biotech corn, only one variety of biotech soybeans has been widely grown in the United States; the EU had approved this GE crop under its regulatory process prior to the moratorium. (The EU also had approved a number of other GMOs prior to the 1998 moratorium.)

The WTO Case. The U.S.-led case began with a request for 60 days of formal consultations with the EU. In addition to the three main filers, Australia, Chile, Colombia, El Salvador, Honduras, Mexico, New Zealand, Peru, and Uruguay expressed their support for the case. On June 19, 2003, a USTR spokesman issued a statement announcing that the consultations were not successful, and that the WTO will now be asked to establish a dispute settlement panel, the next step. At any rate, resolution of the dispute could take up to 18 months.

The United States and its allies argue in part that the EU moratorium violates 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 be operated 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 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 United States has

argued, holds great promise for vastly improving agricultural productivity and feeding growing populations (see also page 11).

EU officials counter that they have shown good faith in moving as quickly as possible to restart the approval process. In early April 2003, the EC threatened to take legal action at the European Court of Justice against the 12 member states if they fail to implement the GE approval legislation once the new labeling and tracing rules are approved. Nonetheless, EU officials have told the United States that their cautious approach to regulating agricultural biotechnology is necessary to restore confidence among European consumers, who may be more wary of changes in how their food is produced due to a series of recent food safety crises.¹³

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, which were concluded before the advent of widespread agricultural biotechnology. If the United States wins, 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 many EU farmers themselves would like to be planting and selling GE crops. However, a win might not open EU markets to more GE imports; the United States might simply have to settle for some form of alternate compensation. Some have suggested that a win could create a backlash among the European public and governments who view the United States as forcing biotechnology on unwilling consumers.

Labeling and Traceability Concerns

As noted, a number of foreign markets for U.S. farm products have been developing systems that will require most or all GE-derived products to be labeled as to their GE content. In the U.S.-EU biotechnology dispute, the U.S.-led WTO challenge to the EU moratorium on GM approvals does not involve the emerging EU labeling regulations. These regulations, if approved as proposed, would require all food, feed and processed products from GMOs to be labeled, even if they no longer contain detectable traces. 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 3 years, after which it drops to 0%. (The current EU regime requires labeling if ingredients contain more than 1% GMO protein or DNA.)

U.S. officials so far have challenged formally only the EU moratorium, but a similar effort against the labeling and traceability rules is possible in the future. U.S.

¹³For example, during the 1990s, bovine spongiform encephalopathy (BSE, or “mad cow disease”) emerged in the United Kingdom and spread to other parts of Europe. In 1999, high levels of dioxin were found in meat products and eggs originating in Belgium. 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.” See: *U.S. vs. EU: An Examination of the Trade Issues Surrounding Genetically Modified Food*.

agricultural interests argue that, even if the GMO approval moratorium is lifted, the new labeling and traceability rules are themselves unworkable and unnecessary, and will continue to discriminate against U.S. exports. Compliance with the EU labeling rule would require 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 would entail 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 could face huge risks and liabilities. All of these problems would discriminate against U.S. shipments, they add. Material from Virginia Cooperative Extension asserts:

Segregating crops at every step during growth, storage, transportation, processing, and exporting would be very difficult and costly to implement. Dr. Susan Harlander, a former vice president of Pillsbury Company, illustrated the situation with the following example: a medium-sized food company can have more than 6,000 products that contain 8,000 ingredients from 1,000 suppliers that move through 30 processing plants on their way to being exported to as many as 100 countries. Implementing a system to track all of these ingredients from their source (as far back as the farm) to the final destination is a daunting task that would cost billions of dollars and even then it may not be infallible.¹⁴

According to Virginia Extension, among the issues to be resolved on labeling and detection of GE material in crops and foods are: the scientific methods used to screen the product; the sensitivity of the detection system; what would actually be detected (DNA or protein); what agency would manage and regulate the testing; and who would be held accountable if a product were mislabeled.

