
# Agricultural Biotechnology: Background, Regulation, and Policy Issues

**Tadlock Cowan**
Analyst in Natural Resources and Rural Development

April 3, 2013

**Congressional Research Service**
7-5700
www.crs.gov
RL32809

**CRS Report for Congress**
*Prepared for Members and Committees of Congress*

# Summary

Biotechnology, as used in this report, 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 last dozen years, GE varieties in the United States have increased from 3.6 million planted acres to 171.7 million acres in 2012. Worldwide, 28 countries planted GE crops on approximately 420.8 million acres in 2012. GE varieties now dominate soybean, cotton, and corn production in the United States, and they continue to expand rapidly in other countries. They are regulated under three federal agencies, the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

Ongoing concerns include ownership concentration in the global seed industry, plant patenting and licensing contracts, 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 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 genetically engineered to grow faster than conventional salmon. Global trade issues involving GE organisms are a long-standing issue, and will be particularly salient in upcoming U.S.-EU trade discussions.

Regulatory non-compliance incidents most pointedly raise concerns about the adequacy of existing U.S. regulatory structures. About 16 major events have occurred since 1995. A more recent concern has been the adequacy of USDA Animal and Plant Health Inspection Service's (APHIS) environmental assessments (EAs) for deregulating GE plants. In 2006, a U.S. district court held that USDA's EA for a variety of GE alfalfa was inadequate for issuing a finding of no significant impact, and ordered APHIS to complete an environmental impact statement (EIS). The final EIS was published in December 2010, and USDA fully deregulated GE alfalfa. A similar case involved APHIS's decision in 2005 to deregulate GE sugar beets on the basis of its EA. In February 2011, APHIS announced that the agency would partially deregulate GE sugar beet until the EIS was completed. In July 2012, GE sugar beets were completely deregulated following publication in June of the final EIS.

In the 113th Congress, three GE-related bills have been reintroduced: the Seed Availability and Competition Act (H.R. 193); a bill to require labeling of GE fish (H.R. 584/S. 248); and a bill (S. 246) to prohibit interstate and foreign sales of GE salmon. On March 24, 2013, a Senate budget resolution also approved an amendment favoring mandatory labeling of GE fish. The Senate Continuing Resolution (H.R. 933, Section 735) enacted on March 26, 2013, requires USDA to issue permits to growers to plant and market a GE plant even though a court may have vacated the deregulation decision and ordered further review, as happened with GE alfalfa and sugar beets. Similar language was included in the House-passed FY2013 agriculture appropriation bill (H.R. 5973, Section 733). The 2012 House farm bill (H.R. 6083) contained provisions that would have significantly modified current regulations for GE plants under the Plant Protection Act. Another provision in that bill directs USDA to develop a national policy for low-level presence of

GE material in crops and commodities for food and processing. The Senate farm bill did not contain these provisions. Farm bill action is pending in the 113th Congress and could be a vehicle for further legislation affecting biotechnology.

# Contents

## Figures



## Tables



## Appendixes



## Contacts

# Adoption of Biotechnology in Agriculture[1]

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 2012, GE crops were planted on an estimated 421 million acres worldwide (**Table 1**), an increase of nearly 124 million acres over 2008. The total number of countries growing such crops reached 28 in 2012. Most of the acreage is highly concentrated among four crops—soybeans, corn, cotton, and canola—and five countries. The United States has approximately 41% of global acreage (171.7 million acres), and Brazil has approximately 21.5% (90.4 million acres). Argentina has 14.0% of global acreage (59.1 million acres), Canada 6.6% (28.6 million acres), and India 6.3% (26.7 million acres).

In the United States, over 60 GE plant varieties were approved by APHIS for commercial use through early 2005.[4] By 2012, 78 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/.

