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Agricultural Biotechnology: Overview and Selected Issues

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Agricultural Biotechnology: Overview and Selected Issues

SUMMARY

Since the first genetically engineered (GE) crops (also known as GM (genetically modified) crops, or GMOs, genetically modified organisms) became commercially available in the mid-1990s, U.S. soybean, cotton, and corn farmers have rapidly adopted them. As adoption has spread, the policy debate over costs and benefits has intensified.

Issues include the impacts of GE crops on the environment and food safety, and whether GE foods should be specially labeled. Underlying these issues is the question of whether U.S. regulation and oversight of biotechnology — with responsibilities spread primarily among the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA) — remain appropriate, particularly as newer applications (e.g., biopharmaceuticals — drugs manufactured with the use of GE crops or animals) emerge that did not exist when the current regulatory regime was established. Relatedly, USDA's Animal and Plant Health Inspection Service (APHIS) published a notice of intent January 23, 2004, to prepare an environmental impact statement evaluating its rules.

Some U.S. agricultural export markets, notably the European Union (EU), have taken a more restrictive approach to regulating agricultural biotechnology than the United States, presenting obstacles for U.S. farm exports. Now before the World Trade Organization (WTO) is a U.S. complaint regarding the EU's de facto moratorium, in place since 1998, on approvals of new GE crops. Even though the EU says it has ended its morato-

rium (by approving in May a GE variety of canned sweet corn for import), U.S. agricultural interests are concerned that new, stricter EU rules for labeling and tracing GE products, now taking effect, will continue to discriminate against U.S. exports. Also, there is debate over whether agricultural biotechnology will improve (according to proponents) or undermine (according to opponents) food security in developing countries.

In the 108th Congress, interest continued in the trade impacts and regulation of agricultural biotechnology. For example, the conference report to accompany the Consolidated Appropriations Act for FY2005 (H.Rept. 108-792; H.R. 4818) provides \$3.3 million to USDA for “cross-cutting trade negotiations and biotechnology resources.” After the U.S. filed its complaint against the EU moratorium, the Senate passed a resolution in support (S.Res. 154), on May 23, 2003. A similar House measure (H.Res. 252) passed on June 10, 2003. Introduced legislation included H.R. 2447, H.R. 3472, and H.R. 4651 to create an interagency task force to promote agricultural biotechnology; H.R. 2916, H.R. 2917, H.R. 2918, H.R. 2919, H.R. 2920, and H.R. 2921 to broaden regulatory oversight of GE foods; and S. 2546, requiring the Food and Drug Administration to review all GE animals and plants that may enter the food supply for environmental and safety issues. None of these bills was enacted.

The 109th Congress may continue to be interested in trade impacts and U.S. regulation, particularly the result of APHIS' evaluation of its rules.

MOST RECENT DEVELOPMENTS

The biotechnology industry and those in U.S. agriculture who support it continue to face challenges in winning global acceptance of genetically modified organisms (GMOs). For example, U.S. officials are challenging in the World Trade Organization (WTO) a long-standing European Union (EU) moratorium on approvals of new GMO crops — even though EU authorities now claim that the moratorium has ended with their approval, in May 2004, of a GM variety of canned sweet corn imports. The EU also approved imports of one GM corn variety for use in food in October 2004, but deadlocked on a decision on a second variety in November 2004. (The US WTO challenge is still pending.) U.S. agricultural groups also are urging the Administration to bring a separate WTO case against the EU for what they say are its equally unfair and unworkable new rules for segregating and labeling GM foods, feeds, and crops. (At this writing, the Administration has not brought such a case.) Many EU consumers remain wary of GM products, and market resistance may have contributed to a May 2004 decision by Monsanto to discontinue efforts to win regulatory approval of a genetically modified wheat variety.

However, other countries such as Canada, Brazil, Argentina, China, and South Africa have been generally supportive of agricultural biotechnology, and the Food and Agriculture Organization (FAO) of the United Nations has given qualified support to agricultural biotechnology. FAO said in a May 2004 report that it can benefit the poor if farmers in developing countries could gain more access to it to complement other needed agricultural improvements.

At home, USDA's Animal and Plant Health Inspection Service (APHIS) is reviewing public comments it received on its January 23, 2004, *Federal Register* notice of intent to prepare an environmental impact statement (EIS) evaluating its biotechnology oversight regulations. Observers expect that the agency could propose a number of potentially major rule changes. APHIS intends to publish a draft EIS by the end of 2004, though it is unclear whether they will meet that deadline. In November 2004, the Food and Drug Administration (FDA) published draft guidance for firms to seek a food safety evaluation of proteins they are using in the early stages of GM crop development.

Also, the Institute of Medicine and the National Research Council released a report on the safety of genetically engineered foods in July 2004. The report concluded that federal agencies should assess any genetically altered food — regardless of whether it is developed through GE or conventional cross-breeding — on a case-by-case basis to determine whether the newly altered food is different enough (in terms of new compounds or levels of substances) to warrant further evaluation.

Congress continues to monitor closely all of these activities, and has passed resolutions supporting U.S. international efforts on agricultural biotechnology. Congress has also provided significant funding for U.S. biotechnology regulation. In the FY2005 USDA appropriation (H.R. 4818), Congress funded USDA's Biotechnology Regulatory Services (BRS) office at \$9.5 million, almost twice the FY2004 enacted level of \$5.4 million.

BACKGROUND AND ANALYSIS

Adoption of Biotechnology in Agriculture¹

Farmers have always modified plants and animals to improve growth rates and yields, create varieties resistant to pests and diseases, and infuse special nutritional or handling characteristics. Such modifications have been achieved by crossbreeding plants and animals with desirable traits, through hybridization and other methods. Now, using recombinant DNA techniques, scientists can genetically modify plants and animals by selecting individual genes that carry the desirable trait (e.g., resistance to a pest or disease) from one organism, and inserting them into another, sometimes very different, organism, that can be raised for food, fiber, pharmaceutical, or industrial uses.

