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Agricultural Biotechnology: Background, Regulation, and Policy Issues

Tadlock Cowan

Analyst in Natural Resources and Rural Development

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Summary

Biotechnology refers primarily to the use of recombinant DNA techniques to genetically modify or bioengineer plants and animals. Most crops developed through recombinant DNA technology have been engineered to be tolerant of various herbicides or to be pest resistant through having a pesticide genetically engineered into the plant organism. U.S. soybean, cotton, and corn farmers have rapidly adopted genetically engineered (GE) varieties of these crops since their commercialization in the mid-1990s. Over the past 15 years, GE varieties in the United States have increased from 3.6 million planted acres to 173 million acres in 2013. Worldwide, 27 countries planted GE crops on approximately 433 million acres in 2013. GE varieties now dominate soybean, cotton, and corn production in the United States, and they continue to expand rapidly in other countries, particularly in Latin America.

Ongoing policy issues include the impacts of GE crops on the environment (e.g., pest and weed resistance), whether GE foods should be labeled, their potential contamination of conventionally raised and organic plants, and issues of liability. Underlying these issues are concerns about the adequacy of federal regulation and oversight of GE organisms, particularly as newer applications (e.g., biopharmaceuticals, multiple GE traits in single organisms, GE trees, GE insects) emerge that did not exist when the current regulatory regime was established in 1986. The FDA is currently considering approval of the first GE animal for human consumption, a salmon engineered to grow to market size in half the normal time. Global trade issues involving GE organisms are a long-standing issue and are particularly salient in current U.S.-EU trade discussions on the Transatlantic Trade and Investment Partnership (T-TIP).

In the United States, agricultural biotechnology is regulated under the 1986 Coordinated Framework for the Regulation of Biotechnology. Three federal agencies—the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA)—share regulatory responsibilities. Regulatory non-compliance incidents and issues associated with environmental effects of GE plants have repeatedly raised concerns about the adequacy of existing U.S. regulatory structures. Questions have also arisen about the adequacy of USDA's Animal and Plant Health Inspection Service's (APHIS's) environmental assessments for deregulating GE plants.

In July 2015, the Administration announced in a memorandum to agency heads a review and update of the Coordinated Framework to ensure the capacity of the regulatory structure to address any future biotechnology risks. This is the first comprehensive review of the Coordinated Framework in nearly 30 years.

The 114th Congress passed a bill, H.R. 1599, to preempt various state laws that have been recently passed in Maine, Vermont, and Connecticut to require mandatory labeling of GE foods. While preserving current jurisdiction and regulatory authority of FDA and APHIS, the Safe and Accurate Food Labeling Act of 2015, as passed by the full House on July 23, 2015, would preempt any state authority over GE labeling in favor of a voluntary National Genetically Engineered Food Certification Program under the federal Agricultural Marketing Act of 1946. The certification program would establish national standards for labeling both GE and non-GE foods. A consultative process under FDA for the introduction of GE foods would continue, and a new notification system for GE plants used in food would be established.

Three bills have been introduced that would require labeling of GE products. One would amend the Federal Food, Drug, and Cosmetic Act to require labeling of GE fish (H.R. 393), and a separate bill would require labeling of all GE foods (H.R. 913/S. 511). A third bill, the Genetically Engineered Salmon Risk Reduction Act (S. 738), would require labeling of GE salmon and further require an environmental impact statement and risk analysis by the Under Secretary for Oceans and Atmosphere of the Department of Commerce.

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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 also genetically modify plants and animals by selecting individual genes that carry desirable traits (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.

Karl Ereky, a Hungarian engineer, coined the term “biotechnology” in 1919 to refer to the science and the methods that permit products to be produced from raw materials with the aid of living organisms.² According to the Convention of Biological Diversity, biotechnology is “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use” (Article 2). According to the FAO’s statement on biotechnology, “interpreted in a narrow sense, ... [biotechnology] covers a range of different technologies such as gene manipulation and gene transfer, DNA typing and cloning of plants and animals.”³

Since genetically engineered (GE, sometimes called genetically modified organism or GMO) crop varieties first became commercially available in the mid-1990s, U.S. soybean, cotton, and corn farmers have rapidly adopted them in order to lower production costs and increase crop yields. Proponents point to the emergence of “second generation” GE commodities that could shift the focus of biotechnology from the “input” side (creating traits that benefit crop production, such as pest resistance) to the “output” side (creating traits that benefit consumers, such as lower-fat oils). These second generation products could offer enhanced nutritional and processing qualities and also industrial and pharmaceutical uses. Future products are expected to 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.

Incidents of regulatory noncompliance have continued to spike concern about the adequacy of regulatory structures. In December 2008, a small amount of unapproved GE cotton was harvested along with commercially available GE cotton. The unapproved GE cotton variety produces a pesticide that is a plant-incorporated protectant (PIP). In August 2006, traces of an unapproved variety of GE rice were reported in commercial rice samples from parts of the southern United States (see “GE Rice,” below). These incidents have added to the ongoing interest in a number of public policy questions. What are the environmental and food safety impacts of GE crops and animals? What obstacles and opportunities are exporters of GE crops encountering in the global marketplace? Is the current U.S. regulatory framework, which is based primarily upon statutory authorities enacted before the rise of agricultural biotechnology, adequate for these new technologies and products?

¹ Among the sources for this report are various materials by USDA’s Economic Research Service (ERS) and Animal and Plant Health Inspection Service (APHIS), the Pew Initiative on Food and Biotechnology, various issues of *Food Chemical News*, a weekly trade publication, and the Biotechnology Industry Organization (BIO).

² OECD. *Policy Brief, Modern Biotechnology and the OECD*, June 1999. <http://www.oecd.org/dataoecd/29/40/1890904.pdf>.

³ FAO. *FAO Biotechnology Glossary*, http://www.fao.org/biotech/index_glossary.asp.

Current Applications

Crops

In 2013, GE crops were planted on an estimated 433 million acres worldwide (**Table 1**), an increase of nearly 144 million acres over 2008. The acreage planted to GE crops has grown globally at an annual rate of 3% since the mid-1990s and currently comprises 12% of all crop acreage. In 2013, 8 industrialized countries and 19 lesser-developed countries had acreage planted to GE crops. Most of the acreage is highly concentrated among four crops—soybeans, corn, cotton, and canola—and five countries. The United States has approximately 40% of global acreage (173.2 million acres), and Brazil has 23% (99.6 million acres). Argentina has 14.0% of global acreage (60.3 million acres), India 6.3% (27.2 million acres), and Canada 6.1% (26.7 million acres). These five countries account for approximately 90% of the global acreage planted to GE crops.

In the United States, over 60 GE plant varieties were approved by APHIS for commercial use through early 2005.⁴ By 2014, 82 plant varieties had been deregulated by APHIS. Ninety-three percent of all U.S. soybean, 94% of all upland cotton, and 88% of all corn acres were planted with GE seed varieties in 2012, according to USDA's National Agricultural Statistics Service (**Table 2**). Virtually all current commercial applications benefit the production side of agriculture, with herbicide tolerance and pest control by far the most widespread application of GE crops in the United States and abroad.

Herbicide-tolerant (HT) crops are engineered to tolerate herbicides that would otherwise kill them along with the targeted weeds. These include HT soybeans, HT upland cotton, and to a lesser extent, HT corn. Many of these are referred to as “Roundup Ready” because they are engineered to resist Monsanto’s glyphosate herbicide, marketed under the brand name “Roundup.” More recently, Monsanto has announced various “stacked trait” varieties—varieties that combine resistance not only to glyphosate/Roundup but also to the herbicides dicamba and glufosinate. The development of these newer varieties of HT crops is being motivated in part by the increasing weed resistance to glyphosate/Roundup.

Insect-resistant crops effectively have the pesticide genetically engineered into the plants themselves to control insect pests for the life of the crop. These varieties are often referred to as having a plant-incorporated protectant (PIP). Many of these crops have been genetically engineered with *Bt* (*Bacillus thuringiensis*, a soil bacterium), which produces a naturally occurring pesticide.⁵ These insect-resistant varieties are most prevalent in upland cotton to control tobacco budworm, bollworm, and pink bollworm; and in corn to control earworm and several types of corn borers. Monsanto is also developing “stacked trait” varieties of soybeans and sugar cane that are resistant to insects as well as glyphosate/Roundup.

⁴ Sources: Information Systems for Biotechnology at Virginia Tech; also, USDA, ERS, *The First Decade of Genetically Engineered Crops in the United States*, April 2006, which can be accessed at <http://www.ers.usda.gov/Publications/eib11/>.

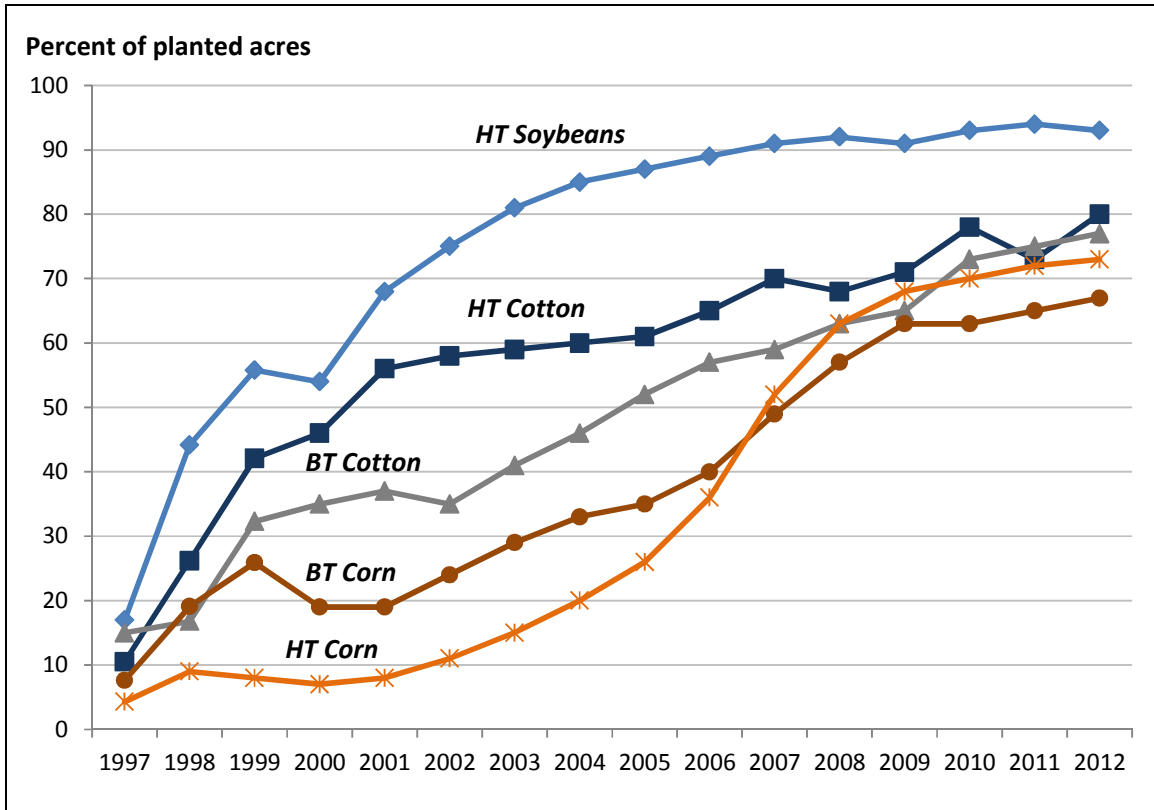
⁵ Because *Bt* is a natural occurring pesticide, it can be used under certain conditions on organically produced plants. Its incorporation into GE commodities concerns some organic producers because of the risk of creating *Bt* tolerant pests thereby decreasing the utility of *Bt* to organic farming operations.