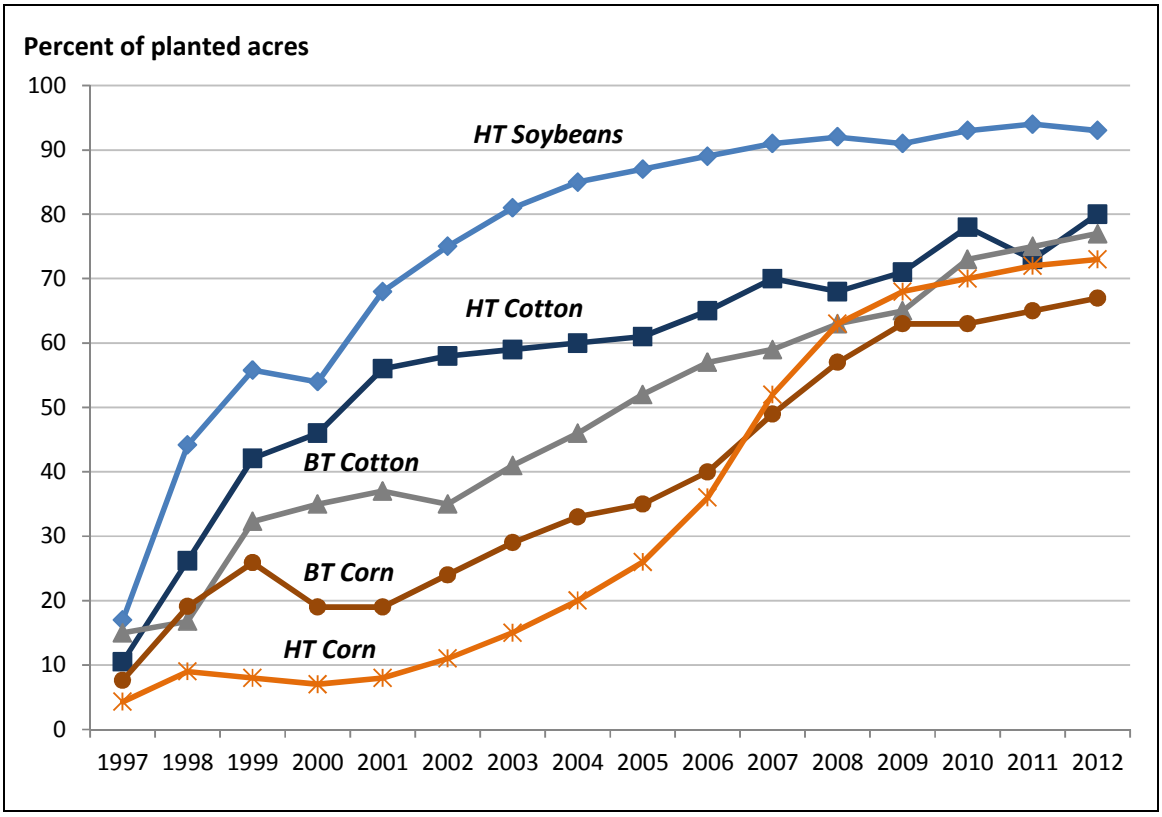
[5] Because Bt is a natural occurring pesticide, it can be used under certain conditions on organically produced plants. Its incorporation into GE commodities concerns some organic producers because of the risk of creating Bt tolerant pests thereby decreasing the utility of Bt to organic farming operations.

**Table 1. Global Area of Biotech Crops by Country in 2012**

| Rank | Country | Area (million acres) | Area (million hectares) | Crops |
|---|---|---|---|---|
| 1 | United States | 171.7 | 69.5 | Corn, soybeans, cotton, canola, sugarbeets, alfalfa, papaya, squash |
| 2 | Brazil | 90.4 | 36.6 | Soybeans, corn, cotton |
| 3 | Argentina | 59.1 | 23.9 | Soybeans, corn, cotton |
| 4 | Canada | 28.6 | 11.6 | Soybeans, corn, cotton |
| 5 | India | 26.7 | 10.8 | Cotton, papaya, soybeans, sugarbeets |
| 6 | China | 9.9 | 4.0 | Cotton, papaya, poplar, tomato, sweet peppers |
| 7 | Paraguay | 8.4 | 3.4 | Soybeans |
| 8 | South Africa | 7.2 | 2.9 | Cotton |
| 9 | Pakistan | 6.9 | 2.8 | Corn, soybeans, cotton |
| 10 | Uruguay | 3.4 | 1.4 | Soybeans, corn |
| 11 | Bolivia | 2.5 | 1.0 | Soybeans |
| 12 | Philippines | 1.7 | 0.7 | Cotton, corn |
| 13 | Australia | 1.2 | 0.5 | Corn |
| 14 | Burkina Faso | 0.74 | 0.3 | Cotton |
| 15 | Myanmar | 0.74 | 0.3 | Cotton |
| 16 | Mexico | 0.49 | 0.2 | Corn |
| 17 | Spain | 0.25 | 0.1 | Cotton, Soybean |
| 18 | Columbia | <0.25 | <0.1 | Cotton |
| 19 | Chile | <0.25 | <0.1 | Corn., soybeans, canola |
| 20 | Honduras | <0.25 | <0.1 | Corn |
| 21 | Portugal | <0.25 | <0.1 | Corn |
| 22 | Czech Republic | <0.25 | <0.1 | Corn, potatoes |
| 23 | Sudan | <0.25 | <0.1 | Cotton |
| 24 | Egypt | <0.25 | <0.1 | Corn |
| 25 | Slovakia | <0.25 | <0.1 | Corn |
| 26 | Costa Rica | <0.25 | <0.1 | Cotton, soybeans |
| 27 | Romania | <0.25 | <0.1 | Corn |
| 28 | Cuba | <0.25 | <0.1 | Corn |
| | **TOTAL** | **420.8** | **170.3** | |