Since genetically engineered (GE, sometimes called genetically modified or GM) crop varieties first became commercially available in the mid-1990s, U.S. soybean, cotton, and corn farmers have been rapidly adopting them in order to lower production costs and raise crop yields. Proponents point to a so-called second generation of GE commodities that could shift the focus of biotechnology from the “input” side (i.e., farm production benefits) to the “output” side (i.e., consumer benefits), including products offering enhanced nutritional and processing qualities, and industrial and pharmaceutical uses. Future products could be livestock as well as crop-based. Critics, meanwhile, complain that biotechnology companies generally have not yet delivered the consumer benefits they have been promising for years.

Nonetheless, the growth of biotechnology has spawned a number of public policy questions. What are the environmental and food safety impacts of GE crops and animals? What challenges and opportunities are exporters of GE crops finding in an increasingly global marketplace? Is the current U.S. regulatory framework, which is based primarily upon statutory authorities enacted before the rise of agricultural biotechnology, still adequate?

Current Applications

In 2003, the most recent year for which figures are available, GE crops were planted on an estimated 167 million acres worldwide. The total number of countries growing such crops had reached 18 by 2003, but most of the acreage was highly concentrated among four crops (soybeans, corn, cotton, and canola) and five countries. The United States had 63% of global acreage, Argentina 21%, and Canada (6%), Brazil (4%), and China (4%) most of the rest.²

In the United States, over 60 GE versions of 13 different plants were approved by APHIS for commercial use through late 2004, although most of the crops are not widely

¹ Unless noted, sources for this issue brief include various materials by USDA’s Economic Research Service and Animal and Plant Health Inspection Service, the Pew Initiative on Food and Biotechnology, the Food Chemical News trade report, and the Biotechnology Industry Organization (BIO).

² International Service for the Acquisition of Agri-biotech Applications (ISAAA), *Global Status of Commercialized Transgenic Crops: 2003*. For information on developments in Brazil, where GM crops were planted illegally prior to 2003, see CRS Report RS21558, *Genetically Engineered Soybeans: Acceptance and Intellectual Property Rights Issues in South America*.

planted.³ Three crops dominate: soybeans, cotton, and corn. Eighty-six percent of all U.S. soybean, 76% of all upland cotton, and 46% of all corn acres were planted with GE seed varieties in 2004, according to USDA's National Agricultural Statistics Service (NASS; see **Table 1**). Almost all commercial applications benefit the production side of agriculture: weed and insect control are by far the most widespread uses of GE crops here and abroad.

Herbicide-tolerant (HT) crops are engineered to tolerate herbicides that would otherwise kill them along with the targeted weeds. These include so-called "Roundup Ready" or HT soybeans, HT upland cotton, and to a lesser extent, HT corn.

Insect-resistant crops effectively have the pesticide inserted into the plants themselves to control insect pests for the life of the crop. Crops relying on *Bt* (*Bacillus thuringiensis*, a soil bacterium) predominate. These insect-resistant varieties are most prevalent in upland cotton to control tobacco budworm, bollworm, and pink bollworm; and corn to control earworm and several types of corn borers.

Table 1. U.S. Acreage in Major GE Crops, 1996 and 2004
(prospective, acres in millions)

	Soybeans		Upland Cotton (UC)		Corn	
	Acres	% of all soy acres	Acres	% of all UC acres	Acres	% of all corn acres
1996	4.2m	7%	2.2m	17%	2.9m	4%
2004	64.9m	86%	10.8m	76%	36.3m	46%

Source: USDA-NASS, *Prospective Plantings*, various issues.

Other crops approved for commercialization include varieties of flax, papaya, potatoes, radicchio, rapeseed, rice, squash, sugar beets, tobacco, and tomatoes. However, these are either not on the market or not widely planted. In addition, several non-crop products are available, notably in dairy production. Chymosin, a biotechnology-produced enzyme, is used widely in cheese production. Bovine somatotropin (BST; also known as bovine growth hormone) is a naturally occurring protein that can be produced in greater quantities through genetic engineering. The GE version of BST was first approved by the U.S. Food and Drug Administration (FDA) in 1993. More than 30% of all U.S. dairy cows are administered BST to boost milk production (by an estimated 10%-15%).

U.S. Food Products Containing GE Crops⁴

Even though only 13 different GE plants have been approved for commercial use in the United States, at least 60% of all U.S. foods likely contain some GE material. That is largely because two such plants (corn and soybeans, where farmers have widely adopted GE varieties) are used in many different processed foods. U.S. biotechnology rules do not require

³ Source: Information Systems for Biotechnology at Virginia Tech. Its website links to both U.S. and international databases for field tests and approved GMOs; see [<http://www.isb.vt.edu/>].

⁴ Sources include Cornell University, Genetically Engineered Organisms Public Issues Education Project (GEO-PIE), website at [<http://www.geo-pie.cornell.edu/>]; and Colorado State University's *Transgenic Crops: An Introduction and Resource Guide*, at [<http://www.colostate.edu/programs/lifesciences/TransgenicCrops/index.html>].

segregation and labeling of GE crops and foods, so long as they are substantially equivalent to those produced by more conventional methods (see “Regulation and Oversight,” below).

Soy-based ingredients include oil, flour, lecithin and protein extracts; corn-based ingredients include corn meal and corn syrups, used in many processed products. Canola oil (mostly imported from Canada, where GE-canola is grown) and cottonseed oil are used in cooking oils, salad dressings, snack foods, and other supermarket items. No GE-produced animals are yet approved for human consumption, although cheeses may contain chymosin, and dairy products may have been produced from milk containing GE-BST.