Table I. Global Area of Biotech Crops by Country in 2013

Rank	Country	Area (million acres)	Area (million hectares)	Crops
1	United States	173.2	70.1	Corn, soybeans, cotton, canola, sugar beets, alfalfa, papaya, squash
2	Brazil	99.6	40.3	Soybeans, corn, cotton
3	Argentina	60.3	24.4	Soybeans, corn, cotton
4	Canada	27.2	11.0	Soybeans, corn, cotton
5	India	26.7	10.8	Cotton, papaya, soybeans, sugar beets
6	China	10.4	4.2	Cotton, papaya, poplar, tomato, sweet peppers
7	Paraguay	8.9	3.6	Soybeans
8	South Africa	7.2	2.9	Cotton
9	Pakistan	6.9	2.8	Corn, soybeans, cotton
10	Uruguay	3.7	1.5	Soybeans, corn
11	Bolivia	2.5	1.0	Soybeans
12	Philippines	2.0	0.8	Cotton, corn
13	Australia	1.5	0.6	Corn
14	Burkina Faso	1.3	0.5	Cotton
15	Myanmar	0.74	0.3	Cotton
16	Spain	0.25	0.1	Cotton, soybeans
17	Mexico	0.25	0.1	Corn
18	Colombia	0.25	0.1	Cotton
19	Sudan	0.25	0.1	Cotton
20	Chile	<0.25	<0.1	Corn., soybeans, canola
21	Honduras	<0.25	<0.1	Corn
22	Portugal	<0.25	<0.1	Corn
23	Cuba	<0.25	<0.1	Corn
24	Czech Republic	<0.25	<0.1	Corn, potatoes
25	Costa Rica	<0.25	<0.1	Cotton, soybeans
26	Romania	<0.25	<0.1	Corn
27	Slovakia	<0.25	<0.1	Corn
	TOTAL	432.9	175.2	

Source: Clive James, International Service for the Acquisition of Agri-Biotech Applications, 2013. Summary report available at <http://www.isaaa.org/resources/publications/briefs/46/executivesummary/default.asp>.

Figure I. Adoption of Genetically Engineered Crops in the United States, 1997-2013



Source: USDA Economic Research Service, "Adoption of Genetically Engineered Crops in the U.S."

Notes: Data for each crop also includes more recently developed varieties engineered with both herbicide tolerance (HT) and pest resistance traits (Bt). These multiple-trait plants are called "stacked trait" varieties.

Table 2. U.S. Acreage in Major GE Crops, 1996 and 2008-2015
(acres in millions)

	Soybeans		Upland Cotton (UC)		Corn	
	Acres	% of all soy planted	Acres	% of all UC planted	Acres	% of all corn planted
1996	4.2	7	2.2	17	2.9	4
2008	68.6	92	7.7	86	69.9	80
2009	70.5	91	7.9	88	73.9	85
2010	73.3	93	9.9	93	75.6	86
2011	70.5	94	12.9	90	83.1	88
2012	70.7	93	11.6	94	88.1	88
2013	71.2	93	9.8	90	91.8	90
2014	78.7	94	10.4	96	84.2	93
2015	80.0	94	8.3	94	81.7	92

Source: USDA-NASS. *Acreage Report*, June 2013.

Other crops approved for commercialization include varieties of flax, papaya, potatoes, radicchio, canola, rice, squash, alfalfa, sugar beets, and tomatoes. Some of these crops are not commercialized or not widely planted. For example, the biotechnology firm 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 peaked a decade ago at 2%-3% of the market; they were discontinued by the seed developer in 2001, mainly after several fast food and snack food companies declined to buy them. Varieties of GE wheat and rice, as well as flax and radicchio, have received regulatory approval but have not been commercially marketed (and/or research has been discontinued), presumably due largely to perceived producer or consumer unease with them. Other crops, such as GE sugar beets, GE canola, and GE alfalfa are widely planted.

In contrast to abandoning certain approved GE products, a variety of white GE corn is now used in tortilla making after initial resistance by food processors. Herbicide resistant GE sugar beets were only planted in large acreage in the 2008 crop year. While commercially available since 2000, Western beet growers did not plant them because sugar-using food companies (e.g., Hershey, Mars) and beet sugar industry groups (e.g., American Crystal Sugar) balked at the idea of GE beets, thinking that consumers would be opposed. That opposition had subsided to the point that GE sugar beets constituted nearly 95% of the sugar beet crop by 2009.⁶ Nonetheless, the Center for Food Safety filed suit in January 2008 challenging APHIS's deregulation of GE sugar beets arguing that wind-pollinated GE sugar beets will inevitably cross-pollinate with related crops being grown in proximity, contaminating conventional sugar beets and organic chard and table beet crops.⁷ (See discussion of the sugar beet legal challenge below).

Between 1987 and 2005, APHIS had approved more than 10,700 applications to conduct field tests of various GE crop varieties (out of 11,600 received from companies and other researchers), which the USDA characterized as "a useful indicator of R&D efforts on crop biotechnology." Over 5,000 applications were approved for corn alone, followed by soybeans, potatoes, cotton, tomatoes, and wheat. More than 6,700 applications were for HT and insect resistant varieties; the others were to test product quality, virus or fungal resistance, or agronomic (e.g., drought resistance) properties.⁸ By 2013, APHIS had approved more than 14,200 field trials of GE plants, most of which continued to be crop plants bearing genes conferring resistance to certain insects or tolerance to certain herbicides.

Animal Products

Fewer animal-based GE products are commercially available, notably excepting 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

⁶ Some of the reduced public opposition to the GE beets may be based on the fact that sugar crystals do not contain any remnants of the GE modified protein and, thus, could pose no dietary risk.

⁷ See CRS Report R41395, *Deregulating Genetically Engineered Alfalfa and Sugar Beets: Legal and Administrative Responses*, by Tadlock Cowan and Kristina Alexander. The legal challenge seeking an injunction against was filed in the U.S. District Court for the Northern District of California and also includes the Sierra Club and the Organic Seed Alliance as plaintiffs. The original court filing may be accessed at <http://www.centerforfoodsafety.org/pubs/Final%20Complaint.pdf>.

⁸ ERS, *The First Decade of Genetically Engineered Crops in the United States*. April, 2006. <http://www.ers.usda.gov/publications/eib11/eib11.pdf>.

can be produced in greater quantities through genetic engineering. The GE version of BST (rBST) was first approved by the U.S. Food and Drug Administration (FDA) in 1993. Reports suggest that more than 30% of all U.S. dairy cows are administered BST to boost milk production (by an estimated 10%-15%).⁹ Several other emerging animal biotechnologies, while not yet commercialized, are believed by researchers to hold great promise (see “Future GE Applications,” below).¹⁰ In February 2009, FDA approved the first product from a transgenic animal, an anti-clotting protein derived from the milk of transgenic goats.¹¹ The animals are genetically engineered to produce a recombinant human antithrombin III protein in their milk.¹² A Netherlands-based biotechnology firm also announced plans to seek U.S. and European approval in 2009 for Rhucin, made from a human protein purified from the milk of genetically engineered rabbits. The protein, C1 esterase inhibitor, helps control inflammation caused by hereditary angioedema. The FDA denied approval of the protein in February 2011, stating that the Biologics License Application was not sufficiently complete to enable a medical review.

In August 2010, the FDA announced that it had begun the approval process of a GE salmon—called AquaAdvantage Atlantic Salmon—developed by the Massachusetts biotechnology firm AquaBounty. The GE salmon would be the first genetically engineered animal approved for human consumption and commercial-level farming. The GE salmon has been engineered with a gene from the ocean eelpout that permits the salmon to grow at approximately twice the rate of a traditional Atlantic salmon. The GE salmon also contains a growth hormone from the Chinook salmon. FDA held a public comment period and a hearing on labeling for the transgenic salmon in September 2011. While the agency has stated that the salmon poses no threats to human health, FDA officials are undecided as to whether they would require any product labeling. Environmental issues associated with potential escape of the GE salmon into the wild were also considered in the Environmental Assessment released to the public in December 2012.¹³ (See further discussion on FDA’s review of GE salmon below.)

⁹ Japan, Australia, Canada, New Zealand, and 27 European countries remain rBST free. Milk containing rBST has also fallen out of favor in some places in the United States. Wal-Mart, the largest grocery retail outlet in the United States, has a private label milk (Great Value Milk) that is rBST free. Kroger completed a phase-out of rBST milk in February 2008. Safeway switched to rBST free milk in its private line, although it continues to sell other rBST milk. Starbucks began using only rBST free milk in January 2008. In August 2008, Monsanto, the developer of rBST, sold its Posilac trademarked rBST to Eli Lilly, although Monsanto retains some financial interest in rBST marketed by Eli Lilly’s subsidiary, Elanco.

¹⁰ Also see CRS Report RL33334, *Biotechnology in Animal Agriculture: Status and Current Issues*, by Tadlock Cowan.

¹¹ “FDA approves drug product from transgenic goats.” *Food Chemical News*, February 9, 2009.

¹² In September 2008, APHIS announced a request for public comment and technical empirical data concerning ongoing and future research on genetically engineered animals.

¹³ See CRS Report R43518, *Genetically Engineered Salmon*, by Harold F. Upton and Tadlock Cowan.

U.S. Food Products Containing GE Crops¹⁴

An estimated 65%-70% of all processed U.S. foods likely contain some GE material. That is largely because two such crops (corn and soybeans, where farmers have widely adopted GE varieties) are used in many different processed foods. In the United States, biotechnology regulations do not require segregation or labeling of GE crops and foods, as 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. A GE-salmon, currently under FDA review, has been determined to be substantially equivalent to non-GE salmon, and could be approved for human consumption (see discussion below).

As noted earlier, because most other government-approved GE crops are not being grown commercially, few other GE-derived foods are currently reaching consumers. This could change in the future as more GE traits are introduced into plants to appeal to consumers, as opposed to the current emphasis on GE traits that are attractive to commodity producers (e.g., herbicide tolerance, pest resistance). For example, a GE variety of table corn developed by Monsanto has been commercialized, although it has not yet shown to be widely accepted by consumers.

Analysts have pointed out that some farmers remain wary of planting GE crop varieties because their customers may be worried about their safety, although as the case of sugar beets noted above suggests, public opposition to GE products in processed food may be declining. Biotechnology supporters contend that safety concerns are unfounded because scientific reviews have found no credible evidence that GE crop varieties are unsafe for human consumption.

Future GE Applications¹⁵

“Input” Traits

For farmers, new insect-resistant and herbicide-tolerant GE varieties are under development or have been developed for other crops besides corn, cotton, and soybeans. These include wheat and

¹⁴ Sources include Cornell University, Genetically Engineered Organisms Public Issues Education Project (GEO-PIE), at <http://www.geo-pie.cornell.edu/crops/eating.html>, accessed on February 3, 2009; USDA, APHIS, Petitions of Nonregulated Status Granted or Pending by APHIS, at http://www.aphis.usda.gov/brs/not_reg.html and Colorado State University, *Transgenic Crops: An Introduction and Resource Guide*. The latter report is available at <http://www.colostate.edu/programs/lifesciences/TransgenicCrops/index.html>. The site is not regularly maintained but archived materials are available through 2004.

¹⁵ Sources include “Review of Agricultural Biotechnology,” hearing before the Subcommittee on Conservation, Credit, Rural Development, and Research of the U.S. House Committee on Agriculture, June 23, 2004 (Serial No. 108-34); BIO; Colorado State University; and ERS, *Economic Issues in Agricultural Biotechnology* (AIB-762), February 2001 (table, p. 19), at <http://www.ers.usda.gov/publications/aib762/>; and *The First Decade of Genetically Engineered Crops in the United States*.

rice (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. In animal agriculture, pigs have been engineered for increased sow milk output to produce faster-growing piglets. GE cattle also have been developed to resist the bacterium that causes mastitis. APHIS approved field trials in June 2007 for a transgenic sunflower with a carp growth hormone inserted. The GE sunflower would be used in aquaculture feed for farm raised shrimp. Currently awaiting government approval for food use is a GE salmon that requires as little as half the usual time to grow to market size (see discussion below). Other such fish could follow later.¹⁶ Some GE insects are in field trials (e.g., pink bollworm) and other GE insects (e.g., medfly, apple codling moth, mosquitoes) are in testing phases.

“Output” Traits

For processors and consumers, research on a range of GE products is continuing: oilseeds low in saturated and trans 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 content to improve flavor; colored cotton; improved cotton fiber; delayed-ripening melons, bananas, strawberries, raspberries, and other produce (delayed-ripening tomatoes already are approved); and naturally decaffeinated coffee. Critics, however, point out that, although biotechnology advocates have been forecasting the adoption of various “output” traits for some time, few have actually reached the marketplace.