The Biosafety Protocol¹⁵

The Cartagena Biosafety Protocol, an outgrowth of the 1992 Convention on Biological Diversity (CBD), was adopted in January 2000 and will take effect this year, now that the required 50 nations have ratified it. The United States is not a party to the 1992 CBD, and therefore cannot be a party to the Protocol. However, it has actively participated in the negotiations over the Protocol text and in countries' preparations for implementation.

The Protocol addresses a major area of concern not resolved by the parent CBD in 1992 — the safe handling, transfer and transboundary movement of bio-engineered organisms and products. It enables countries to obtain information about biotech organisms (i.e., “living modified organisms” or LMOs) before they are imported into those countries. It recognizes each country’s right to regulate such organisms so long

¹⁴Vines, Randy, Virginia Cooperative Extension Specialist, Biotechnology Information. *The Regulation of Biotechnology*. Publication 443-006, May 2002. To view the material, see [<http://www.ext.vt.edu/pubs/biotech/443-006/443-006.html>]. See also GAO, *International Trade: Concerns Over Biotechnology Challenge U.S. Agricultural Exports*.

¹⁵Sources: CRS Report RL30954, *Biosafety Protocol for Genetically Modified Organisms: Overview*; U.S. State Department, *Fact Sheet: Update on the Cartagena Protocol on Biosafety*, July 11, 2002; and USDA’s notes accompanying its FY2004 budget request.

as they are consistent with existing international agreements, and provides for an international clearinghouse for the exchange of LMO information.

The Protocol establishes the use of “Advance Informed Agreements” (AIA) between the importing and exporting parties that cover the first transboundary movement of any GMO. The purpose of AIAs is to ensure that recipient countries have the opportunity to assess environmental risks associated with the importation of biotechnology products. The Biosafety Protocol creates the procedure by requiring exporters to seek consent from importers before the first shipment of a GMO is introduced into the environment (applies to seeds for planting, fish for field release, and microorganisms for environmental bioremediation). In addition, article 11 also requires that bulk shipments of GMO commodities for food, feed, or processing be accompanied by declarations stating that such shipments “may contain” GMOs and are “not intended for intentional introduction into the environment.”

One section of the Protocol states that “Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that LMO ... in order to avoid or minimize such potential adverse effects.” Defenders of the application of this approach (essentially the “precautionary principle”) maintain that it is only “a temporary mechanism” that gives time for scientific inquiry. Policymakers in Europe recognize, as do those in the United States, the need for an assessment of risks based on accepted scientific facts. However, critics worry that adopting the precautionary principle in formal agreements like the Protocol may create false public expectations of absolute safety and the demand for zero environmental risks. Further, some critics maintain, the precautionary approach can be used as disguised protectionism — as they say already has occurred on the part of the EU in blocking U.S. beef imports containing growth hormones and in delaying approvals of new GMOs.

Implementation of the AIAs, and of provisions on documentation that countries can require for GMOs and GM-containing shipments, also are of major concern to the United States and other GMO exporters. Government and industry officials from the exporting countries have been meeting with each other, and with the ratifying countries, to ensure that bulk grain shipments, processed foods, and other trade in products that may contain GMOs are not disrupted due to confusing, repetitive, or inconsistent new requirements, shipping delays, burdensome paperwork, and the like.

Food Aid and GMOs

Six countries in southern Africa — Lesotho, Malawi, Mozambique, Swaziland, Zambia, and Zimbabwe — are experiencing continuing severe food shortages. In 2002, the United Nations World Food Program (WFP) announced an appeal for food aid to meet the needs of some 14 million people in the six countries. However, provision of food aid to meet the needs of food-short people in the region has been made more difficult and costly by a debate over the presence of genetically modified corn in U.S. food aid shipments. Some of the countries expressed reluctance to accept GE corn on account of perceived environmental and commercial risks

associated with potential introduction of GE seeds into southern Africa agriculture. One, Zambia, refused all shipments of food aid with GE corn out of health concerns as well.