Because most other government-approved GE crops are not being grown commercially, few other GE-derived foods are reaching consumers. Possible exceptions are some zucchini and yellow squash varieties, which few farmers are growing, and Hawaiian papayas, although most U.S. papayas are non-GE imports from Brazil, Mexico, and the Caribbean. Calgene’s FlavrSavr tomato, first marketed to consumers from 1995 to 1997, was withdrawn after Calgene determined that the varieties being grown were not of consistently high quality. GE potato varieties may have peaked several years ago at 2%-3% of the market, but were discontinued by the seed developer in 2001 mainly after several fast food and snack food companies declined to buy them. GE sugar beets, rice, flax, and radicchio have received government approval but have not been commercially marketed, presumably due largely to perceived producer or consumer unease with them.

Analysts say some farmers are wary of planting GE crop varieties because their customers may be worried about their safety. Biotechnology supporters contend that such concerns are unfounded because scientific evidence has found that GE crop varieties are safe, and that foreign governments are simply using such concerns to maintain barriers to imports.

Future GE Applications⁵

“Input” Traits. For farmers, insect-resistant and herbicide-tolerant GE varieties are under development for other crops, including wheat (see below), alfalfa, peanuts, sunflowers, forestry products, sugarcane, apples, bananas, lettuce, strawberries, and eventually other fruits and vegetables. Other traits being developed through genetic engineering include drought and frost tolerance, enhanced photosynthesis, and more efficient use of nitrogen. Tomatoes that can be grown in salty soils, and recreational turf grasses that are herbicide tolerant, pest resistant, and/or more heat and drought tolerant also are under development.

“Output” Traits. For processors and consumers, a range of GE products may be on the horizon, such as oilseeds low in saturated fats; tomatoes with anti-cancer agents; grains with optimal levels of amino acids; rice with elevated iron levels; and rice with beta-carotene, a precursor of Vitamin A (“golden” rice). Other future products could include “low-calorie” sugar beets; strawberries and corn with higher sugar to improve flavor; colored cotton; improved cotton fiber; delayed-ripening melons, strawberries, raspberries, and other produce (such tomatoes already are approved); and naturally decaffeinated coffee. Critics point out that biotechnology advocates have been forecasting the adoption of various “output” traits for some time, but few are actually reaching the marketplace.

⁵ Sources: ERS, *Economic Issues in Agricultural Biotechnology* (AIB-762), February 2001 (table, p. 19), at [<http://www.ers.usda.gov/publications/aib762/>]; BIO; and Colorado State University.

Plants being developed but not yet commercialized could become “factories” for pharmaceutical compounds, to be extracted and purified for human and animal health uses (among concerns are whether they could “contaminate” food crops; see “Plant-Based Pharmaceuticals from Biotechnology” later in this report). Future transgenic livestock also might yield pharmaceuticals and/or human organ and tissue replacements. Other transgenic livestock traits might include more rapid growth, less fat, disease resistance, and longer useful lives. Awaiting government approval for food use are GE salmon that require as little as half the usual time to grow to market size; other such fish could follow later.⁶

Regulation and Oversight

Coordinated Framework for Regulation of Biotechnology

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). A key principle is that genetically engineered products should continue to be regulated according to their characteristics and unique features, not their production method — that is, whether or not they were created through biotechnology. The framework provides a regulatory approach intended to ensure the safety of biotechnology research and products, using existing statutory authority and previous agency experience with traditional breeding techniques. The three lead agencies are USDA’s Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

USDA’s Animal and Plant Health Inspection Service (APHIS). APHIS regulates the importation, interstate movement, and field testing of GE plants and organisms that are or might be plant pests under the Plant Protection Act (PPA; 7 U.S.C. §7701 *et seq.*). APHIS regulates animal biologics (i.e., viruses, serums, toxins for animal vaccines) under the Virus, Serum, and Toxins Act (21 U.S.C. 151 *et seq.*). Specifically, GE plants that are or might be plant pests are considered “regulated articles” under APHIS regulations (7 CFR 340-340.9). APHIS authorization must be obtained prior to import, interstate movement, or environmental release, including field testing.

More specifically, a “regulated” plant cannot be introduced into the environment — even field tested — unless its developer obtains APHIS authorization through either the (1) permit process or (2) notification process. Permits impose restrictions on movement and planting to prevent escape of plant material that may pose a pest risk. Sponsors follow APHIS guidance on testing and movements to ensure that the plant will not damage agriculture, human health, or the environment. Plant-based pharmaceuticals virtually always must be developed under the permit process. However, most other GE crops have been developed under the notification option, an expedited procedure that is less rigorous than permitting. Notification can be used in lieu of permitting when the plant species is not considered a noxious weed (or weed in the release area) and other APHIS standards are met.

⁶ So far only one GE fish, the “Glofish,” has been marketed in the United States. It is an aquarium fish that is not approved for consumption. For more on genetically engineered fish, see CRS Report RS21996, *Genetically Engineered Fish and Seafood*.

Regardless of the process chosen, after testing is completed, a developer next seeks “non-regulated status” from APHIS, the typical route to full commercialization and no further formal oversight. The developer must provide APHIS with extensive information on plant biology and genetics, and potential environmental and plant pest impacts that may result from the modification. APHIS conducts a formal environmental assessment (EA) and has public comment periods before deciding whether to approve the developer’s request for “non-regulated status.”

Food and Drug Administration (FDA). FDA regulates food, animal feed additives, and human and animal drugs, including those from biotechnology, primarily to ensure that they pose no human health risks, mainly under the Federal Food, Drug and Cosmetic Act (FFDCA; 21 U.S.C. §301 *et seq.*) and the Public Health Service Act (42 U.S.C. §201 *et seq.*). Under the FFDCA, all food and feed manufacturers must ensure that the domestic and imported products they market are safe and properly labeled. All domestic and imported foods and feeds, whether or not they are derived from GE crops, must meet the same standards. Any food additive, including any introduced through biotechnology, cannot be marketed before it receives FDA approval. However, additives that have been determined to be “generally recognized as safe” (GRAS) do not need such preapproval.