**Source:** Clive James, International Service for the Acquisition of Agri-Biotech Applications, 2012. Summary report available at http://www.isaaa.org/resources/publications/briefs/44/executivesummary/default.asp.

**Figure 1. Adoption of Genetically Engineered Crops in the United States, 1996-2011**




**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 2008-2012**

(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 |

**Source:** USDA-NASS. *Acreage Report*, June 2012.

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).

USDA reported that between 1987 and early 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." Nearly 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 October 2008, APHIS had approved more than 13,000 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 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

[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

[9] Japan, Australia, Canada, New Zealand, and 27 European countries remain rBST free. Milk containing rBST has also (continued...)

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 AquAdvantage 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. (See further discussion on FDA's review of GE salmon at "Current Legislative Issues" below).

## U.S. Food Products Containing GE Crops[13]

An estimated 60%-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).

(...continued)

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] 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.

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 is currently in field trials and could be available in summer 2012.

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 Applications[14]

### "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 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.[15] 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.

[14] 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*.

[15] So far one GE fish, the "Glofish," has been marketed in the United States. It is an aquarium fish that is not approved (continued...)

### "Output" Traits

For processors and consumers, research on a range of GE products is continuing: oilseeds low in saturated and transfats; 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 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).

### 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 CFR 340-

(...continued)

for consumption. For more on genetically engineered fish, see CRS Report RL32974, *Genetically Engineered Fish and Seafood*, by Rachel Borgatti and Eugene H. Buck.

340.9).[16] 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.

## Food and Drug Administration (FDA)

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

To help sponsors of foods and feeds derived from GE crops comply, FDA encourages them to participate in its voluntary consultation process. All GE-derived products now on the U.S. market have undergone this process. With one exception, none of these foods and feeds were considered to contain a food additive, so they did not require approval prior to marketing. However, a May 1992 FDA policy statement 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.[17]

[16] 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

[17] See the FDA biotechnology website at http://www.cfsan.fda.gov/~lrd/biocon.html#policy.

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.[18]

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 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).[19]

## 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 FFDCA, 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

[18] 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.

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

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.

## Assessments of Current Policy

The biotechnology industry (represented by the Biotechnology Industry 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.[20]

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.

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 several years, legislative activity has been relatively subdued. 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 FY2013 is $16.7 million. This was approximately $1.4 million less than in FY2012. 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.

[20] 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*.

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.[21] 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.[22] The same issues also arose with 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."[23]

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).

[21] 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

[22] 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.

[23] 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_1OB?contentidonly=true&contentid=AC21Reports.xml.

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.[24] 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.[25]

## Views on the 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 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.[26]

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.[27] The case was subsequently dropped by agreement with the parties.

Currently, FDA is 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 provision (21 U.S.C. 321 et seq.). Questions have been raised about the adequacy of this provision to address the myriad issues that approving the salmon might create. Additionally, 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

[24] 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/.

[25] "Vilsack Tells AC21 Panel to 'Lead from the Middle' on Coexistence," *Food Chemical News Week in Review*, December 9, 2011.

[26] 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.

[27] 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.

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 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.[28]

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."[29]

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.[30]

[28] 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.

[29] "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.

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

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.[31]

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.[32] In October 2008, APHIS proposed a revision of its regulations regarding the importation, interstate movement, and environmental release of certain GE organisms.[33] 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 was held in April 2009. The final rule has not yet been published, although it is expected in summer 2013.