A concern of the southern Africa countries is that corn contained in U.S. food aid shipments could be planted either accidentally or intentionally by African farmers and damage future trade with the European Union. Introduction of genetically modified corn into their food systems could mean that crops grown for export or used in livestock feed would contain genetically modified components. As noted, the EU has approved and permits imports of genetically modified soybeans, but has not yet approved imports of most varieties of genetically modified corn. The EU is expected soon to put in place a system of tracing and labeling of food products as to their GE content. While livestock products will be exempted from such labeling, some of the African countries express fears that EU consumers already antipathetic to GE foods will reject meat products that might have been produced from animals fed GE grain.

The governments of Zimbabwe and Mozambique have accepted U.S. food aid shipments of corn only if it is milled prior to distribution. Malawi has requested that corn be milled, but according to the U.S. Agency for International Development (USAID), is allowing distribution of whole grain corn due to limited milling capacity. Swaziland and Lesotho have expressed reservations about food aid shipments of GE corn, but are accepting them. Only Zambia has rejected any food aid containing bio-engineered grain.

The United States has blamed EU policies for southern Africa countries' views on food aid containing GE products. President Bush, for example, has stated that EU governments, because of their policies on GE products, are hindering the cause of ending hunger in Africa.¹⁶ The United States maintains that genetically modified crops are safe to eat; and that there is little likelihood of GE corn entering the food supply of African countries for several reasons, including the fact that bio-engineered varieties of corn are not well adapted to African growing conditions.¹⁷

Biotechnology and Developing Countries

Relatedly, there is considerable debate over the potential contribution of biotechnology to food security and agricultural development in developing countries. Critics of biotechnology argue that the benefits of biotechnology in developing countries have not been established and that the technology poses unacceptable risks or problems for developing country agriculture.¹⁸ They argue that bio-engineered

¹⁶Commencement Address to the U.S. Coast Guard Academy, May 21, 2003.

¹⁷ For more details, see [http://www.usaid.gov/about/africafoodcrisis/bio_answers.html].

¹⁸Typical of the arguments against introducing bioengineered crops into developing country agriculture is a report by the Kasisi Agricultural Training Centre (Zambia) and the Jesuit Centre for Theological Reflection entitled *What is the Impact of GMOs on Sustainable Agriculture in Zambia*, August 15, 2002, available at [<http://www.jctr.org.zm>]. For arguments in support of introducing bioengineered crops, see: House Committee on Agriculture hearing, *Review of Artificial Barriers to U.S. Agricultural Trade and Foreign* (continued...)

crops could adversely affect the health of consumers and that genetically engineered crops pose unacceptable environmental risks for agriculture in developing countries. Critics suggest that intellectual property rights (IPR) protection impedes development and dissemination of GE crops in developing countries and also gives multinational companies control over developing country farmers. Proponents, however, say that the development of GE technology appears to hold great promise, with the potential to complement other, more traditional research methods, as the new driving force for sustained agricultural productivity in the 21st century. They maintain that GE foods are safe to consume, that environmental risks are both negligible and manageable, and that IPR difficulties have been exaggerated.¹⁹

Congressional Response

Members of the House and Senate Agriculture, House Ways and Means, House Science, and Senate Finance Committees are among those in the 108th Congress who are closely monitoring biotechnology developments in the international arena, as well as the Administration's response. If this Congress follows the lead of its predecessors, it is more likely to be supportive of agricultural biotechnology in international trade than to seek constraints on GE commodities traded internationally and domestically. For example, 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 June 10, 2003, by a suspension vote of 339-80. Separately, H.R. 2447, introduced June 12, 2003, would establish a federal interagency task force, composed of senior Administration officials, to promote the benefits, safety, and uses of agricultural biotechnology

The House Agriculture Committee held a hearing on March 26, 2003, where the theme was the EU's moratorium on GMO approvals and its possible influence on decisions by developing African countries to reject or delay U.S. food aid.²⁰ The House Science Subcommittee on Research held a hearing on June 12, 2003, to examine plant biotechnology research and development challenges and opportunities in Africa.

Earlier, the 107th Congress included biotechnology provisions in the 2002 farm bill (P.L. 107-171) including: a biotechnology and agricultural trade program, aimed at barriers to the export of U.S. products produced through biotechnology (Section 3204); competitive grants for biotechnology risk assessment research (Section 7210); agricultural biotechnology research and development for developing countries

¹⁸(...continued)

Food Assistance, March 26, 2003, at [<http://agriculture.house.gov/hearings/1081.pdf>].