To help sponsors of foods and feeds derived from GE crops comply, FDA encourages them to participate in its voluntary consultation process. All GE-derived products now on the U.S. market have undergone this process. With one exception, none of these foods and feeds were considered to contain a food additive, so they did not require approval prior to marketing. However, a May 1992 FDA policy statement still in force notes that GE foods must undergo a special review under certain conditions, such as if the gene transfer produces unexpected genetic effects, changes nutrients or toxicant levels from the food’s traditional variety, might contain an allergen from another crop, or would be used to host an industrial or pharmaceutical substance, for example.⁷ In November 2004, FDA published draft guidance under which developers can choose to provide FDA with any information about new proteins they are using in the early stages of crop development. FDA can then perform an “early food safety evaluation” to deem whether the proteins would be safe for human consumption if low levels of it crossed into the food supply. FDA believes that any potential risk from the low-level presence of such material in the food supply would be limited to the possibility of it containing or consisting of a new protein that might be an allergen or toxin.⁸ FDA is accepting comments on the draft guidance through January 24, 2005.

Environmental Protection Agency (EPA). EPA must approve the use of all pesticides, including those genetically engineered into plants, which it terms “plant-incorporated protectants” (PIPs). EPA essentially determines a PIP’s environmental safety through its authority under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA; 7 U.S.C. §136 *et seq.*). Also, under the FFDCA, the EPA establishes tolerances (i.e., safe

⁷ See the FDA biotechnology website at [<http://www.cfsan.fda.gov/~lrd/biocon.html#policy>]; and CRS Report RL30198, *Food Biotechnology in the United States: Science, Regulation, and Issues*.

⁸ Allison A. Freeman, “FDA Proposes Safety Approval Program for Field Trials,” *Greenwire*, November 24, 2004; FDA, “FDA Proposes Draft Guidance for Industry for New Plant Varieties Intended for Food Use,” FDA Talk Paper, November 19, 2004, accessed at [<http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01327.html>] on December 8, 2004.

levels) for pesticides in foods. Pre-commercial regulation is through a system of notifications for small-scale field tests or Experimental Use Permits for larger field tests. As for any pesticide, EPA requires the manufacturer of a PIP to obtain a registration through a regulatory process intended to ensure its safe use environmentally.

In practice, all three agencies have more detailed procedures than those described above for monitoring and approving the development and commercialization of GE crops and foods, particularly if they are for new uses (e.g., pharmaceuticals). However, the fundamental policy assumption since 1986 has been that the biotechnology process poses no unique or special risks; therefore it demands no new laws beyond those that already govern the health, safety, efficacy, and environmental impacts of more traditional production methods.

Assessments of Current Policy

The biotechnology industry, leading U.S. agricultural groups, and many scientific authorities continue to subscribe to this longstanding U.S. policy approach. They cite various studies in asserting that there is no evidence that current GE crops have harmed the environment or human health. These studies include the Institute of Medicine/National Research Council 2004 report *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*; the National Academy of Sciences / National Research Council (NAS/NRC) 2002 report *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*; the NAS/NRC 2000 report *Genetically Modified Pest-Protected Plants: Science and Regulation*; the Council for Agricultural Science and Technology (CAST) 2001 report *Evaluation of the U.S. Regulatory Process for Crops Developed Through Biotechnology*; and the CAST 2002 report *Comparative Environmental Impacts of Biotechnology-derived and Traditional Soybean, Corn, and Cotton Crops*.

These reports generally conclude that current GE crops likely pose no greater risks than conventional varieties, and that the current U.S. regulatory framework is adequate. However, the reports have suggested a number of administrative or regulatory changes that might be adopted to improve oversight. Critics have gone further, raising questions about whether the current laws themselves remain adequate to protect human health and the environment, particularly as emerging GE applications — such as plant-based pharmaceuticals and industrial compounds, and transgenic animals, including insects — increasingly challenge the agencies' regulatory capabilities. They see gaps in the existing pre-market approval processes, and in post-market oversight of GE crops, that they contend may expose humans and the environment to unwarranted risks. These critics believe that only new legislation can clarify agency roles and strengthen their regulatory authority, particularly over future novel GE applications. Most recently, these critics have cited a September 2004 EPA study showing that seed from genetically modified bentgrass pollinated its wild relatives up to 13 miles away, much further than previous studies would have indicated.⁹ (For additional discussion, see “Food Safety and Labeling” and “Environmental Concerns,” below.)

A number of agricultural organizations, while not necessarily clamoring for new laws, have expressed wariness about some new biotechnology products now awaiting approval.

⁹ Proceedings of the National Academy of Sciences, “Evidence for landscape-level, pollen-mediated gene flow from genetically modified creeping bentgrass with CP4 EPSPS as a marker,” Watrud et al., accessed on September 29, 2004, at [<http://www.pnas.org/cgi/doi/10.1073/pnas.0405154101>].

Among other concerns, they worry about consumer acceptance, potential difficulties exporting these varieties to countries demanding the segregation and labeling of GMOs (or their outright prohibition), and the potential for inadvertently mixing GE with non-GE crops. One related question is the definition of “mixing” and the question of whether there should be a threshold *de minimis* amount of GE material permissible in non-GE material. A second related question is how to assess liability if such mixing does occur, or if GE plants prove harmful to the environment. For example, to what extent if any should biotechnology companies share liability with producers and others who use their products?