These proposed revisions are the first since the regulations were established in 1987. 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 subject 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.[34] The proposed regulations also include regulating GE seedlings, tubers, cuttings, bulbs, spores, etc.

APHIS further proposes to reorganize the regulations for permit applications and evaluation procedures by discontinuing its notification procedure, while retaining the permitting procedure. The proposed regulations would also establish 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 proposes 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 proposes 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 are also proposed for potential harm

[31] 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.

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

[33] *Federal Register*, Vol. 73, No. 197, 60009-60048, October 9, 2008.

[34] 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.

caused by the GE trait. Other proposed regulatory changes include 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.

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 significant impact on international trade.[35] 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.[36] 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.

The 2012 House farm bill (H.R. 6083) contained provisions that would significantly modify existing regulatory procedures for GE plants under the PPA. Should these proposed legislative changes be enacted, it is likely that APHIS's proposed changes as described in the draft programmatic would require further assessment before any final rule was implemented.

# The National Environmental Protection Act and APHIS

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."[37] NEPA requires that environmental analyses use an interdisciplinary approach "which will insure the integrated use of

[35] "Industry, NGOs, strongly oppose proposed USDA biotech regulation." *Inside U.S. Trade*, October 17, 2008. .

[36] Food Chemical News. "USDA Proposed Biotech Regulatory Overhaul to Mixed Reviews," vol. 50, no. 34, October 13, 2008.

[37] 42 U.S.C. §4332(2)(C).

the natural and social sciences and the environmental design arts in planning and in decisionmaking."[38]

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 five 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 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.[39]

## 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.[40] 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.[41] 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,

[38] 42 U.S.C. §4332(2)(A).

[39] 76 *Federal Register* 19309 (April 7, 2011).

[40] 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.

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

2010. The final EIS, which addressed the nearly 135,000 comments received, was published December 16, 2010.[42]

The court's decision to enjoin planting GE alfalfa until the final EIS was published was appealed to the Supreme Court.[43] 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 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. The Center for Food Safety immediately filed suit claiming the deregulation violated both NEPA and the Plant Protection Act.[44] The district court held that APHIS had complied with the law in its decision to fully deregulate GE alfalfa. That decision is being appealed. Oral arguments were held October 24, 2012.

## 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).[45] 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.[46] 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

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

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

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

[45] 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.

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

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 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.[47]

## 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").[48] 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.[49]

[47] 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.

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

[49] 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 know 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.

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.[50] 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 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.[51]

### GE Apples

A British Columbian biotechnology firm, Okanagan Specialty Fruits, petitioned APHIS in December 2010 to approve a GE variety of apple. The apple has been genetically modified to resist turning brown after being sliced. The apples have yet to be tested for their safety for human consumption. 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. APHIS is currently considering the petition. As of 2013, the GE apple had not been deregulated.

## 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

[50] "USDA Fully Deregulates GE "Ethanol Corn," *Food Safety News*, February 12, 2011, http://www.foodsafetynews.com/2011/02/usda-fully-deregulates-ethanol-corn/.

[51] *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.

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.[52]

## 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."[53]

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.

[52] 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 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.

[53] "Statement by Agriculture Secretary Mike Johanns Regarding Genetically Engineered Rice," August 18, 2006. LL stands for "Liberty Link," a trademark name for the herbicide glyphosinate. LL crops are engineered to tolerate the herbicide, making for more effective weed control.

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.

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%).[54]

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.[55] 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.

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

[55] Center for Food Safety, "Unapproved, Genetically Engineered Rice Found in Food Supply," August 18, 2006, press release.

## 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.

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.[56]

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 U.S. some wheat producers.[57]

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."[58] 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.[59] 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."[60] Monsanto anticipates that it will be at least 10 years before their research and development efforts produce a commercial variety of GE wheat.

---

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

[57] See http://www.gmofoodforthought.com/2007/10/time_is_right_for_biotech_whea.html.

[58] The joint statement can be accessed at http://www.wheatworld.org/userfiles/file/FINAL%20Trilateral%20Biotech%20Statement.pdf.

[59] *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.

[60] "Second Round of Fighting Begins Over Genetically Engineered Wheat," *Digital Journal*, July 17, 2009, at http://www.digitaljournal.com/article/276000.

## U.S.-EU Dispute

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.[61] 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.