¹⁹IFPRI, *Biotechnology and Genetic Resource Policies*, Briefs 1-6, January 2003, Brief 3. See also CRS Report RL31568, *Plants, Patents, and Seed Innovation in the Agricultural Industry*; and CRS Report RL31132, *Multinational Patent Acquisition and Enforcement: Public Policy Challenges and Opportunities for Innovative Firms*.

²⁰The transcript of *Review of Artificial Barriers to U.S. Agricultural Trade and Foreign Food Assistance* is at [<http://agriculture.house.gov/hearings/1081.pdf>].

(Section 7505); and a program of public education on the use of biotechnology in producing food for human consumption (Section 10802). In addition, legislation that gives the President Trade Promotion or “fast track” authority (P.L. 107-210) contains language providing that U.S. trade negotiators should seek to negotiate rules and dispute settlement procedures that will eliminate unjustified restrictions and requirements, including labeling, of biotechnology products.

Bills also were introduced in the 107th Congress that took other approaches to regulating agricultural biotechnology, and some could reappear in the 108th. They included H.R. 4814, which called for mandatory labeling of GE foods; and other bills in the 107th (H.R. 4812, H.R. 4813, and H.R. 4816) which dealt respectively with legal issues raised by cross-pollination with GE plants, a study of the safety of GE foods, and liability for injury caused by GE organisms. No comparable bills had been introduced as of early June 2003.

Appendix: U.S. Agency Roles in Agricultural Biotechnology Trade

General²¹

Responsibility for biotechnology trade issues and activities is shared by numerous federal agencies and departments. Officials who deal with them on a day-to-day basis say they communicate often, either individually or in working groups, to share information, resolve jurisdictional questions, and coordinate efforts.

As more difficult or controversial trade-related issues arise, officials from relevant agencies may meet at successively higher levels to discuss how to formulate and implement a policy response. According to U.S. officials, years of experience — along with established statutory authorities and the 1986 Coordinated Framework — have provided them with a strong, if somewhat tacit, understanding on how they will handle any given problem, including which agency should take the lead role. Such experience has fostered an increasingly coordinated, if not yet widely-enunciated, formal approach to biotechnology trade policy, several U.S. officials argued.

Nonetheless, some agencies are more prominent than others. The Office of the U.S. Trade Representative (USTR) is generally regarded as the lead agency on biotechnology trade issues as part of its overall mandate to coordinate U.S. trade policy, including negotiating trade agreements and dealing with major disputes. USTR leads the U.S. delegation of agency representatives at quarterly SPS and TBT meetings convened by the WTO, where biotechnology matters generally are covered. Back home, biotechnology questions pass through the USTR staff-level offices that handle agricultural, SPS, and TBT matters. USTR convenes and coordinates an interagency SPS Trade Policy Staff Committee consisting of representatives from agencies throughout government. This committee meets frequently, but on an “as-needed” basis, on biotechnology trade issues, some of which may arise from ongoing bilateral or multilateral negotiations, and others from disputes with trading partners. USTR also convenes a higher-level SPS Trade Policy Review Group, composed of more senior agency officials, to discuss and resolve more controversial SPS questions, including those on biotechnology.²²

However, other agencies take the lead on specific biotechnology issues. The State Department, for example, is at the forefront in dealing with countries implementing the Cartagena Biosafety Protocol. FDA, supported by USDA’s Food Safety and Inspection Service (FSIS), leads on Codex matters (see **Table 1**).

²¹Sources for this section include: telephone interviews with White House, USTR, and USDA officials in late March and early April 2003; and GAO’s *International Trade: Concerns Over Biotechnology Challenge U.S. Agricultural Exports*.

²²GE labeling concerns are within the purview of the separate TBT Trade Policy Staff Committee and Review Groups, also coordinated by USTR.