All sides of the debate appear to agree that whatever policy course is pursued in the future, it should provide for a clear, predictable, trusted regulatory process.¹⁰ Utilizing its current legislative authorities, APHIS has taken a number of actions over the past several years intended to improve regulatory oversight. These have included consolidation of its activities under a new Biotechnology Regulatory Services (BRS) office; development of a compliance and enforcement unit to ensure GE developers’ adherence to the rules, and, in 2003, the publication of more stringent permit conditions for GE-derived plants for pharmaceuticals and industrials (see “Plant-Based Pharmaceuticals from Biotechnology,” below). Congress also increased USDA’s oversight budget for FY2005 to \$9.5 million (from \$5.4 million in FY2004).

More recently, APHIS announced that it is considering whether to overhaul its existing biotechnology regulations. In the January 23, 2004, *Federal Register*, the agency published a notice of its intent to prepare an environmental impact statement (EIS) evaluating these regulations, and requesting public comments (accepted through April 13, 2004) on a number of possible changes. These include whether to broaden APHIS’s regulatory scope to cover GE plants that may pose a noxious weed risk or may be used as biological control agents; whether to establish new categories for field testing that delineate requirements based upon relative levels of potential risk; and whether to change (e.g., strengthen) its environmental reviews and permit conditions for GE plants for pharmaceuticals and industrials, and differentiate between food and non-food crops for these products. APHIS also solicited comments on ways that it might ease its requirements for lower-risk products. The agency has received over 3,000 comments on its proposal.¹¹ Although APHIS has stated its intention to finish the EIS by the end of December 2004, it is unclear whether that goal will be met.

Global Trade Concerns

The U.S. approach to agricultural biotechnology regulation contrasts with that of many major trading partners. For example, the European Union (EU), Japan, South Korea, New Zealand, and Australia either have or are establishing separate mandatory labeling requirements for products containing genetically modified ingredients; in many of these countries, consumer and official attitudes toward GE foods are more skeptical. Differing regulatory approaches have arisen at least partly because widely accepted international

¹⁰ The various arguments are explored at length in an April 2004 Pew Initiative report, *Issues in the Regulation of Genetically Engineered Plants and Animals*. See [<http://pewagbiotech.org/>].

¹¹ Personal communication with APHIS Legislative and Public Affairs Office, August 2, 2004.

standards are still evolving. Meanwhile, some U.S. exports have been disrupted and trade tensions have grown, as discussed below.¹²

Biotech Wheat

Such concerns have been crystalized by the voluntary withdrawal of a GE herbicide-tolerant wheat from public markets. Monsanto had asked the U.S. and Canadian governments for their approval, and other GE wheat varieties had been under development. Some producers wanted to plant the wheat as soon as it became available; others feared rejection by foreign customers of not only GE wheat, but all U.S. and Canadian wheat, out of concern that even non-GE shipments might unintentionally contain some GE grain. The latter group wanted developers and regulators to wait for more market acceptance before releasing GE wheat varieties.

This resistance likely contributed to a decision by St. Louis-based Monsanto to discontinue its efforts to win regulatory approval of a genetically modified wheat variety. Monsanto announced its decision on May 10, 2004, noting that after a portfolio review and “dialogue with wheat industry leaders, we recognize the business opportunities with Roundup Ready spring wheat are less attractive relative to Monsanto’s other commercial priorities.” Although Monsanto withdrew its applications for regulatory approval from EPA and APHIS, it did not withdraw its FDA application. FDA subsequently approved the application in July 2004. However, FDA approval alone is not sufficient to bring the GM wheat to market.

In early 2003, a group of U.S. wheat producers had petitioned the Administration to conduct a more thorough assessment of the environmental impacts of the Monsanto request; 27 farm, religious, and consumer advocacy organizations endorsed the petition in early 2004. Underlining these concerns, Japanese consumer groups in March 2004 reportedly told U.S. officials in wheat-dependent North Dakota that their country would not import any U.S. wheat products if the Monsanto application was approved.¹³

U.S.-EU Dispute

Another controversial trade case is the U.S. complaint against the EU’s former *de facto* moratorium on approvals of new GE crops. In May 2003, the United States, Canada, and

¹² See also CRS Report RL31970, *U.S. Agricultural Biotechnology in Global Markets: An Introduction*. This issue brief does not discuss the trade challenges encountered by the biotechnology companies themselves. Among other problems, besides foreign resistance to agricultural biotechnology in general, these companies also face often divergent laws on international property rights (IPR), where their patent or plant breeding rights in one country may be nonexistent in another. In the developing world in particular, the policy challenge is to find a balance between companies’ IPR and the ability to use the new technologies. For details, see International Food Policy Research Institute, *Biotechnology and Genetic Resource Policies*, Briefs 1-6, January 2003; 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*.

¹³ Sources include *Food Chemical News*, various issues; Cornell University GEO-PIE; and several news wire service reports.

Argentina initiated a case before the World Trade Organization (WTO). U.S. agricultural interests contend that the moratorium not only has blocked exports such as corn and other products to the EU, but also has fueled unwarranted concerns about the safety of agricultural biotechnology throughout the world. The United States and its allies argue that the EU moratorium violates WTO rules stating that a country's actions to protect health and the environment must be scientifically based, and approval procedures must be operated without undue delay. The WTO named a panel on March 4, 2004, to consider the case; their decision is expected in March 2005.¹⁴

EU officials have told the United States that their cautious approach to regulating agricultural biotechnology is necessary to restore confidence among European consumers, who have become much more wary of changes in how their food is produced, particularly after a series of major food safety crises that were not related to GE crops. At the same time, EU officials assert that they have shown good faith in moving as quickly as possible to restart the approval process. On January 28, the European Commission, the EU executive body, took steps it said soon would lead to the approval of the first new GM products. Later, in May 2004, the Commission approved a GE variety of canned sweet corn for import. In July, the EU also approved the importation of a second GE corn variety for animal feed, and approved imports of the same variety for use in food in October 2004. However, the EU deadlocked on whether to allow imports of a different variety of corn in November 2004, and some of its member countries have passed bans on certain EU-approved GM products. At least one EU country, Germany, has addressed the issue of potential liability from GM crops — passing a law in November 2004 that holds farmers who plant GM crops liable for damages to nearby non-GM fields (even if the GM farmers adhered to planting instructions and regulations). Some U.S. interests countered that the moratorium will not effectively end until the EU clears several more of some 30 GE food and agricultural products still awaiting regulatory approval — and EU member states actually implement the approvals.