Other plants being developed could become “factories” for pharmaceutical compounds. The compounds would 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” discussion below). Some varieties of plants under development could also produce “bioindustrial” molecules, including plastics and polyurethane. Future transgenic livestock also might yield pharmaceuticals and/or human organ and tissue replacements. To date, none of these innovations have been commercialized.

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 regulatory principle in the U.S. biotechnology regulatory structure is that genetically engineered products should continue to be regulated according to their characteristics and unique features, not their production method—that

¹⁶ So far 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 RL32974, *Genetically Engineered Fish and Seafood*, by Rachel Borgatti and Eugene H. Buck.

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) at the Department of Health and Human Services, and the Environmental Protection Agency (EPA). The Obama Administration announced on July 2, 2015, an initiative to update the 1986 framework. In particular, the initiative would formulate a long-term strategy to ensure that the regulatory system can adequately assess any risks associated with future biotechnology products.¹⁷

Animal and Plant Health Inspection Service

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 also 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 C.F.R. 340-340.9).¹⁸ 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, or 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.

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) under the National Environmental Protection Act and has public comment periods before deciding whether to approve the developer's request for “non-regulated status.” A determination of non-regulated status ends further federal regulatory oversight of the GE plant.

¹⁷ For more detail on the White House initiative, see CRS report, Administration Initiative to Update the 1986 Coordinated Framework for Regulation of Biotechnology, by Tadlock Cowan.

¹⁸ The genus *Agrobacterium* was on the APHIS list of regulated items. In practice, DNA sequences from *Agrobacterium tumefaciens* were almost universally used in GE plant procedures. The presence of *A. tumefaciens* DNA in the resulting plant would often be enough to subject the GE plant to regulation under the PPA.

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 was considered to contain a food additive, so they did not require approval prior to marketing. However, a May 1992 FDA policy statement noted 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.¹⁹

In June 2006, FDA published new guidance under which developers of new plant varieties intended for food use—including those that are bioengineered—can provide FDA with any information about new proteins they are using in the early stages of crop development. This voluntary consultation is to occur prior to the stage of development where the new proteins might “inadvertently” enter 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 remote possibility of it containing or consisting of a new protein that might be an allergen or toxin.²⁰

On January 15, 2009, the U.S. Food and Drug Administration (FDA) released final guidance on how it is to regulate GE animals and products. FDA is to do so under its existing statutory authority and regulations. Generally, GE-derived foods, for example, are to be regulated like non-GE foods; if their nutritional composition does not differ from their conventional counterparts, they will not have to be labeled. Nonetheless, developers of GE animals and of GE-derived products must gain FDA pre-market approval.

Although animal biotechnology involves many techniques other than cloning, this latter technology has attracted widespread attention. A final risk assessment and industry guidance on the safety of meat and milk from cloned cattle, pigs, and goats and their offspring were released in January 2008 by FDA. The documents generally echoed FDA’s December 2006 draft risk assessment, which found that such products are as safe to eat as those of conventionally bred animals. The FDA also concluded that cloning poses the same risks to animal health as those found in animals created through other assisted reproductive technologies—although the frequency of such problems is higher in cloning. (Scientists stress that cloning is an assisted

¹⁹ See the FDA biotechnology website at <http://www.cfsan.fda.gov/~lrd/biocon.html#policy>.

²⁰ FDA’s Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use can be accessed at <http://www.cfsan.fda.gov/~dms/bioprgu2.html>. The guidance was issued in draft form in November 2004 and had earlier been proposed by OSTP in 2002.

reproduction technique that does not involve any transfer or alteration of genes through GE.) The agency said it was no longer asking industry to refrain voluntarily from marketing the products of cloned animals and their offspring, although USDA did ask that it be continued for products from clones (but not from the offspring of clones).²¹

Environmental Protection Agency (EPA)

EPA registers and approves 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 FFDCFA, the EPA establishes tolerances (i.e., safe levels) for pesticides in foods. Pre-commercial regulation occurs through a system of notifications for small-scale field tests or experimental use permits for larger field tests. As with 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 described here 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 guiding policy assumption since 1986 has been that biotechnology processes such as genetic engineering poses no unique or special risks; therefore the general framework demands no new laws beyond those that already govern the health, safety, efficacy, and environmental impact of more traditional production methods. A regulatory determination of “substantial equivalence” established by the general framework precludes regulatory action based on the process by which a product is grown or produced: It is the product that is regulated, not the process.

White House Initiative on Biotechnology Regulation

New biotechnology developments, continuing opposition by consumer groups and environmentalists, and perceived inadequacies of federal regulation have begun putting increased strain on the existing Coordinated Framework for Biotechnology Regulation established in 1986 (discussed above). The laws governing biotechnology regulation were written for purposes other than modern biotechnology. Moreover, with the Coordinated Framework now nearly 30 years old, the fragmentation of the existing regulatory structure governing federal biotechnology policy today, the perceived lack of public transparency, and the overall confusion that biotechnology regulation seems to engender, the Obama Administration issued a memorandum on July 2, 2015, to update the Coordinated Framework to ensure that the regulatory structure is capable of meeting any biotechnology risks in the future.²²

The memorandum observes that each of the federal agencies regulating biotechnology has developed its own regulations and guidance documents to implement its authority under current statutes, resulting in “a complex system for assessing and managing health and environmental risks of the products of biotechnology.” Moreover, since the 1992 update, advances in science and technology have “dramatically altered the biotechnology landscape.” Scientists can now identify

²¹ See CRS Report RL33334, *Biotechnology in Animal Agriculture: Status and Current Issues*, by Tadlock Cowan.

²² Memorandum may be accessed at https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf.

and alter genes in ways not known when the 1992 Coordinated Framework was published. The memorandum states that a new update to the Coordinated Framework is now needed to “facilitate the appropriate federal oversight by the regulatory system and increase transparency while continuing to provide a framework for advancing innovation.”

The memorandum initiates a process to achieve the following objectives over the next 12 months: (1) update the Coordinated Framework to clarify the agencies’ roles and responsibilities to regulate biotechnology products; (2) formulate a long-term strategy to ensure that the regulatory system can adequately assess any risks associated with future products of biotechnology while “increasing transparency and predictability and reducing unnecessary costs and burdens”; and (3) commission an external, independent analysis of the future landscape of biotechnology products.

The memorandum establishes a Biotechnology Working Group under the Emerging Technologies Interagency Policy Coordination Committee. The working group will include representatives of the White House, EPA, FDA, and USDA. After public input, the working group will update the Coordinated Framework to clarify agency responsibilities with respect to which biotechnology product areas are within the authority of each agency and, where biotechnology product areas involve multiple agencies, how agency roles relate to each other in the course of regulatory assessment.

While some agency modification of current regulations could be an outcome of the working group’s review, any proposed changes to the existing statutes that govern biotechnology regulation would require congressional action. If the working group’s review of the Coordinated Framework results in greater transparency for the public and greater predictability for the industry, the effort could help reduce the increasingly rancorous debate that has characterized the introduction of biotechnology products over the past decade.

Assessments of Current Policy

The biotechnology industry (represented by the Biotechnology Innovation Organization—BIO), prominent U.S. agricultural producer groups, and many scientific authorities continue to subscribe to the current coordinated framework described above. They cite various studies in asserting that there is no credible evidence that current GE crops have harmed the environment or human health.²³

Most scientific reports generally have concluded that current GE crops likely pose no greater risks than conventional varieties, that each GE product should be assessed on a case-by-case basis, and that the current U.S. regulatory framework remains adequate. However, reports have also suggested a number of administrative or regulatory changes that might be adopted to improve oversight.

²³ 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*.

Congress generally has been supportive of GE products, although some Members have expressed wariness about their adoption and concerns about how they are regulated. Over the past decade, legislative activity has been relatively subdued, although bills to require labeling of GE foods have been prominent in the 113th and 114th Congresses. Congress continues to fund a variety of biotechnology-related activities at USDA, primarily through regular annual appropriations. Most of the USDA spending for biotechnology related programs is for various types of research (mainly through the Department's Agricultural Research Service and the National Institute for Food and Agriculture). APHIS's estimated BRS budget for FY2015 is \$17.4 million. This was approximately \$1.4 million less than in FY2013. The CR enacted on March 26, 2013, authorizes the same amount for FY2013 as for FY2012—\$18.1 million.

Critics, including some consumer and environmental groups, 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 have argued that new legislation is needed to clarify agency roles and strengthen their regulatory authority, particularly over future novel GE applications. The increasing incidence of herbicide-resistant weeds, and the increased use of herbicides as more acreage expands with GE planting, have also suggested that future environmental effects could be different from what has occurred over the first decade or so of GE planting.

A number of agricultural organizations, while not necessarily clamoring for new laws, have expressed wariness about some new biotechnology products now awaiting approval. Among other concerns, they worry about consumer acceptance, potential difficulties exporting these varieties to countries demanding the segregation and labeling of GMOs (or outright prohibition of GMOs), and the potential for inadvertently mixing GE with non-GE crops. The 2006 discovery of an unapproved variety of GE rice in commercial U.S. rice supplies, and the 2008 discovery of an unapproved GE cotton variety harvested with an approved variety, are indicative of the problem.

The legal challenge to deregulating Monsanto's GE alfalfa also raised important concerns about the adequacy of APHIS regulatory regime. In May 2007, U.S. District Court for the Northern District of California in San Francisco held that APHIS had failed to properly consider the environmental effects of the GE alfalfa in granting approval.²⁴ A coalition of farmers, consumers, and environmentalists, led by the Center for Food Safety, filed suit in 2006 alleging that GE alfalfa could create "super weeds" resistant to herbicide, hurt production of organic dairy and beef products, and cause farmers to lose export business due to risks of contamination to natural and organic alfalfa. Perhaps more than some other GE varieties, the GE alfalfa case raised important issues about the limitations of coexistence between traditional and GE production methods. The issue of whether gene flow from GE alfalfa could permanently harm growers who did not want to adopt GE varieties case was particularly clear in this case.²⁵ The same issues also arose with

²⁴ In January 2008, APHIS announced the preparation of an environmental impact statement on GE alfalfa. See *Federal Register*, Vol. 73, No. 4, January 7, 2008: 1198-1200.

²⁵ For a discussion of the technical issues in growing GE alfalfa in proximity to non-GE alfalfa, see the following University of California-Davis study: <http://alfalfa.ucdavis.edu/2007AlfalfaConference/2007/07-96.pdf>.

respect to an application to deregulate GE sugar beets (see discussion of the GE alfalfa and sugar beet cases below).

USDA Advisory Committee Report

In late August 2006, USDA released a long-awaited status report by its Advisory Committee on Biotechnology and 21st Century Agriculture (AC21). The report covered biotech adoption and regulation, and included a discussion of the many outstanding policy issues. The AC21 report observed, for example, that “U.S. regulations are evolving slowly and many governing statutes were written before modern agricultural biotechnology was developed. That system may not be optimal to meet the needs of producers and consumers.”²⁶

Although all the AC21 members agreed on the importance of ensuring the food and feed safety of transgenic crops, they had differing views “about whether the current FDA regulatory system for transgenic crops was adequate to ensure safety and public acceptance.” Among other observations, the AC21 cited the lack of a “clear, comprehensive federal regulatory system to assess the environmental and food safety of transgenic animals before they are commercialized.” This concern is currently at the core of the approval process for GE salmon (see discussion on GE salmon below).

All sides of the debate, however, continue to agree that whatever policy course is pursued in the future, it should provide for a clear, predictable, trusted regulatory process.²⁷ In December 2011, the AC21 Group was charged by the Secretary of Agriculture to develop recommendations on the issues of liability and promoting “co-existence” among traditional, organic, and GE agriculture.²⁸ In November 2012, AC21 issued a final report recommending that USDA develop greater capacity to strengthen coexistence among different farming methods.²⁹

Views on FDA Guidance

FDA guidance on early food safety evaluations for new plant varieties (issued in June 2006; see page 10) is widely viewed as that agency’s current policy thinking on AP. The Biotechnology Industry Organization (BIO) supported the FDA guidance, noting that it “provides safety assurance, while also recognizing the fact that ‘adventitious presence’ is a natural part of plant biology, seed production, and the distribution of commodity crops.” Several food industry officials also characterized the guidance as an important step toward a science-based policy regarding low-level presence, or “adventitious presence” of GE material. However, critics such as the Center for Food Safety (CFS), a food safety and environmental advocacy organization, have

²⁶ USDA Advisory Committee on Biotechnology and 21st Century Agriculture. *Opportunities and Challenges in Agricultural Biotechnology: The Decade Ahead*. July 13, 2006. The committee consists of biotech industry, agricultural, consumer and scientific representatives. Accessed January 2009 at http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_10B?contentidonly=true&contentid=AC21Reports.xml.