In preliminary negotiations on a U.S.-EU free trade agreement expected in June 2013, the difference between the United States and the European Union regarding genetically engineered products and labeling of foods containing GE material are expected to be areas of significant conflict.

## 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.

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.[62]

## GMOs in the Developing World

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 nearly 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

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

[62] 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.

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.[63]

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.[64]

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. However, as **Table 1** above shows, developing countries, as least those with regulatory regimes in place, have become more accepting of GE crops.

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 process is transparent, predictable and science-based."[65] Other groups have been more pointed in

[63] "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.

[64] 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/

[65] 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.

criticizing GE crops, arguing that they can have hidden costs that are inadequately examined by biotechnology advocates.[66]

# The Global Seed Industry

Investments in crop variety research, including plant breeding, since the 1930s have led to tremendous growth in agricultural productivity. In the United States, corn productivity increased from 20 bushels per acre in 1930 to 140 bushels by the mid-1990s, a 600% increase. Much of this growth arose from innovations in major crop seeds, for example, hybridization. Such innovations have also led to further specialization in agriculture as commercial firms marketed elite crop lines developed in public land grant universities and agriculture experiment stations. This early specialization between the public and private research and development sectors has continued and accelerated, especially with innovations in plant genetic engineering and subsequent changes in intellectual property rights protection. Over the past 25-30 years, crop variety research and development has moved from a predominantly public activity to a largely private sector. Between 1960 and 1996, private investment in crop varieties increased 14-fold in inflation-adjusted dollars, while public expenditure remained largely unchanged.[67]

Seeds have distinct production processes and markets, but plant breeding, including genetic engineering and other biotechnologies, is the foundation of the seed industry today. Large, vertically integrated corporations now dominate the research and development, distribution, and marketing of seed varieties, although smaller companies may still operate under licensing and marketing agreements with the large firms. A new seed variety is typically contracted out to farmers and/or private firms for production and multiplication. Breeders provide growers with registered seed for large-scale production. Registered seed is then used to produce certified seed, which is sold commercially to farmers. Breeders closely manage contract growers to ensure that the desirable plant characteristics are retained in future seed generations.

Certified seed is dried, cleaned, sorted, and packaged ("conditioned") for sale. Under various state programs, the seed may be subjected to inspection to ensure quality. Large seed firms then market the seed to national and international markets. These firms may also license marketing to private firms to increase access to local markets. Distribution channels can differ depending on where the seed is marketed. For example, in the Midwest, most corn seed is sold through farmer-dealers trained by the seed company. In the South, corn seed is largely sold through agricultural supply firms. In addition, a large seed firm may sell directly to large farming operations.

## The Structure of the Seed Industry

The global agribusiness sector has been undergoing consolidation and concentration for some time now. Through divestitures, mergers, and acquisitions, a few major integrated corporations currently dominate much of the agricultural input sector, (e.g., agricultural chemicals, seeds, and biotechnology traits). With the emergence of innovations in plant genetic engineering in the early

[66] 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%20I%20Who%20Benefits%202008%20-%20Full%20Report%20FINAL%202-6-08.pdf

[67] Ferdandez-Cornejo, Jorge and David Schimmelpfennig. "Have seed industry changes affected research effort?" *Amber Waves*. Economic Research Service, USDA, February 2004.

1980s, an upsurge of takeovers and mergers began within the seed industry. Chemical and pharmaceutical industries were the major purchasers of independent seed companies. By 2005, according to Phillipps McDougall, a UK agribusiness consulting firm, the top 10 companies were estimated to comprise 51% of the world's commercial seed sales.[68] This figure is based on a 2005 global seed market of $19.0 billion. A smaller group of transnational firms—Monsanto, DuPont/Pioneer, Syngenta—are the industry leaders today. Between 2004 and 2005, there was an increase in seed industry acquisitions. Monsanto, through its acquisition of Seminis in 2005, displaced Dupont/Pioneer as the world's largest seed corporation (**Table 3**).

**Table 3. World's Largest Seed Companies**

| Company | Seed Sales (Millions) |
|---|---|
| Monsanto (United States) | $6,700[a] |
| Dupont/Pioneer (United States) | $6,400 |
| Syngenta (Switzerland) | $3,850 |
| Group Limagrain (France) | $3,400 |
| Land O'Lakes (United States) | $756 |
| KWS AG (Germany) | $615 |
| Bayer Crop Science (Germany) | $430 |

**Source:** ETC Group, Communique #99: Patenting the "Climate Genes" ... and Capturing the Climate Agenda." May/June 2008.

a. Includes sales from Seminis, acquired by Monsanto in 2005, and Delta and Pine Land, acquired in 2007.