Also, the current WTO case does not involve the EU's new regulations, also now taking effect, to require most food, feed, and processed products from GMOs to be labeled, even if they no longer contain detectable traces of GM material (meat and livestock products generally are exempt). GE-based products also must be segregated from non-GE products, with documentation. U.S. agricultural interests argue that, even if and when the moratorium is lifted, the new labeling and traceability rules are themselves unworkable and unnecessary, and can mislead consumers by wrongly implying that GM-derived products are inherently different than non-GM foods or pose safety concerns.¹⁵

The Biosafety Protocol

The Cartagena Biosafety Protocol, an outgrowth of the 1992 Convention on Biological Diversity (CBD), was adopted in January 2000 and took effect in 2003. The United States is not a party to the 1992 CBD, and therefore cannot be a party to the protocol. However, because its shipments to ratifying countries will be affected, it has actively participated in the negotiations over the protocol text and in countries' preparations for implementation.

¹⁴ Ag Biotech Reporter, "WTO Meeting Summary," Volume 21, Issue 9, September 30, 2004.

¹⁵ See CRS Report RS21556, *Agricultural Biotechnology: The U.S.-EU Dispute*.

The protocol, which nearly 90 countries have ratified, permits a country to require formal prior notifications from countries exporting biotech seeds and living modified organisms (LMOs) intended for introduction into the environment. The protocol requires that shipments of products that may contain LMOs, such as bulk grains, be appropriately labeled and documented, and provides for an international clearinghouse for the exchange of LMO information, among other provisions. The United States objects to implementing measures, approved during an international conference in Kuala Lumpur in February 2004, that would mandate what it says are overly detailed documentation requirements and that would potentially expose exporters to unwarranted liability damages if imported GMOs harm the environment or human health. These and other rules could disrupt U.S. exports, U.S. government and industry officials believe.¹⁶

GMOs in the Developing World

In 2002, the United Nations (UN) World Food Program (WFP) announced an appeal for food aid to meet the needs of some 14 million food-short people in six southern African countries, Lesotho, Malawi, Mozambique, Swaziland, Zambia, and Zimbabwe. However, a debate over the presence of genetically modified corn in U.S. food aid shipments made the provision of food aid more difficult and costly. Some of the countries expressed reluctance to accept unmilled GE corn on account of perceived environmental and commercial risks associated with potential introduction of GE seeds into southern African agriculture. Zambia refused all shipments of food aid with GE corn out of health concerns as well. In late March 2004, Angola said it too would ban imports of GE food aid, including thousands of tons of U.S. corn, despite a need to feed approximately 2 million food-short people there.

The United States has blamed EU policies for southern African 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. 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 bioengineered varieties of corn are not well adapted to African growing conditions.

Also, there is 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 countries' agriculture. 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 IPR difficulties have been exaggerated.

¹⁶ Sources include CRS Report RL30954, *Biosafety Protocol for Genetically Modified Organisms: Overview*; and various USDA and U.S. State Department background materials on the protocol.

The UN's Food and Agriculture Organization (FAO) recently gave a qualified endorsement of agricultural biotechnology in *The State of Food and Agriculture 2003-2004*. FAO said that biotechnology including genetic engineering "can benefit the poor when appropriate innovations are developed and when poor farmers in poor countries have access to them on profitable terms. Thus far, these conditions are only being met in a handful of developing countries." Biotechnology research and development should complement other agricultural improvements that give priority to the problems of the poor, and the public sector should direct more resources to such improvements, FAO said, adding: "Regulatory procedures should be strengthened and rationalized to ensure that the environment and public health are protected and that the process is transparent, predictable and science-based."

Other Selected Issues

Food Safety and Labeling

Many consumers may be wary of GE foods out of fear that introduced genes could prove allergenic, introduce increased toxicity, or otherwise be harmful to human health. Some critics express concern that FDA is placing all the responsibility on manufacturers to generate safety data, as it does normally under its pre-market approval system, and is reviewing only the conclusions of industry-sponsored studies, rather than conducting its own tests. They also believe that the process lacks transparency and adequate public scrutiny of data. Others defend the current system. They counter that additional testing and oversight are unnecessary because all foods must meet the same rigorous federal safety standards regardless of whether or not they are genetically engineered.

In July 2004, the Institute of Medicine and the National Research Council (IOM/NRC) of the National Academies of Science released a report generally supporting the proponents' view. The IOM/NRC found that food safety should be assessed based on the composition of the altered food (e.g. whether it contains new compounds, unusually high levels of nutrients, or other significant traits) rather than how the food was produced (by genetic engineering or conventional methods). However, the IOM/NRC determined that the safety of modified foods should be assessed on a case-by-case basis and cautioned that scientists' current ability to predict adverse consequences of genetic changes is limited.¹⁷

U.S. policy also does not require GE-derived foods to be so labeled as long as they are substantially the same as their more conventional counterparts. Nonetheless, some consumer groups continue to seek mandatory labeling of all GE foods. These groups argue that U.S. consumers, like their EU counterparts, should have an opportunity to see all relevant information on a label so that they can make food choices based on their own views about its perceived quality or safety. The food industry generally opposes compulsory biotech labeling. One of its concerns is that consumers might interpret GE labels as "warning labels" implying that the foods are less safe or nutritious than conventional foods, even though the preponderance of science indicates otherwise. The industry also has pointed out that

¹⁷ Press release, "Composition of Altered Food Products, Not Method Used to Create Them, Should Be Basis for Federal Safety Assessment," The National Academies, July 27, 2004. Accessed at [<http://www4.nationalacademies.org/news.nsf/isbn/0309092094?OpenDocument>] on August 2, 2004.

mandatory labeling would require development of a costly and possibly unattainable system to ensure that GE and non-GE foods remain segregated from the farm to the store, with no added benefit to the consumer. The industry has asserted that if consumers want to purchase GE-free products, the market will support a voluntary system, as exists for organic foods (where rules already prohibit GE foods to carry the “organic” label).