²⁷ The various arguments are explored in more depth in an April 2004 Pew Initiative report, *Issues in the Regulation of Genetically Engineered Plants and Animals*. See <http://pewagbiotech.org/>.

²⁸ “Vilsack Tells AC21 Panel to ‘Lead from the Middle’ on Coexistence,” *Food Chemical News Week in Review*, December 9, 2011.

²⁹ USDA Advisory Committee on Biotechnology and 21st Century Agriculture (AC21), *Enhancing Coexistence: A Report to the Secretary of Agriculture*, November 19, 2012, http://www.usda.gov/documents/ac21_report-enhancing-coexistence.pdf.

complained that the guidance will more likely encourage “contamination” of the food supply by GE varieties rather than improve safety oversight. Moreover, the policy does not attempt to define or quantify an acceptable level, or levels, of adventitious presence.³⁰

In 2006, CFS sued FDA for allegedly failing to adopt any pre-market safety requirements for GE foods, or to require labels identifying foods containing GE material. The lawsuit sought the establishment of a mandatory, pre-market review system for all such foods.³¹ The case was subsequently dropped by agreement with the parties.

FDA continues its analysis for considering final approval for commercializing a GE salmon. FDA is reviewing the data on GE salmon under the Food, Drug, and Cosmetic Act’s New Animal Drug approval process. (21 U.S.C. 321 et seq.). Questions have been raised about the adequacy of using this regulatory protocol to address the myriad issues that approving the salmon might create. FDA issued an Environmental Assessment in December 2012 on the potential environmental effects of commercializing GE salmon. Concerns continue to be raised about FDA’s relevant environmental experience and expertise to assess the environmental impact (see discussion below on GE salmon).

APHIS Oversight

USDA’s APHIS has taken a number of actions over the past several years intended to improve its regulatory oversight (like FDA, using its current legislative authority under the Plant Protection Act). 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 the publication of more stringent permit conditions for GE-derived plants for pharmaceuticals and industrials (see “Plant-Based Pharmaceuticals from Biotechnology,” below).

In the January 23, 2004, *Federal Register*, the agency published a notice of its intent to prepare a programmatic environmental impact statement (EIS) evaluating these regulations, and requesting public comment 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 (i.e., strengthen) its environmental reviews and permit conditions for GE plants producing pharmaceuticals and industrials. APHIS also solicited comments on ways that it might ease its requirements for lower-risk products. The agency received over 3,000 comments on its proposal.

OIG Criticisms

In a December 2005 audit report, USDA’s Office of Inspector General (OIG) criticized APHIS’s current biotech regulation. Noting the approval, at that point, of more than 10,600 applications for GE tests at more than 49,300 field sites, the OIG expressed concern that “the Department’s efforts

³⁰ As reported in “FDA issues ‘adventitious presence guidance for biotech plants,” in *Food Chemical News*, June 26, 2006. See page 17 for additional discussion of the AP issue.

³¹ A copy of the lawsuit and an accompanying press release can be viewed at the CFS website at http://www.centerforfoodsafety.org/Ge_Foods_FDA_Complaint6_7_2006.cfm.

to regulate those crops have not kept pace.” Various weaknesses in the approval and inspection process “increase the risk that regulated genetically engineered organisms will inadvertently persist in the environment before they are deemed safe to grow without regulation,” the report observed.³²

More specifically, the OIG stated that APHIS lacked basic information about the field test sites that it has approved, including their precise locations; and about what becomes of the crops—including those tested for pharmaceutical or industrial uses—after testing ends. Where notifications (rather than permits) were used, APHIS did not review applicants’ containment protocols. Among other things, the OIG noted that APHIS site inspection requirements were vague and not always fulfilled by inspectors, and that the agency’s guidance for containing GE crops and seeds needed strengthening.

Responding to the audit report, APHIS stated that most of the OIG recommendations “reaffirm APHIS’ decision to create the new Biotechnology Regulatory Service (BRS) and devote greater resources toward regulating biotechnology. Most of the recommendations are in line with changes that BRS has already enforced, is currently undertaking, or plans to implement.”³³

In January 2009, the OIG released another report concluding that the department did not have an import control policy to regulate GE animals and that its import policy for GE crops could become outdated as other countries increase the number of biotechnology products.³⁴

In 2011, the OIG published an audit critical of APHIS’s controls over GE animal and insect research. The OIG report stated that APHIS had not issued regulations pertaining to the introduction, interstate movement, or field release of GE animals or insects.³⁵

The successful court challenges to APHIS’s initial deregulation of GE alfalfa and GE sugar beets based on its environmental assessments (EAs) have further raised questions about the adequacy of the agency’s environmental review process.

APHIS Regulatory Changes

In July 2007, APHIS published a draft programmatic environmental impact statement (EIS) as part of the evaluation of its regulatory structure.³⁶ In October 2008, APHIS proposed a revision of its regulations regarding the importation, interstate movement, and environmental release of certain GE organisms.³⁷ The public comment period initially was to end in November 2008, but was extended to June 2009. A subsequent issue-focused meeting on the proposed rule changes

³² USDA, OIG. *Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits*, accessed January 2009 at <http://www.usda.gov/oig/webdocs/50601-08-TE.pdf>.

³³ “BRS OIG Report Frequently Ask Questions,” which responds in more detail to the OIG criticisms. It can be viewed at http://www.aphis.usda.gov/brs/brs_oig.html.

³⁴ USDA, Office of the Inspector General, Southwest Region, *USDA Controls Over Importation of Transgenic Plants and Animals*, Report No. 50601-17-Te, December 2008.

³⁵ USDA, Office of Inspector General. *Controls Over Genetically Engineered Animal and Insect Research*, May 2011, <http://www.usda.gov/oig/webdocs/50601-16-TE.pdf>.

³⁶ The Draft EIS may be accessed at http://www.aphis.usda.gov/brs/pdf/complete_eis.pdf.

³⁷ *Federal Register*, Vol. 73, No. 197, 60009-60048, October 9, 2008.

was held in April 2009. A final rule was never published, and in March 2015, APHIS withdrew the proposed regulatory changes.

Although now withdrawn, the proposed regulatory changes would have been the first since the regulations were established in 1987. The proposed changes would have addressed a number of issues that both proponents and opponents of GE products have raised about APHIS's regulatory process.

Under current regulations, a GE organism is a regulated article if it is a plant pest or there is reason to believe it might become a plant pest. In the notification of the proposed regulation revisions, APHIS stated that technological advances have led to the possibility of developing GE organisms that do not fit within the plant pest definition, but still might cause environmental or other physical harm by the definition of a plant pest under the Plant Protection Act. According to APHIS, the new regulations would have subjected a GE organism to oversight based upon known plant pest and noxious weed risks of the parent organisms, or based upon the traits of the GE organism, or based upon the possibility of unknown risks as a plant pest or noxious weed when insufficient information is available.³⁸ The proposed regulations would also have included regulating GE seedlings, tubers, cuttings, bulbs, spores, etc.

APHIS had proposed to reorganize the regulations for permit applications and evaluation procedures by discontinuing its notification procedure, while retaining the permitting procedure. The proposed regulations would have established a new petition procedure for APHIS to approve a new conditional exemption from the permit requirements, which is currently done by amending regulations.

For environmental releases, APHIS would have developed a permitting system based on two primary risk-related factors: (1) the ability of the unmodified recipient plant species to persist in the wild and (2) the potential of the GE trait to cause harm based on the plant pest and noxious weed definitions. With respect to the persistence factor, APHIS had proposed grouping plant species into four risk categories based on the risk of persistence of the plant or its progeny in the environment without human intervention. Four similar risk categories were also proposed for potential harm caused by the GE trait. Other proposed regulatory changes included remediation authorities for failure to comply with regulations, and agency response to low-level presence (LLP) of regulated plant materials in commercial seeds or grain that may be used for food or feed.

APHIS received over 74,000 comments on the proposed changes. Reactions to the proposed regulatory revisions were mixed, and were, in part, the reason APHIS extended the original comment period and held public meetings on some of the more controversial proposed changes (e.g., scope of the regulatory changes, incorporation of the Plant Protection Act's noxious weed authority into APHIS's regulatory authority, revision of the permit process, and environmental release of GE crops that produce pharmaceutical and industrial compounds). In their comments on the proposed rule changes, biotechnology industry representatives and nongovernmental organizations expressed opposition to the expansion of APHIS authority to regulate GE organisms if they posed a risk as a noxious weed. The industry representatives also took issue with the proposal to take a voluntary approach to GE regulation, arguing that it could have a

³⁸ Only a small fraction of weeds are considered to be noxious weeds. APHIS currently lists 98 aquatic, terrestrial, or parasitic plant taxa as noxious weeds.

significant impact on international trade.³⁹ The Center for Food Safety (CFS) denounced the proposals, stating that “these proposed regulations may set in motion a process that would put many GE crops completely beyond the bounds of regulation.” CFS said that its biggest concern is that the proposed rules remove established criteria in determining the very scope of regulation. In a similar response, the Union of Concerned Scientists denounced the proposed rules for failing to adequately protect the U.S. food supply from potential contamination from biopharm crops through cross-pollination or seed mixing between biopharm food crops and those food crops intended for consumption.⁴⁰ In March 2009, more than 80 advocacy groups signed a letter urging Secretary of Agriculture Tom Vilsack to halt approving GE crops until the agency changes its regulatory approach to biotechnology.

APHIS has not indicated what its future plans are with regard to the proposed revisions. Concerns about the adequacy of APHIS regulatory procedures may be addressed in the recently announced (July 2, 2015) initiative to update the 1986 General Framework for Biotechnology Regulation.

Environmental Assessments of GE Plants and Animals

After a GE variety is approved for release into the environment on a test basis, the owner of the GE seed generally petitions APHIS for “deregulated status” of the particular GE “event” that has been approved. This is the last step to full-scale commercialization of the GE plant. Once the GE plant is deregulated, it is no longer subject to APHIS regulation under the PPA (7 C.F.R. Part 340). A significant step in the deregulation process involves an assessment of the plant’s environmental impact. The National Environmental Policy Act (NEPA) requires federal agencies to prepare a detailed Environmental Impact Statement (EIS) for all “major Federal actions significantly affecting the quality of the human environment.”⁴¹ NEPA requires that environmental analyses use an interdisciplinary approach “which will insure the integrated use of the natural and social sciences and the environmental design arts in planning and in decisionmaking.”⁴²

The regulations governing the finding of a significant effect are promulgated by the Council on Environmental Quality (CEQ). When an EIS is not categorically required, an agency may determine, from the data already at hand, that the environmental impacts are not significant enough to warrant an EIS. This judgment permits the agency initially to prepare an Environmental Assessment (EA) rather than the lengthier and more detailed EIS. An EA is a public document that briefly provides the basis for determining whether to move forward with an EIS or to make a finding of no significant impact (FONSI).

Several cases over the past several years have raised issues about the adequacy of APHIS’s regulatory structure in moving to deregulate a GE plant. APHIS on several occasions has issued a FONSI on the basis of an EA and deregulated a GE plant, only to have that decision decisively

³⁹ “Industry, NGOs, strongly oppose proposed USDA biotech regulation.” *Inside U.S. Trade*, October 17, 2008.

⁴⁰ Food Chemical News. “USDA Proposed Biotech Regulatory Overhaul to Mixed Reviews,” vol. 50, no. 34, October 13, 2008.

⁴¹ 42 U.S.C. §4332(2)(C).

⁴² 42 U.S.C. §4332(2)(A).

challenged in court. In April 2011, APHIS announced that it was soliciting letters of interest to participate in its National Environmental Policy Act pilot project to explore ways of improving the EAs and EISs to mitigate the increasingly contentious deregulation process.⁴³

GE Alfalfa

A U.S. District Court held in February 2007 that APHIS failed to properly consider the environmental effects of Monsanto's GE alfalfa. The court vacated APHIS's June 2005 decision deregulating GE alfalfa on the basis of an EA. In March 2007, the District Court of the Northern District of California issued a preliminary injunction, and in May 2007 the court issued a permanent injunction against planting or selling Monsanto's line of GE alfalfa until a final EIS was prepared. In June 2009, the Ninth Circuit Court of Appeals affirmed the illegality of APHIS's approval of deregulated status for Monsanto's GE alfalfa.