On occasion, particularly thorny issues and/or jurisdictional disputes must be resolved at the White House level, which ultimately decides overall U.S. biotechnology policy with input from its Office of Science and Technology Policy (OSTP). The President's Special Assistant for Agricultural Trade and Food Aid, and a biotechnology working group composed of high-level officials under the aegis of the White House National Economic Council (NEC), periodically may be called upon to discuss or referee such issues. The National Security Council also has been involved in discussions, e.g., those concerning whether to challenge formally the EU over its de facto moratorium on new GMO approvals.

Some critics assert that the U.S. response to biotechnology remains largely reactive, ad hoc, and not well coordinated. Thus, on any issue, jurisdictional discussions may precede substantive action, they contend, arguing that a more comprehensive long-term strategy is needed. The Biotechnology Industry Organization (BIO) has reported on its website that USTR has circulated among interested agencies a draft paper spelling out such a strategy. However, as of early June 2003, the paper had not emerged publicly.²³

USDA

Biotechnology issues and activities, including international ones, are addressed both at the departmental level (across agencies) and within the various agencies themselves. USDA's Biotechnology Coordinating Committee is a staff-level interagency group that has met periodically to share information and work on biotechnology issues of mutual concern (both domestic regulatory as well as trade-related matters). A higher-level Biotechnology Policy Group is convened at least several times monthly by the Secretary of Agriculture's special counsel on trade to discuss policy, receive updates, and map plans for upcoming interdepartmental and international meetings. Secretary of Agriculture Ann Veneman, on April 8, 2003, named 18 people to a new Advisory Committee on Biotechnology and 21st Century Agriculture (authority for a previous advisory committee expired in 2001). Eleven of the members represent agribusiness companies or agricultural producer groups; the rest are from academia or consumer advocacy organizations.

Section 3204 of the 2002 farm bill (P.L. 107-171) created a new Biotechnology and Trade Program to provide grants for public and private sector projects that will address nontariff barriers to U.S. agricultural exports involving biotechnology, food safety, disease, or other SPS concerns; or that will develop, through bilateral negotiations, protocols on animal health, grain quality, and GMOs. The measure authorizes appropriations of up to \$6 million annually through FY2007.

USDA's FY2004 budget proposal recommends new funding of \$6.6 million and 20 new staff positions "to support a number of important cross-cutting, trade-related and biotechnology activities of the Department and to ensure that adequate funds are available to address them effectively." Of this amount, \$2.1 million would be specifically for work on GMO trade issues, presumably approximately a third of the

²³Based in part on information from BIO, including *Agriculture Biotechnology International Trade Fact Sheet*, available at [<http://www.bio.org/foodag/priorities/tradefacts.asp>].

authorized funding under Section 3204. Of this amount, \$600,000 would be for the Foreign Agricultural Service's new biotechnology unit (see below), and the other \$1.5 million for U.S. activities in other countries, according to a Department official.²⁴ (Congress had not yet acted on the FY2004 USDA appropriation by mid-June 2003.) The budget documents note that USDA "faces a growing array of challenges related to biotechnology, including a rapidly expanding number of regulatory, market access, and trade barrier issues." The funds would be appropriated directly to the Secretary to provide her with flexibility in allocating them among various agencies.

At the agency level, the **Foreign Agricultural Service (FAS)** facilitates and promotes agricultural trade, including trade in the products of biotechnology. FAS activities include education, training, technical assistance, and issue resolution. In recent years, FAS attention has been shifting increasingly from biotechnology capacity building (e.g., technical assistance on the science and application of biotechnology in agriculture), to monitoring and dealing with foreign regulatory policies and restrictions on trade in GMO products. FAS programs include:²⁵

- An Overseas Biotech Training/Education Program involving seminars, symposia, and educational materials on various biotechnology issues aimed at foreign educators, public officials, and others;
- Cochran Fellowship Program Biotechnology Training, offering short-term U.S. training for foreign scientists, regulators, journalists, and policymakers, to provide information about the technology's benefits and about U.S. regulation;
- Biotechnology Short Courses, a new series of quarterly, two-week programs in the United States for foreign participants intended primarily to impart "biotechnology's relationship to market access and trade in agricultural products, and the factors influencing that relationship";
- Capacity Building for the Seed Trade Industry to expand seed trade with Eastern Europe, Africa, and Asia;
- Biotechnology Research Capacity Building, supporting the development of science-based research and regulatory programs and promoting global food security, particularly in developing and newly emergent economies;
- Biotechnology Activities With International Organizations, utilizing a variety of approaches like briefings staged at multinational meetings (e.g., at Codex and at the Rome World Food Summit in 2002) and at regional workshops.