In the House Appropriations Committee report on H.R. 4766, the FY2005 agriculture appropriations bill, the committee called on the FDA to finalize guidance for manufacturers who wish to label their products as containing (or not containing) ingredients developed through biotechnology.¹⁸ The Senate report for S. 2803 did not comment on this issue.

A closely related issue is the so-called adventitious presence (AP) of GE material in non-GE crops. In general terms, AP refers to any incidental appearance of very small amounts of foreign material in a commodity, which can occur at any time during production, harvesting, storage, or marketing. In the grain business, even shipments of the highest grades are permitted to contain some specified low levels of unwanted material, such as weeds, damaged kernels, and/or stems and leaves. Corn graded No. 1, for example, may contain up to 2% foreign material. As more crops and acreage are devoted to GE varieties, it becomes increasingly difficult, if not impossible, to avoid their trace presence in non-GE varieties.

Moreover, no internationally recognized standards exist for what amounts, if any, of AP GE material should be permitted in a non-GE crop, especially if that crop or a food derived from it will be labeled as non-GE. In the absence of such standards, individual countries are establishing their own, often varying, thresholds. The lack of consistent, scientifically sound standards is confusing consumers and disrupting trade, the biotech industry has asserted. For example, the new EU regulation sets a tolerance level for non-GM foods, feeds, and processed products at 0.9%. All products with more than 0.9% must be labeled as GM. U.S. agricultural interests consider the EU regulation in particular to be unworkable and discriminatory. EU officials counter that their standards not only are reasonable but also are being demanded by consumers. (See also “U.S.-EU Dispute,” above.)

In its January 23 notice, APHIS asked for comments on if, and how, its regulations should address the AP question for GE plant material. Questions include whether such presence should be exempt from regulation, what thresholds (levels) of AP might be acceptable, and under what conditions. Major grain and biotechnology industry organizations responded by urging the FDA, EPA and APHIS to establish a policy governing AP.

Environmental Concerns

Supporters of biotechnology claim that GE crops offer environmental advantages over conventionally produced organisms. They note that the technology is more precise than traditional methods like crossbreeding. The latter methods transfer unwanted and unanticipated characteristics along with the desired new traits from one organism to another. Biotechnology also has made it possible to apply fewer and less toxic chemical herbicides

¹⁸ H.Rept. 108-584, July 7, 2004, p. 87.

and insecticides and to reduce soil tillage (thereby decreasing erosion and improving soil fertility), supporters of the technology assert.

Critics counter that genetic engineering is not like traditional breeding. It creates crop and animal varieties that would not otherwise occur in nature, posing unpredictable risks to the environment (and to human health), they point out. Because they are living organisms, GE crops are difficult to control, greatly increasing the potential for escaping into the environment, crossbreeding with and overtaking wild species, and generally disrupting the natural ecosystem, critics believe. For example, GE, herbicide-tolerant seeds or pollen could inadvertently create “superweeds” that out-compete cultivated or wild plants, critics argue.

A 2002 NAS/NRC report stated that it could find no new distinctions between the types of environmental risks posed by GE plants and those posed by more conventionally bred crops (and that, in fact, there is a need to re-evaluate the potential environmental effects of the latter). The study concluded that the current APHIS regulatory system for biotechnology has improved substantially since it was first initiated and is more rigorous than the environmental oversight for other agricultural products and practices. The study did find areas of concern, including the need for greater transparency and public input into the regulatory process, and for more ecological monitoring after GE plants are approved and enter the marketplace.

A more recent NAS/NRC report cited studies to conclude that some GE organisms are viable in natural ecosystems and can breed with wild relatives. The report urged developers of GE organisms to consider biological techniques such as induced sterility in order to prevent transgenic plants and animals from escaping into the environment. “Because no single bioconfinement method is likely to be 100% effective,” and because few are well-developed, such developers should create a redundant system by using more than one method of containment. The report called for more research to improve both containment methods and public confidence in regulation.¹⁹ In May 2004, a separate report by University of Arizona and Texas A&M University researchers confirmed the spread of GE corn into a nearby field of non-GE corn.²⁰ In September 2004, a team of researchers from the Environmental Protection Agency confirmed the spread of GE grass pollen to non-GE grass up to 13 miles away.²¹

¹⁹ NAS/NRC, respectively, *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*, 2002; and *Biological Confinement of Genetically Engineered Organisms*, 2004. Among numerous other studies that examine environmental impacts and the adequacy of regulation are Council for Agricultural Science and Technology, *Comparative Environmental Impacts of Biotechnology-derived and Traditional Soybean, Corn, and Cotton Crops*, June 2002; and Pew Initiative on Food and Biotechnology, *Post-Market Oversight of Biotech Foods — Is the System Prepared?* (prepared for Pew by Resources for the Future), April 2003.

²⁰ “Contamination of refuges by *Bacillus thuringiensis* toxin genes from transgenic maize,” Charles F. Chilcutt and Bruce E. Tabashnik, *Proceedings of the National Academy of Sciences*, May 18, 2004, 752-7529.

²¹ See footnote 9.