Not only did the GE alfalfa have environmental implications for domestic producers, the suit, brought by a coalition of farmers and the Center for Food Safety, also cited the concerns of farmers who sell to export markets.⁴⁴ Japan and South Korea, America's most important alfalfa customers, have warned that they will discontinue imports of U.S. alfalfa if a GE variety is grown in this country. U.S. alfalfa exports total nearly \$480 million per year, with about 75% going to Japan. The court disagreed with USDA's assertion that exports to Japan would not be harmed by the deregulation of GE alfalfa.

On January 12, 2010, APHIS announced that the draft environmental impact statement concerning Monsanto and Forage Genetics International lines of GE alfalfa was available for public comment.⁴⁵ A series of public meetings in several cities was also held on February 3, 4, and 9, 2010. After a three-week extension for comments, the comment period ended March 3, 2010. The final EIS, which addressed the nearly 135,000 comments received, was published December 16, 2010.⁴⁶

The court's decision to enjoin planting GE alfalfa until the final EIS was published was appealed to the Supreme Court.⁴⁷ The Court agreed to hear that case on January 15, 2010, and on April 27, 2010, the Court heard oral arguments. Monsanto's appeal concerned whether the federal courts in the Ninth Circuit properly applied and interpreted the injunction standard in NEPA cases when they permanently enjoined planting until the EIS was complete. On June 21, 2010, in a 7-1 opinion written by Justice Alito, the Supreme Court reversed the injunction, saying that the Ninth Court had overreached itself procedurally in halting the plantings.

Based in part on the comments received, the final EIS considered a rule for "partial deregulation," a modification of existing planting restrictions for regulated organisms, perhaps limiting planting to specific geographic areas under controlled procedures. Secretary Vilsack had indicated in

⁴³ 76 *Federal Register* 19309 (April 7, 2011).

⁴⁴ Alfalfa is an open-pollinated plant. Non-GE alfalfa would be at risk of being pollinated through windborne pollen from GE alfalfa. The impact on non-GE alfalfa growers was deemed a significant environmental impact.

⁴⁵ The draft EIS may be downloaded at APHIS's website: http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gealfalfa_deis.pdf.

⁴⁶ The final EIS on GE alfalfa may be accessed at http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gt_alfalfa%20_feis.pdf.

⁴⁷ *Monsanto Co. v. Geerston Seed Farms*, 130 S. Ct. 2743 (2010)

earlier comments that he was considering a policy of “co-existence,” one where conventional, GE, and organic production could all flourish. On January 27, 2011, however, the Secretary announced that, under the authority of the Plant Protection Act, he was granting GE alfalfa full deregulation.

GE Sugar Beets

In February 2005, APHIS issued a finding of no significant impact on the environment (FONSI) for the cultivation and agricultural use of a Monsanto-developed variety of glyphosate-tolerant sugar beet (Event H7-1).⁴⁸ The ruling meant that GE beets were no longer a regulated article under 7 C.F.R. Part 340. The GE beets were first planted in the western United States in spring 2008. Similar to the response to APHIS’s FONSI regarding GE alfalfa, a case was filed in U.S. District Court for the Northern District of California by the Center for Food Safety and Earthjustice in January 2008 representing a coalition of farmers and consumers.⁴⁹ As with the alfalfa case, the plaintiffs claimed that APHIS had violated NEPA by not conducting an EIS before granting the GE beets deregulated status.

Sugar beet seed is grown primarily in Oregon’s Willamette Valley. The area is also an important seed growing area for crops closely related to sugar beet (e.g., chard and table beets). Sugar beets, like alfalfa, are wind pollinated. Eventually, GE beets would cross-pollinate with related crops. This would have significant economic impacts on organic producers of Swiss chard and table beets being grown in the same areas as the GE beets. In his September 2009 order requiring APHIS to prepare an EIS, the presiding judge determined that “the potential elimination of a farmer’s choice to grow non-genetically engineered crops, or a consumer’s choice to eat non-genetically engineered food, [is] an action that potentially eliminates or reduces the availability of a particular plant [and] has a significant effect on the human environment.” The court concluded that there was no support in the record for APHIS’s conclusion of no significant impact.

At a meeting in December 2009, the U.S. District Court for the Northern District of California set out a schedule and process for determining the remedies regarding the sugar beets. The process did not interfere with the planting of the beets in 2010. Oral arguments were heard on June 11, 2010. On August 13, 2010, the court revisited the issue of whether to issue an injunction, as had been done with GE alfalfa. Given that the Supreme Court had just ruled that the injunction for GE alfalfa was improper, the Ninth Court vacated APHIS’s deregulation decision without enjoining planting. While avoiding the “drastic remedy,” as the Supreme Court described the injunction of GE alfalfa, the practical effect of vacating APHIS’s GE sugar beet deregulation decision is that planting GE sugar beet is now effectively halted. Because nearly 95% of sugar beets planted in 2009/2010 are the GE variety, this raised questions about the availability of non-GE sugar beet seed for the 2011 planting season.

APHIS subsequently issued four permits authorizing seedling (“steckling”) production that would not permit flowering without additional authorization. In November 2010, a judge ordered the seedlings pulled from the ground. The Ninth Circuit Court temporarily halted that decision in December 2010, ultimately holding in February 2011 that the seedlings did not have to be

⁴⁸ Monsanto Company and KWS SAAT AG Petition 03-323-01p for Determination of Nonregulated Status for Roundup-Ready Sugar Beet Event H7-1. USDA/APHIS Environmental Assessment and Finding of No Significant Impact, February 2005. Document available at http://www.aphis.usda.gov/brs/aphisdocs2/04_11001p_com.pdf.

⁴⁹ *Center for Food Safety v. Vilsack*, No. C08-00484 JSW (N.D. Cal. 2009).

removed. The EIS was published in June 2012, and APHIS deregulated GE sugar beets for *root* production in July 2012, although full regulated status for sugar beet *seed* crop production was in effect until December 31, 2012. APHIS issued an EA and a FONSI for this action.⁵⁰ APHIS fully deregulated GE sugar beets in July 2012.

GE Ethanol Corn

In June 2009, APHIS filed a request for additional comments on a petition by Syngenta Seeds, Inc. to deregulate Alpha-Amylase Maize Event 3272 (marketed under the name “Enogen”).⁵¹ This variety of corn is genetically engineered to contain high levels of a heat-resistant and acid-tolerant enzyme derived from marine microorganisms. APHIS has prepared a draft EA and plant pest risk assessment for review and comment. Most relevant in this request is that it is the first request to deregulate a GE plant variety that is intended solely for the use in the production of ethanol. The corn variety is not cultivated for human consumption or livestock feed, but rather is grown to improve the efficiency of converting corn starch to industrial ethanol. A concern is that there is inadequate scientific data or documentation to evaluate the possible impacts on food and feed should this variety be commingled with commodity corn supplies.⁵²

In February 2011, APHIS announced that it was deregulating GE ethanol corn. Syngenta Seeds said the seed is available for 2011 planting for a small number of growers. By 2012, the seed was available for large-scale commercial planting under contracted, closed production.⁵³ The Center for Food Safety, the Union of Concerned Scientists, and other groups were critical of APHIS’s decision, citing concerns about contamination and its potential to cause allergies. Trade groups and companies involved in milling, refining, and exporting corn, including the Corn Refiners Association, National Grain and Feed Association, North American Export Grain Association, and North American Millers’ Association, also opposed APHIS’s approval of this GE corn, citing concerns that its engineered protein could damage food products such as breakfast cereals and snack foods and disrupt exports of such products.

GE Eucalyptus

APHIS granted a permit in May 2010 to import a eucalyptus tree that is genetically engineered for “cold-tolerance.” If commercialized, the hybrid eucalyptus would be used for pulp and biofuel production. Eucalyptus is a fast-growing tree that dominates tropical timber plantations. It is not native to the United States and has become invasive in some places. The permit was issued to ArborGen, LLC. ArborGen is a joint initiative of International Paper, MeadWestvaco, and Rubicon. The permit authorizes planting and flowering on 28 sites across seven southern states (Alabama, Florida, Georgia, Louisiana, Mississippi, South Carolina, and Texas). The Center for

⁵⁰ For a detailed examination of the GE sugar beet case, see CRS Report R41395, *Deregulating Genetically Engineered Alfalfa and Sugar Beets: Legal and Administrative Responses*, by Tadlock Cowan and Kristina Alexander.

⁵¹ *Federal Register*, vol. 74, 106, June 4, 2009, http://www.aphis.usda.gov/brs/fedregister/BRS_20090604b.pdf.

⁵² In February 2008, APHIS, EPA, and FDA announced a coordinated response to a notification by Dow AgroSciences that the company had detected an unregistered GE pesticide product known as a plant-incorporated protectant (PIP) in three lines of its commercial hybrid seed lines. Concerns that plant-derived pharmaceutical and industrial products could enter the food and feed system are based on difficulties in ensuring that unapproved plants are not commingled with approved varieties.

⁵³ “USDA Fully Deregulates GE “Ethanol Corn,” *Food Safety News*, February 12, 2011, <http://www.foodsafetynews.com/2011/02/usda-fully-deregulates-ethanol-corn/>.

Biological Diversity and other organizations have sued to set aside the approval on grounds that the potential environmental impacts have not been properly evaluated, nor has APHIS complied with congressional mandates enacted in the 2008 farm bill (P.L. 110-246) requiring more rigorous oversight of field testing for GE organisms.⁵⁴

GE Apples

A British Columbian biotechnology firm, Okanagan Specialty Fruits, petitioned APHIS in December 2010 to approve a GE variety of apple, the “Arctic Apple.” The apple has been genetically modified to resist turning brown after being sliced. In a letter to Secretary of Agriculture Tom Vilsack, the Northwest Horticultural Society has asked that APHIS reject the request, citing concerns about adverse marketing should the apples be permitted into the general market. Two public comment periods on the deregulation of the Arctic Apple drew more than 175,000 comments, almost all opposed to approval. In February 2015, APHIS deregulated the GE apple. The biotechnology firm is currently engaged in a voluntary food assessment consultation with FDA.

GE Salmon

On August 25, 2010, FDA announced that it had begun the regulatory approval process of a GE salmon—called AquaAdvantage Atlantic Salmon—developed by the Massachusetts biotechnology firm AquaBounty. The GE salmon has been engineered with a gene from the ocean eelpout that permits the salmon to grow at approximately twice the rate of a traditional Atlantic salmon. The GE salmon also contains a growth hormone from the Chinook salmon. FDA also announced at the same time that it would hold a public comment period and a hearing on labeling for the transgenic salmon. While the agency has stated that the salmon poses no threats to human health, FDA officials are undecided as to whether they would require any product labeling. Environmental issues associated with potential escape of the GE salmon into the wild are also being considered.

The GE salmon would be the first genetically engineered animal approved for human consumption and commercial-level farming. FDA scientists stated in a briefing document that the GE salmon is safe for human consumption and poses no risk to the environment. On September 19 and 20, 2010, FDA held a Veterinary Medicine Advisory Committee (VMAC) meeting on science-based issues surrounding the application for approval of the GE salmon. The meetings were open to the public. Committee members heard from FDA about GE animals generally and about the agency’s evaluation and approval process. On the second day, FDA presented data supporting AquaBounty’s claim that the fish grew faster than conventionally bred Atlantic salmon.

The VMAC is currently reviewing FDA’s recommendations and public comments. FDA released its Environmental Assessment (EA) in December 2012. The comment period on the EA ended April 26, 2013. The VMAC is advising FDA officials whether to approve the salmon and make recommendations regarding the need to label the fish, although FDA has already indicated that it

⁵⁴ *Center for Biological Diversity, et. al v. Animal and Plant Health Inspection Service*. Case 2:10-cv-14175-KMM. Document available at http://www.biologicaldiversity.org/programs/public_lands/forests/pdfs/Eucalyptus-Complaint-signed.pdf.

is safe for human consumption and would not require labeling. FDA's position is that labeling should not suggest that GE foods are different from other foods. On May 10, 2011, the California Assembly Health Committee passed AB88, the Consumer's Right to Know Act, which requires the labeling of all GE salmon entering or sold in the state. In March 2013, grocery chains Whole Foods Market, Trader Joe's, and Aldi stated that they would not sell the GE salmon created by AquaBounty Technologies.