FAS generally convenes a USDA interagency team weekly to review SPS and TBT problems in agricultural trade, including those in GE products; is involved in developing policy on matters requiring higher-level decisions; and leads or accompanies other agency officials on overseas missions to discuss and resolve issues.

²⁴USDA also has asked Congress for \$500,000 in FY2004 to conduct a series of regionally-based short courses on the specifics of the Cartagena Protocol to ensure that countries implement it in a "science-based, transparent, and non-discriminatory" manner.

²⁵See the FAO website, *Biotechnology and U.S. Agricultural Trade, Training and Capacity Building*, at [<http://www.fas.usda.gov/itp/biotech/development.html>].

FAS staff have long been engaged in biotechnology trade issues, but generally not on a full-time basis. Seeking to improve its focus and work, the agency in 2002 established a new Biotechnology Office reporting to the Administrator and Associate Administrator. The office hopes to have 10 full-time staffers on board by August 2003 organized around four teams devoted exclusively to biotechnology work: bilateral relations in Asia and the Americas; bilateral relations in Europe, the Middle East, and Africa; international organization work (e.g., with WTO, FAO, etc.); and one devoted to technical assistance, capacity building, and outreach.

USDA's **Animal & Plant Health Inspection Service (APHIS)** regulates the movement, testing, and commercialization of new GE crop varieties (and GE veterinary biologics) in the United States. In addition, as the lead federal agency regulating commodity imports and exports, APHIS works to minimize trade disruptions caused by animal and plant health issues, including those related to biotechnology. APHIS staff participate, and sometimes take the lead, in U.S. negotiations with trading partners and in multinational forums to resolve SPS-related disputes and to harmonize international standards, to ensure that such issues are not used as unfair barriers to trade.

An increasing share of APHIS harmonization work revolves around trade in GE products. The agency has sought both to ensure that international biotechnology policies are science-based, and to promote the global credibility of the U.S. GE regulatory process. It is involved in Codex, IPPC, OIE, the Cartagena Protocol, and the OECD, among other organizations, and is in ongoing negotiations with Canada on harmonization, which led recently to a draft bilateral agreement on environmental assessment criteria for transgenic plants. In FY2002, APHIS consolidated its biotechnology personnel under a single new office, Biotechnology Regulatory Services, covering both domestic regulatory activities; and international trade, policy, and capacity building. The office was assigned 46 staff slots in FY2002.²⁶

The Federal Grain Inspection Service of USDA's **Grain Inspection, Packers & Stockyards Administration (GIPSA)** spells out official grain quality standards, establishes standard testing methodologies, and, for a fee, tests grain (a requirement for most exports) to ensure they meet such standards. GIPSA has articulated a biotechnology program in response to the "emergence of value-enhanced grains and oilseeds, development of niche markets for non-biotech commodities, and establishment of new regulatory requirements by U.S. trading partners [which] has created a need for greater product differentiation in the marketplace."²⁷

GIPSA has been evaluating the performance of tests to detect the presence of GMOs in grains and oilseeds and offering a proficiency program for organizations testing for biotechnology-derived grains and oilseeds to improve reliability. The agency also has developed sampling guidelines for the industry, among other

²⁶USDA. *2004 Budget Explanatory Notes*.

²⁷GIPSA. *GIPSA's Biotechnology Program*, which can be viewed at [<http://www.usda.gov/gipsa/newsroom/backgrounders/biobackgrounder.htm>].

services. GIPSA itself has not been testing for GMOs in shipments, except for the presence of StarLink™ corn, as a voluntary fee-based service.²⁸

²⁸In 2001, StarLink™, a GE corn approved only for animal and not human food, was found in taco shells. See CRS Report RS20732, *StarLink™ Corn Controversy: Background*.