Plant-Based Pharmaceuticals from Biotechnology

Worldwide, hundreds of GE plants are under development for use as “factories” for pharmaceuticals (and other industrial compounds). GE pharmaceuticals might include, for example, vaccines or medicines for forms of cancer, infectious diseases, cardiovascular and nervous system diseases, metabolic disorders, and agents of biowarfare. Proponents believe plant-based pharmaceuticals will provide a far more cost-effective alternative to conventional pharmaceutical production, which now requires major investments both in large volumes of purified culture mediums and in manufacturing plants. Plant-based pharmaceuticals, on the other hand, could be easily incorporated into the existing agricultural infrastructure, providing a significant new source of farm income, they believe.²²

However, critics are concerned about impacts on the food supply if food crops like corn (the most widely planted U.S. crop, an intensively researched plant for biotechnology, and also an airborne pollinator) are “pharmed.” In 2002, for example, material from GE-altered corn plants that had been test-planted in a prior growing season in Nebraska for pharmaceutical use (for ProdiGene, Inc.) was inadvertently mixed with some 500,000 bushels of soybeans, which had to be quarantined by USDA to keep them out of the food supply. USDA officials observed that the soybeans never reached the food or feed supply, evidence that current regulatory oversight is effective.

Nonetheless, concerns persist among both consumer groups and the food manufacturing industry about producing GE plant-made pharmaceuticals in food crops. Some want 100% prevention systems in place before the first product is commercialized. Some of these groups suggest that only non-food crops should be used for GE plant-made pharmaceuticals, or that, at a minimum, pharmaceutical crops should be banned from agricultural areas where food and feed crops are produced. Other potential issues include whether manufacturers of plant-based pharmaceuticals will be able to maintain consistency in dosages and overall quality, and unanticipated environmental problems (e.g., threatening endangered species).²³

Responding to such concerns, APHIS published in the March 10, 2003, *Federal Register* a notice tightening permit conditions for its 2003 field tests of GE plants with pharmaceutical and industrial traits. The changes included (1) doubling the minimum distance allowed between traditional corn fields and test sites of pharmaceutical or industrial corn; (2) for all pharmaceutical crops (corn and other), doubling fallow zones around test sites; (3) restricting what can be grown on a test site and fallow zone in the next growing season; (4) using dedicated machinery (e.g., harvesters, planters) and storage facilities only for pharmaceutical production — adequate cleaning for other uses is no longer acceptable; (5) submitting for APHIS approval equipment cleaning and seed cleaning and drying procedures; (6) increasing APHIS field site inspections from one per season to five per season plus two visits the following year to look for any volunteer plants; (7) more record-

²² Also see CRS Report RS21418, *Regulation of Plant-Based Pharmaceuticals*.

²³ The 2004 NAS/NRC report observed that an organism widely used for food “probably would be a poor choice as a precursor for an industrial compound” unless it were strictly confined. Alternative nonfood host organisms should be sought, the report concluded.

keeping and training requirements. APHIS issued a letter on January 14, 2004, aimed at clarifying and updating its previous guidance on permits.²⁴

In Congress

In the 107th Congress, lawmakers included both in the 2002 farm law (P.L. 107-171) and in trade promotion legislation (P.L. 107-210) provisions aimed at supporting use of GE farm products, including new programs to challenge foreign barriers to U.S. exports of such products and to educate the public on GE-based foods. In the 108th Congress, the conference report to accompany the Consolidated Appropriations Act for FY2004 (H.Rept. 108-401; P.L. 108-199) notes that \$3.3 million is provided to USDA for “cross-cutting trade negotiations and biotechnology resources.” The measure also includes approximately \$5 million for APHIS’s office of Biotechnology Regulatory Services (BRS). H.R. 4818, the Consolidated Appropriations Act for FY2005, provides level funding for the trade negotiations and provides \$9.5 million for BRS. The increase funds additional inspections, particularly of trials for plant-produced pharmaceutical and industrial compounds; upgraded permitting and tracking systems; a new BRS Office of Science; and other improvements.²⁵

After the Administration launched its formal challenge of the EU GM moratorium, the Senate on May 23, 2003, passed by unanimous consent a resolution (S.Res. 154) in support of the action. A similar House measure (H.Res. 252) was passed on June 10, 2003, by a suspension vote of 339-80. In the 108th Congress, Representative Nick Smith introduced bills (H.R. 2447, H.R. 3472, H.R. 4651) to create an interagency task force to promote the benefits of agricultural biotechnology. Both bills were referred to the House Agriculture Committee, but no subsequent action has been taken on them. Representative Kucinich introduced a series of bills (H.R. 2916, H.R. 2917, H.R. 2918, H.R. 2919, H.R. 2920, H.R. 2921) that would have prescribed a variety of legislative changes intended to mandate labeling of GE-based foods, broaden FDA oversight, protect producers from any potential legal and environmental risks from agricultural biotechnology, prohibit unapproved U.S. exports of GE plants and animals, and tighten rules for producing and handling GE pharmaceutical and industrial crops, among other things. These bills have been referred to various House committees, but no further action has been taken on them. Also Senator Durbin introduced a bill, S. 2546, to require premarket consultation and approval for GE foods at the FDA. The bill was referred to the Senate Agriculture Committee, but no further action was taken on it.

A hearing on biotechnology was held on June 23, 2004, before a subcommittee of the House Agriculture Committee. The hearing focused on the use of biotechnology in agriculture and products currently under research. The Committee also held a hearing on March 26 regarding trade barriers for agricultural biotechnology products. Issues for the 109th Congress may include continued interest in the export markets for U.S. GM foods, particularly the EU, and U.S. regulatory mechanisms for approving biotech foods.

²⁴ This guidance is available at [<http://www.aphis.usda.gov/brs/pdf/011404.pdf>].

²⁵ USDA FY2005 Budget Justification, pp. 15-52 and 15-53.