FDA is evaluating the GE salmon under its New Animal Drug Application Process (NADA), because the recombinant DNA construct that is intended to change the fish meets the definition of a drug as defined under the Federal Food, Drug, and Cosmetic Act. This means that much of the supporting data AquaBounty supplies to FDA is confidential. A coalition of 31 organizations and restaurant chefs is demanding that FDA deny approval. Various environmental organizations are concerned that the GE salmon could escape from fish farms and threaten the wild salmon population. AquaBounty, however, says it would encourage producers to grow the GE Atlantic salmon only at in-land fish farms.

Congressional Members have raised concerns about FDA's approval process. In a September 29, 2010, letter, 39 Members of both the House and Senate requested that FDA Commissioner Margaret Hamburg halt the approval process. The letter stated that the Members had "serious concerns" regarding the process for review and approval of the GE salmon. In particular, the letter stated that the FDA process was "inadequate" and "sets a dangerous precedent: the environmental review is flawed and the consumer's right to know ignored." In addition to concerns about the adequacy of the data supporting the safety for human consumption of the GE salmon, Members also expressed their concerns that the GE fish could pose serious risks to the wild population of fish, such as Atlantic, Coho, and Chinook salmon. Although the company intends to raise the fish at an egg hatchery facility on Prince Edward Island, Canada, and the GE salmon would be sterile, Members expressed their concern that the GE fish could pose threats to the remaining wild Atlantic salmon. AquaBounty acknowledged that 5% of the fish could remain fertile and potentially mate with wild populations. A coalition of 53 consumer and environmental organizations and businesses endorsed the letter from House and Senate Members. The Center for Food Safety, a central actor in opposing federal regulatory standards for biotechnology, and a coalition of allied groups also submitted nearly 172,000 comments from individuals opposing the approval.

Biotechnology and Global Trade Concerns

The U.S. approach to 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 standards continue to evolve. Incidents, such as those discussed below, have disrupted U.S. exports and contributed to trade tensions.⁵⁵

⁵⁵ See also CRS Report RL31970, *U.S. Agricultural Biotechnology in Global Markets: An Introduction*, by Geoffrey S. Becker and Charles E. Hanrahan. This report 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 (continued...)

GE Rice

Although several GE varieties of rice have been approved for commercial use (“deregulated,” in regulatory parlance), none have been marketed, although they have been planted on test plots in the United States. In August 2006, the Secretary of Agriculture announced that “trace amounts” of an unapproved variety of GE rice had been found in samples of the 2005 crop of U.S. long grain rice. The Secretary and other USDA officials sought to reassure the rice trade and consumers that the findings posed no human health, food safety, or environmental concerns.

Owner Bayer CropScience had not asked APHIS to deregulate this particular line, called LLRICE601, which had been field tested between 1998 and 2001. Two other Bayer GE rice varieties, known as LLRICE62 and LLRICE06, had received commercial approval but have not been commercialized, USDA stated. Also, “[t]he protein in LLRICE601 is approved for use in other products” and “has been repeatedly and thoroughly scientifically reviewed and used safely in food and feed, cultivation, import and breeding in the United States, as well as nearly a dozen other countries around the world.”⁵⁶

Nonetheless, the discovery unsettled rice markets and rekindled longtime criticisms of U.S. biotechnology regulatory policies. The U.S. rice crop is valued at nearly \$2 billion annually. Exports represent approximately one-half or more of U.S. rice production annually on a volume basis, of which about 80% is long grain (the type in which GE material was detected), according to USDA statistics. Although the United States produces only about 1.5%-2% of the world rice crop, it was the fourth-leading exporter (behind Thailand, Vietnam, and India), with more than 13% of world market share in 2005.

Of the 4.4 million metric tons (MMT) exported in 2005, Mexico was by far the leading buyer, at 753,000 MT. Japan was the second-leading market at nearly 424,000 MT. Various Central American and Caribbean countries took a total of 1.4 MMT; Iraq, 310,000 MT; and European Union (EU) countries, a total of 306,000 MT, USDA data show. Much of the long grain crop is produced in southern U.S. states, which generally ship from Gulf ports to Latin America, the Caribbean, and Europe, for example. California grows mainly medium and short grain rice varieties, which are marketed in Asia, including Japan.

Following USDA’s notification that U.S. rice supplies had traces of GE material, September 2006 closing rice futures dropped from \$9.70 per cwt. (100 pounds) on August 18, closing at \$8.99 per cwt. on August 25, 2005. (One year ago, the closing price was less than \$7.00 per cwt.) The European Union (EU), which bought 279,300 MT of U.S. long grain rice in 2005, reacted by adopting a measure requiring all such shipments to be tested and certified as free of LLRICE601. Japan has indicated that it was suspending shipments of U.S. long grain rice although, as noted, most U.S. rice exports there are short and medium grain.

(...continued)

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; and CRS Report RL31568, *Plants, Patents, and Seed Innovation in the Agricultural Industry*, by John R. Thomas.

⁵⁶ “Statement by Agriculture Secretary Mike Johanns Regarding Genetically Engineered Rice,” August 18, 2006. LL stands for “Liberty Link,” a trademark name for the herbicide glyphosate. LL crops are engineered to tolerate the herbicide, making for more effective weed control.

According to a statement by the producer cooperative Riceland Foods, Inc., of Stuttgart, AR, the GE material was initially discovered by one of its export customers in January 2006. Riceland then sent a sample to a U.S. laboratory, which confirmed the Bayer GE trait, which is known to be present in (and approved for) corn, soybeans, canola, and cotton. Riceland said it collected samples from several storage locations in May 2006 and found positive results that were “geographically dispersed and random throughout the rice-growing area.” Bayer was notified in early June, and its tests confirmed the presence of the GE trait in the equivalent of 6 per 10,000 kernels (0.06%).⁵⁷

In August 2006, USDA officials offered few additional details about the cause or extent of the problem. They indicated that they had not been informed by Bayer of the discovery until July 31, after which the department began its own investigation, they stated. Among other actions, USDA said that APHIS was now moving to approve (i.e., deregulate) LLRICE601. Also, USDA’s Grain Inspection, Packers, and Stockyards Administration (GIPSA) has verified the use of two standardized tests that can test for the GE protein in rice shipments.

Consumer and environmental advocacy groups were harshly critical of APHIS and USDA, noting that officials waited three weeks to make the discovery public—and still did not know where the samples were grown or how they entered the food supply. One group, the Center for Food Safety, subsequently called for a moratorium on all new field testing permits until oversight can be improved.⁵⁸ In August 2006, rice farmers in Arkansas, Missouri, Mississippi, Louisiana, Texas, and California filed a class action lawsuit against Bayer CropScience, accusing the company of negligence in allowing unapproved genetically engineered rice to find its way into the commercial supply chain. By November 2006, APHIS declared the rice variety LLRICE601 safe for human consumption and deregulated the variety. USDA essentially declared that the new variety was similar to two Bayer varieties that had already been approved.

In July 2011, Bayer AG agreed to a \$750 million settlement with the U.S. rice farmers who had sued the company. About 11,000 farmers in Arkansas, Louisiana, Mississippi, Missouri, and Texas will divide the settlement. According to attorneys for the plaintiffs, farmers who planted rice in each of the five years from 2006 to 2010 will be eligible to receive \$310 per acre. Those who planted a specific strain of rice that was contaminated in 2006 were eligible for another \$100 per acre.

GE Wheat

Trade concerns were apparent in the debate over whether to introduce (commercialize) a variety of glyphosate/Roundup-resistant wheat. 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.

⁵⁷ Statement of Bill J. Reed, Riceland Foods’ vice president for public affairs, August 18, 2006, as quoted by the website AgWeb.com.

⁵⁸ Center for Food Safety, “Unapproved, Genetically Engineered Rice Found in Food Supply,” August 18, 2006, press release.

In early 2003, a group of U.S. wheat producers 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.⁵⁹

This resistance likely contributed to a decision by Monsanto to discontinue its efforts to win regulatory approval of a genetically modified wheat variety. Monsanto announced its decision in May 2004. 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 GE wheat to market.

While opposition to GE wheat remains strong among many U.S. trading partners, a spokesman for the joint biotechnology committee of the National Association of Wheat Growers and U.S. Wheat Associates indicated in 2007 that support for planting and exporting GE wheat was growing among some U.S. wheat producers.⁶⁰

In May 2009, wheat grower associations in the United States, Canada, and Australia issued a joint statement announcing that they intend to “work toward the goal of synchronized commercialization of biotech traits in our wheat crops.... [W]e believe it is in all of our best interests to introduce biotech wheat varieties in a coordinated fashion.”⁶¹ This joint statement produced an immediate reaction by various environmental and consumer organizations. Canada’s Farmers Union, the Organic Federation of Australia, the U.S. Organic Consumers Association, and other organizations drafted a statement opposing commercializing GE.⁶² In July, Monsanto Canada’s spokesperson stated that the future “GE wheat will not be Roundup ready.... It will have increased drought tolerance, increased yield, and improved nitrogen efficiency.”⁶³ Monsanto anticipates that it will be at least 10 years before their research and development efforts produce a commercial variety of GE wheat.

While no GE wheat has been deregulated, Monsanto, the GE wheat developer, did secure permits from APHIS to field test GE wheat in 16 states between 1998 and 2005. In May 2013, USDA announced that a variety of GE wheat had been discovered in a field in eastern Oregon. APHIS began an investigation while several U.S. trade partners (e.g., South Korea, EU) temporarily suspended new purchases. Had the presence of the non-approved wheat been widespread, serious trade impacts could have followed. A similar discovery of GE wheat in Montana was reported in September 2014.⁶⁴

⁵⁹ Sources include *Food Chemical News*, various issues; Cornell University GEO-PIE; and several news wire service reports.

⁶⁰ See http://www.gmofoodforthought.com/2007/10/time_is_right_for_biotech_whea.html.

⁶¹ The joint statement can be accessed at <http://www.wheatworld.org/userfiles/file/FINAL%20Trilateral%20Biotech%20Statement.pdf>.

⁶² *Definitive Global Rejection of Genetically Engineered Wheat*. The statement can be accessed at <http://cban.ca/Resources/Topics/GE-Crops-and-Foods-Not-on-the-Market/Wheat/Definitive-Global-Rejection-of-Genetically-Engineered-Wheat>.

⁶³ “Second Round of Fighting Begins Over Genetically Engineered Wheat,” *Digital Journal*, July 17, 2009, at <http://www.digitaljournal.com/article/276000>.

⁶⁴ See CRS Report R43100, *Unapproved Genetically Modified Wheat Discovered in Oregon and Montana: Status and Implications*, by Tadlock Cowan.

U.S.-EU Regulatory Conflicts

In May 2003, the United States, Canada, and Argentina initiated a complaint before the World Trade Organization (WTO) regarding the EU's de facto moratorium on approvals of new GE crops. U.S. agricultural interests contended that the moratorium not only blocked exports such as corn and other products to the EU, but also was fueling unwarranted concerns about the safety of agricultural biotechnology throughout the world. The United States and its allies further argued that the EU moratorium was violating 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 in March 2004 to consider the case. Although the EU effectively lifted the moratorium in May 2004 by approving a genetically engineered corn variety, the three complainants pursued the case, in part because a number of EU member states have continued to block approved biotech products. In February 2006, the WTO dispute panel, in its interim confidential report, ruled that a moratorium existed, that bans on EU-approved GE crops in six EU member countries (Austria, France, Germany, Greece, Italy, and Luxembourg) violated WTO rules, and that the EU failed to ensure that its approval procedures were conducted without "undue delay." The final ruling was circulated to the parties in May 2006 and made public in September 2006.

The dispute panel's ruling dismissed several other U.S. and co-complainant claims, and did not address such sensitive issues as whether GE products are safe or whether an EU moratorium on GE approvals continued to exist. The final ruling, among other things, directed the EU to bring its practices in line with WTO rules. It concluded that the EU had breached its commitments with respect to 21 products, including types of oilseed rape, maize, and cotton. It also said individual bans in Austria, France, Germany, Greece, Italy, and Luxembourg were illegal.

The EU initially agreed on a November 2007 deadline for compliance with the WTO dispute ruling. The parties subsequently agreed to extend the time for EU compliance with the ruling to January 2008. The EU missed this deadline in large measure. Brussels has found it hard to implement the WTO ruling because some of the 27 EU member states operate their own bans on GE crops. Individual countries (e.g., Austria, France, Greece) have prohibited the sale or cultivation of certain EU-approved varieties of GE corn (e.g., MON810, a variety produced by Monsanto). In 2008, France also initiated a temporary national moratorium on GE crops. Spain continues to dominate the EU in GE crop cultivation.

Although positive action has been slow, the United States has temporarily suspended WTO sanctions. U.S. agricultural interests, however, remain concerned that the stricter EU rules for labeling and tracing GE products will continue to discriminate against U.S. exports. If progress is not made, the issue is likely to return to the WTO's dispute settlement body. The United States could retaliate against the EU to compensate for the annual value of lost U.S. exports, royalties, and licensing fees to the EU from biotech crops. These could be levied by imposing extra tariffs on EU goods or lifting other WTO agreements regulating agriculture or health and safety.

The WTO case did not involve the EU's new "labeling and traceability" regulations, in effect as of April 2004, to require most food, feed, and processed products from GMOs to be labeled. GE-based products also must be segregated from non-GE products, with documentation. U.S. agricultural interests argue that, even if the EU regularly approves GMOs, the 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.⁶⁵ The EU, however, continues to defend its mandatory labeling regime.

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 more of some two dozen or more GE food and agricultural products still awaiting regulatory approval—and EU member states actually implement the approvals.

Differences between the United States and the EU regarding genetically engineered products and labeling of foods containing GE material are areas of significant conflict in the Transatlantic Trade and Investment Partnership (T-TIP) discussions. Several EU countries have banned the cultivation of GE crops in their territories or have specific rules on the trade of GE seeds. In general, EU officials have been cautious in allowing GE products to enter the EU market, and all GE-derived food and feed must be labeled as such.

The EU's regulatory framework regarding biotechnology is generally regarded as one of the most stringent—and onerous—systems worldwide. To date, few GE varieties have been approved by EU authorities for commercial cultivation. Many U.S. producers assert that EU labeling and traceability regulations and lack of timelines and transparency in the EU process for admitting GE crops and products have effectively limited certain U.S. agricultural exports to the EU. This could become a more contentious issue in the context of the T-TIP negotiations. Also, in January 2015, the European Parliament voted to allow each member country to ban or approve GE crops in their respective countries. This action will likely further complicate T-TIP negotiations on biotechnology policy.

From the United States perspective, the objectives for both the T-TIP and Trans-Pacific Partnership (TPP) negotiations are a common framework for GE approvals, the development of labeling practices consistent with the U.S. Food and Drug Administration guidelines, and the implementation of policies concerning GE presence that are consistent with the Codex Alimentarius Commission Annex on Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food. At this time, positions appear to be hardening between the United States and the EU relative to agricultural biotechnology. Any progress toward narrowing the differences between the U.S. and EU approaches to agricultural biotechnology will likely revolve around harmonizing the U.S. and EU regulatory regimes. To date, little movement toward a common position has been seen.

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 are affected, it has actively participated in the negotiations over the protocol text and in countries' preparations for implementation.

⁶⁵ See CRS Report RS21556, *Agricultural Biotechnology: The U.S.-EU Dispute*, by Charles E. Hanrahan.

The protocol, which 134 other nations had ratified as of August 2006, 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 Protocol further establishes a process for considering more detailed identification and documentation of LMO commodities in international trade.

The United States objected to implementing measures approved during an international conference in Kuala Lumpur in February 2004. According to the United States, the measures would mandate overly detailed documentation requirements and potentially expose exporters to unwarranted liability damages if imported GMOs harm the environment or human health. U.S. government and industry officials believe that these and other rules could disrupt U.S. exports.⁶⁶

Food Safety and GE Labeling

In the United States, 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 counter that additional testing and oversight are unnecessary because all foods must meet the same rigorous federal safety standards regardless of whether 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.

Federal policy also does not require GE-derived foods to be so labeled as long as they are substantially the same as their 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 labels so that they can make food choices based on their own views about its perceived quality or safety. The food and biotechnology industries generally oppose compulsory labeling. They contend that consumers might interpret GE labels as "warning labels" implying that the foods are less safe or nutritious than conventional foods, whereas the industry believes the preponderance of scientific evidence indicates otherwise. The industry has also asserted that mandatory labeling would require development of a costly and possibly unattainable supply chain management system to ensure that GE and non-GE foods remain segregated from the farm to the store, with no added

⁶⁶ Sources include CRS Report RL30594, *Biosafety Protocol for Genetically Modified Organisms: Overview*, by Alejandro E. Segarra and Susan R. Fletcher; and various USDA and U.S. State Department background materials.

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 from being called “organic”).

In fall 2012, Californians voted on Proposition 37, which would have required labeling of all foods containing GE material. Opponents of labeling, including many large food companies and grocery outlets, spent heavily to defeat the proposal. In 2014, Vermont became the first state to pass a mandatory GE labeling law. The law will not be implemented until July 2016. Connecticut and Maine also passed mandatory GE labeling laws in 2013 and 2014, respectively, but they will not go into effect until five contiguous states also pass mandatory GE labeling laws.

The Safe and Accurate Food Labeling Act of 2015 (H.R. 1599)

On July 23, 2015, the full House passed a voluntary labeling bill, H.R. 1599, to preempt current and future state laws that have been recently passed in Maine, Vermont, and Connecticut to require mandatory labeling of GE foods. Opponents of labeling have feared that in the absence of a national labeling law, each state could pass its own specific labeling requirements for GE foods, requiring costly management changes in commodity supply chains to comply with different state laws. Proponents of labeling are unlikely to find the proposed federal labeling law to their liking. H.R. 1599 would stop the Vermont labeling law from being implemented and would repeal Alaska’s 2005 law requiring labeling on GE fish.

Unlike the labeling bills passed by Vermont, Maine, and Connecticut, H.R. 1599 would preempt any state authority over GE labeling in favor of a voluntary National Genetically Engineered Food Certification Program under amendments to the federal Agricultural Marketing Act of 1946. The bill would prohibit a state now or in the future from “directly or indirectly establishing under any authority, or continue in effect, as to any covered products in interstate commerce, any requirement for the labeling of a covered product indicating the product has been produced from, containing, or consisting of a genetically engineered plant” unless the state establishes a voluntary program that is accredited by USDA as identical to the standards established by H.R. 1599. While this language is aimed at preempting state labeling laws, questions arose concerning whether the preemption language might also end local non-GE protections—for example, Oregon’s GE-free zones that protect the state’s seed growing regions. A manager’s amendment in the final bill clarified the language as pertaining only to a state regulating a GE food product.

While preserving current jurisdiction, policies, definitions, and regulatory authority of FDA and APHIS, the Safe and Accurate Food Labeling Act of 2015 would also amend the Plant Protection Act by adding a new subtitle, the Coordination of Food Safety and Agriculture Programs. This new subtitle is intended to strengthen the objectives of the 1986 Coordinated Framework for Regulation of Biotechnology by affirming the safety of foods produced from or containing GE plant material.

The voluntary consultative process under FDA’s 1992 policy guidelines for the introduction of GE foods would continue. Many opponents of GE products have long supported making FDA’s voluntary consultation process a mandatory one. H.R. 1599, as reported, would create a new notification program for GE plants prior to their use in foods by requiring a written notification from FDA that the agency has determined that the GE food is safe and that the agency has no

objections to its use in human or animal foods. Products developed by GE technologies but used as a food processing aid or enzyme would not require the premarket notification.⁶⁷

Under the bill, the voluntary National Genetically Engineered Food Certification Program within USDA would establish national standards for labeling both GE and non-GE foods. A “certifying agent” of a state, an official responsible for state agricultural operations, would certify whether food products are produced with or without GE technologies. Food products labeled as not produced with the use of GE technologies would be subject to supply chain process controls to ensure that the producer planting the seed is not using a GE variety. Further supply chain controls would cover the growth, harvesting, storage, processing, and transportation of the non-GE product. In the case of products from livestock, the livestock, products consumed by the livestock, and the products used in the processing of products consumed by livestock must be produced without the use of GE technology.

Producers seeking certification under the non-GE labeling program would be required to submit a food plan addressing their handling and processing procedures. These food plans would be subject to review by USDA and state certifying agents. The Secretary of Agriculture would also have authority to stipulate other information on the label deemed appropriate. A subsection of the bill prohibits labeling or advertising from suggesting that non-GE food products are safer or of a higher quality than those produced from or containing GE material.

For entities that wish to label their products as deriving from GE materials or containing GE ingredients, a food must be produced and handled in compliance with a GE food plan submitted to USDA and state certifying agents. Consistent with current FDA labeling laws, the GE label must be neither false nor misleading. As with non-GE labeling, a GE label must not claim that the product is safer or of a higher quality than a comparable non-GE product.

Other provisions of H.R. 1599:

- Imports could be labeled as produced with or without GE technology if USDA determines that they have been produced and handled under a GE certification program equivalent to the USDA labeling standards.
- USDA would establish a program to accredit state officials or private citizens as certifying agents. Those accredited to certify an organic farm or handling operation would be deemed accredited to certify GE and non-GE products.
- Producers who want to use a GE or non-GE food label must maintain records that are subject to USDA review. USDA can initiate investigations to verify any reported information.

H.R. 1599 further directs FDA to define the term *natural* and promulgate regulations governing its use on food product labels. The bill amends the Federal Food, Drug, and Cosmetic Act to deem a food misbranded if its label contains an express or implied claim that the food is “natural” unless the claim uses terms defined by and established in regulation by FDA.

⁶⁷ Many enzymes used in baking and cheese production are genetically engineered.

GE Plants in Less-Developed Countries (LDCs)

The framing of the debate over GE products as one of “sound science” versus “politics” is a central dynamic in the public controversy over GE products, not just in and between the United States and the EU but increasingly as a factor in the acceptance of GE products in less-developed countries (LDCs), particularly those countries with historical ties to Europe. For poor countries without a well-articulated regulatory regime or scientific infrastructure for the introduction of GE products into their countries, the “science-based regulation” framing of the issue in the United States that underlies their promotion of GE crops conflicts with the EU precautionary principle. For LDCs that trade extensively with the EU, the introduction of GE crops that are banned by their trading partners is a factor in the acceptance or rejection of GE crops and foods within their own countries.

Political pressures to ban GE cultivation, to label GE foods, and to reinforce doubts about risks and benefits have limited the expansion of GE products in many LDCs. As noted above, several major biotechnology firms have essentially abandoned their plans to increase sales of GE seed in the EU. Opposition to new plant varieties and foods (e.g., GE eucalyptus trees, GE apple) and mandatory labeling efforts in the United States are also increasing and could further dampen public acceptance of GE foods in LDCs.

The ongoing GE debate in the EU and U.S. about perceived risks can influence the public acceptance of GE foods and crops in LDCs. With the successes, however limited at this time, that the anti-GE forces have had in the United States and EU to limit the expansion of GE agriculture, the biotechnology industry is turning to the LDCs as their most promising future market. This development, however, may be occurring at the same time the technology is beginning to offer food products that consumers and small producers in poor countries may find more attractive than the traits of herbicide tolerance and/or pest resistance that have appealed to large-scale commodity producers. To date, the major GE crop cultivated in LDCs is cotton. Pest resistant food crops, increased nutritional quality of foods widely consumed in poor countries, and the promise of higher yields in arid climates or where soils are less fertile are GE traits that could, in coming years, find greater acceptance in LDCs than they have in the industrial economies. Also, as indigenous agricultural science and technology expertise develops, genetic engineering for local cropping systems and locally consumed foods could become more readily accepted by the public in the future. New GE technologies could also help attenuate the opposition to the current varieties of GE plants.

In Asia, particularly China and India, governments view GE varieties as a way to produce more food for burgeoning populations, despite some in-country opposition and support for labeling GE products. China has been researching GE corn, cotton, wheat, soy, tomatoes, and peppers since 1986. Currently, China has over 10 million acres planted to GE varieties, mostly Upland cotton. As China’s urban population grows, the country is likely to begin considering planting GE soy and corn. If so, it would be the first time a GE plant was used widely as a staple food, and may influence the decisions of other Asian countries with regard to accepting GE foods.⁶⁸

⁶⁸ “China Could Be First Nation to Approve Sale of GM Rice,” *Science*, 306:1458-1459 (November 26, 2004); plus various USDA agricultural attached reports. This point was also underlined by USDA’s agricultural biotech advisory committee in its July 13, 2006, report.

In the debate over the potential contribution of biotechnology to food security in developing countries, critics argue that the benefits of biotechnology in such countries have not been established and that the technology poses unacceptable risks. They also suggest that intellectual property rights (IPR) protection gives multinational companies control over developing country farmers. Proponents 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.⁶⁹

Differences on this issue were featured in 2002, when 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 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 Angolans.

The United States has blamed EU policies for southern African countries' views on food aid containing GE products. 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 current bioengineered varieties of corn are not well adapted to African growing conditions. South Africa is the only African country to commercialize biotech crops widely. However, as **Table 1** above shows, developing countries, at least those with regulatory regimes in place, have become more accepting of GE crops.

Concerns that an industrial cropping system is also highly dependent on the GE seeds, research, and inputs owned by a handful of global agro-food corporations is also a theme in the debates over GE crops and food in LDCs. There is concern that GE technology concentrates power and resources with large multinational corporations that own intellectual property rights in these technologies. There is fear that this could permit the corporations that dominate biotechnology to exploit farmers and limit their right to save and exchange seeds. The biotechnology industry believes that its proprietary seeds can offer innovation and superior performance and play an important role in lessening the environmental impact of agriculture through soil improvements, cleaner water, fewer pesticides, and reduced fuel use.

The Food and Agriculture Organization (FAO) of the United Nations has also offered a qualified endorsement of agricultural biotechnology, stating that it “can benefit the poor when appropriate innovations are developed and when poor farmers in poor countries have access to them.... 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, FAO said, adding: “Regulatory procedures should be strengthened and rationalized to ensure that the environment and public health are protected and that the

⁶⁹ A United Nations Report recognized that biotechnology could play a positive role in development. See UN Human Development Report, *Making New Technologies Work for Development*. 2001. Report available at <http://hdr.undp.org/en/reports/global/hdr2001/>

process is transparent, predictable and science-based.”⁷⁰ Other groups have been more pointed in criticizing GE crops, arguing that they can have hidden costs that are inadequately examined by biotechnology advocates.⁷¹

Other Issues

Low-Level Presence of GE Material

A related question is the definition of “mixing” and whether there should be a threshold *de minimis* amount of GE material permissible in non-GE material. “Adventitious presence” (AP), or low-level presence (LLP), refers to any incidental appearance of very small amounts of foreign material in a commodity, food, or feedstuff. This can occur at any time during production, harvesting, storage, or marketing. Beyond setting thresholds, and developing testing protocols, a related issue is assessing 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?

Presently 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.

No internationally recognized standards have existed for what amounts, if any, of 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 international standards (and given the increasing global sourcing of food), individual countries are establishing their own, often varying, AP thresholds. The lack of consistent, scientifically sound standards is confusing consumers and disrupting trade, the biotech industry has asserted. For example, 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. These issues, like that of different approval processes for GE crops in the United States and European Union, will loom large in any forthcoming U.S.-EU trade discussions. (See also “U.S.-EU Regulatory Conflicts” above.)

In its January 23, 2004, notice, APHIS asked for comments on if, and how, its regulations should address the LLP question for GE plant material. Questions include whether such presence should be exempt from regulation, what thresholds (levels) of low-level presence (LLP) 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 LLP. In March

⁷⁰ Food and Agriculture Organization, *The State of Food and Agriculture 2003-2004*, at http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/006/y5160e/y5160e00.htm.

⁷¹ See Friends of the Earth. *Who Benefits from GM Crops?: The Rise in Pesticide Use*. January, 2008. Report may be accessed at <http://www.centerforfoodsafety.org/pubs/FoE%201%20Who%20Benefits%202008%20-%20Full%20Report%20FINAL%202-6-08.pdf>.

2007, APHIS published a *Federal Register* notice describing how the agency responds when LLP of regulated GE materials occurs in commercial seed or grain that may be used for food or feed.⁷² In the proposed APHIS regulation revisions discussed above, APHIS had proposed establishing criteria under which the occurrence of LLP may not be cause for agency remedial action. The new provision would permit APHIS to determine that a LLP event is non-actionable when the criteria support the conclusion that the LLP is unlikely to result in the introduction or dissemination of a plant pest or noxious weed. A provision in the 2012 House farm bill (H.R. 5973), would have required USDA to begin developing an LLP standard. The provision was not included in the final bill (P.L. 113-79).

Environmental Concerns

Two main issues continue to drive the science and public debate on the environmental impacts of GE plants, and now, GE salmon. One issue is the transfer of the introduced genes to wild plants and non-GM crops (i.e., gene flow from GE plants). This was most clearly seen with GE alfalfa and GE sugar beet. Because they are pollinated by the wind and bees, contamination of organic and conventional alfalfa is a distinct possibility. With GE sugar beets, the concern is that it could contaminate table beets and Swiss chard, two closely related species. Similarly, with GE salmon there is some probability, however small, that the fish could escape into the wild and breed with native salmon, thereby wiping out native Atlantic salmon. As other GE fish are approved, the problem of escape into the wild will mount.

The second environmental issue concerns the indirect effects of the GE crops themselves on the local environment. Widespread planting of crop varieties engineered to be resistant to glyphosate herbicide, trademarked by Monsanto as RoundUp, has, after 15 years, created significant weed resistance, leading to the development of newer GE varieties that are tolerant of older and (some would argue) potentially more environmentally harmful herbicides (e.g., 2, 4-D, dicamba). A survey of thousands of U.S. farmers found that 49% had problems with herbicide-resistant weeds in 2012 and that over 40 million acres in the United States now have weed resistance problems from glyphosate resistance. This weed resistance is increasing annually. According to the International Survey of Herbicide Resistant Weeds, in 2013 there were 29 species of weeds around the world with some level of resistance to glyphosate. Weed resistance to glyphosate is also a major problem in Brazil and Argentina.

Biotechnology advocates 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 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

⁷² Federal Register. Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Material." Vol., 14649-14651, March 29, 2007.

overtaking wild species, and generally disrupting the natural ecosystem, critics believe. For example, GE, herbicide-tolerant seeds or pollen could 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 had 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 2004 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.⁷³ 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.⁷⁴ 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, much further than previous studies would have indicated.⁷⁵

Plant-Based Pharmaceuticals from Biotechnology

Worldwide, hundreds of GE plants are under development for use as “factories” for pharmaceuticals (and other industrial compounds). Between 2004 and 2007 approximately 485 acres in the United States were planted to regulated GE plants for field testing of plants producing pharmaceuticals, industrial compounds, and value-added chemicals for human consumption or phytoremediation.⁷⁶ None of these compounds has been commercialized to date. 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.

⁷³ 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.

⁷⁴ “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.

⁷⁵ *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., at <http://www.pnas.org/cgi/doi/10.1073/pnas.0405154101>.

⁷⁶ APHIS release permits (e.g., *NEPA Documents and Supplement Permit Conditions*) are publicly available at http://www.aphis.usda.gov/brs/ph_permits.html.

A National Research Council Report in 2004 recognized that “biopharm crops pose a wholly different order” of environmental and human health risks.⁷⁷ APHIS announced in 2007 that an environmental impact statement was being prepared for field trials of a transgenic sunflower that is engineered to produce human proinsulin, which tests have shown to be structurally, chemically, and functionally the same as pharmaceutical grade human insulin.

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, may be more easily incorporated into the existing agricultural infrastructure, providing a significant new source of farm income, they believe.

Critics are concerned about impacts on the food supply if 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. Some critics argue that GE plants producing pharmaceuticals and industrial compounds should be evaluated by criteria different from those used to evaluate crops intended for food. Others have argued that biopharm plants should not be food crops.

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).⁷⁸

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-keeping and training requirements. APHIS issued a letter on January 14, 2004, aimed at clarifying and updating its previous guidance on permits.⁷⁹ The proposed APHIS revisions for

⁷⁷ National Research Council. *Biological Confinement of Genetically Engineered Organisms*. Washington, DC, 2004.

⁷⁸ 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.

⁷⁹ The latest version of this guidance (*Draft Guidance for APHIS Permits for Field Testing or Movement of Organisms* (continued...))

regulating GE plants discussed above would put GE plants expressing pharmaceuticals or industrial compounds in a risk category where the engineered trait had a high potential for harm. It is not the highest risk category. APHIS equated the biopharmed plants with a poplar engineered to produce enzymes for heavy metal remediation.⁸⁰

More recently, a variety of rice, produced by California-based Ventria Bioscience, has been developed that contains human genes. The rice, nearly ready to be approved for commercial production, produces some of the human proteins found in breast milk and saliva. The developers say the rice could be used to treat children with diarrhea in poor countries. The rice developers have received preliminary approval for growing the rice on 3,000 acres in Kansas. The company plans to harvest the proteins from the rice and use them in various food products.

In early August 2006, a U.S. district court judge in Hawaii ruled that APHIS had violated the federal Endangered Species Act (P.L. 93-205) and the National Environmental Policy Act (P.L. 91-190) because it had failed to consider potential impacts on endangered species and critical habitats prior to approving field trials for pharmaceutical corn on more than 800 acres throughout the Hawaiian Islands. The four companies issued the permits by APHIS were ProdiGene, Monsanto, Hawaii Agriculture Research Center, and Garst Seed. All of the companies' plants used to make pharmaceutical crops had been harvested before the suit was filed and the companies stopped planting the crops under the permits. Spokesmen for both Syngenta, which subsequently bought Garst, and Monsanto, said at the time they no longer intend to pursue research into making drugs from plant crops.

Future Policy Concerns

In the coming decade, several policy issues are likely to be at the center of attention by industry, consumer groups, and policymakers. From a general perspective, some of the issues revolve around managing the coexistence of traditional agricultural production with the increased presence of GE-based agricultural production. This issue was a major source of conflict in the decision to deregulate GE alfalfa and sugar beets. In some respects, the policy and regulatory issues may not be fundamentally new or different from the biotechnology issues of the past 20 years. Rather, certain issues are increasing in importance as the industry matures, technologies evolve, and these longer-standing regulatory issues take new forms. While not exhaustive, some of these issues may include:

- evolving technologies, including the introduction of new “stacked trait” varieties—plant varieties with multiple genetically engineered traits—which is likely to increase; continuing development and the eventual commercialization of GE plant-based industrial and pharmaceutical output traits; oversight of second-generation biotechnology traits such as improved nutritional qualities and resistance to environmental stress (e.g., drought);

(...continued)

with *Pharmaceutical or Industrial Intent*, March 31, 2006) is available at http://www.aphis.usda.gov/brs/pdf/Pharma_Guidance.pdf.

⁸⁰ *Federal Register*. Vol. 73, No. 197, October 9, 2008: 60008-600048.

- transgenic animals and the food and industrial/pharmaceutical products derived from them; animal welfare concerns;
- importation of GE products;
- developing a low-level presence standard for unapproved GE materials in food and feed products;
- legal challenges to environmental assessments of transgenic plants and animals;
- issues related to transparency and the participation in policy and regulatory issues by various stakeholders (e.g., consumers, religious groups, animal welfare activists);
- compliance with existing and emerging regulatory structures in the United States and our trading partners, particularly the European Union; testing and measurement issues; traceability and labeling of GE products.

As noted above, the evolution of herbicide-resistant weeds, especially those resistant to glyphosate, is a growing concern. As herbicide resistance increases among weed varieties, there could be increased reliance on herbicides that are arguably less benign than glyphosate (e.g., dicamba, 2,4 D). Biotechnology companies have engineered new plant varieties that are tolerant to these herbicides, or varieties where several herbicide-tolerant traits are “stacked” into a single variety.⁸¹ The environmental effects of the increasing herbicide resistance and the resort to other herbicides may become policy issues as companies commercialize these new varieties.

Author Contact Information

Tadlock Cowan
Analyst in Natural Resources and Rural
Development
tcowan@crs.loc.gov, 7-7600

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⁸¹ A dicamba-tolerant soybean and cotton varieties were approved by APHIS in January 2015. Dow AgroScience has developed a 2, 4-D tolerant variety of corn that was approved by APHIS and EPA in 2014.