Determining whether concentration and consolidation in the seed industry have reached a point where anti-competitive behavior becomes a concern requires accurate data on market share of individual firms and the total market value of the industry. Estimates for the size of the global seed market are not precise. According to one estimate, the 2006 global value of the commercial seed market was $22.9 billion. The International Service for the Acquisition of Agri-Biotech Applications (ISAAA) estimated the 2005 global market at $30 billion. In 2005, the International Seed Federation estimated the size of the market of seed and "other planting material" in 56 counties at $25.2 billion. The ETC Group estimated the total to be $21 billion. Assuming a global seed market value of $21 billion, the top 10 firms (**Table 3**) dominated approximately 49% of the market in 2004-2005.

The Herfindahl-Hirschman Index (HHI) is a measure of the size of firms relative to the overall industry and is an indicator of the degree of competition among them. As such, it is a simple measure of the degree to which a given market can be said to be competitive. The HHI is defined as the sum of the squares of the market shares of each individual firm. As the HHI decreases, it indicates a reduction in firm pricing power and an increase in competition. As the HHI increases, a few firms' pricing power increases with a corresponding decline in market competition for the particular industrial sector.

[68] Phillips McDougall, "Seed Industry Consolidation," July 2005. Unpublished report cited in United Nations Environmental Program, Convention on Biological Diversity, Compilation of Submissions on Potential Socio-economic Impacts of Genetic Use Restriction Technologies (GURTs) on Indigenous and Local Communities. UNEP/CBD/WG8J/4/INF/6, December 14, 2005.

The Department of Justice's Antitrust Division uses the HHI to determine whether a proposed merger would be anticompetitive (i.e., increase the pricing power of a few firms within a sector). The HHI for the top four global seed firms is 393. The Antitrust Division considers an HHI of 1000-1800 to be moderately concentrated. An HHI of 1800 or more is a concentrated industry.

Based on of the HHI, the global seed industry appears highly competitive. The simple HHI, however, can understate within-group concentration. While Monsanto, the largest seed company, has approximately 13%-14% of the global seed market, it has far greater dominance in particular seed categories. Monsanto's Roundup Ready cotton, soybeans, and canola, for example, dominate the world's genetically engineered (GE) crops, which have become an increasing share of global crop production.[69] In 2004, Monsanto's GE seed and/or its patented trait technology accounted for 175.7 million acres, approximately 88% of the total global GE crop area.[70] Monsanto has 41% of the global GE corn seed and 25% of global GE soybean seed sales.[71] **Table 4** shows Monsanto's dominance of GE commodity crops.

**Table 4. Monsanto's Global Share of Genetically Engineered Crops**

| Crop | Total Global GE Acreage | Monsanto Share of Global GE Acreage |
|---|---|---|
| GE Soybeans | 119.5 million acres | 91% |
| GE Corn | 47.7 million acres | 97% |
| GE Cotton | 22.2 million acres | 63.6% |
| GE Canola | 10.6 million acres | 59% |

**Source:** ETC Group, Global Seed Industry Concentration, 2005.

In addition to these bulk commodities, Monsanto has, with its 2005 acquisition of Seminis, become a dominant force in the vegetable seed market. Seminis supplies over 3,500 seed varieties to fruit and vegetable growers in 150 countries (**Table 5**).

**Table 5. Monsanto's Share of Global Vegetable Seed Markets**

| Vegetable Crop | Global Share of Seed Market |
|---|---|
| Beans | 31% |
| Cucumber | 38% |
| Hot Pepper | 34% |
| Sweet Pepper | 29% |
| Tomato | 23% |
| Onion | 25% |

**Source:** ETC Group, Global Seed Industry Concentration, 2005.

[69] Roundup is the trademark name for Monsanto's glyphosate herbicide. GE varieties developed and patented by Monsanto are resistant to glyphosate

[70] ETC Group. *Global Seed Industry Concentration–2005*. ETC Group Communique, September/October 2005

[71] Ibid., page 5.

Monsanto also announced in August 2006 that it would buy Delta and Pine Land (D&PL), the world's largest seed cotton company. Together, D&PL and Monsanto account for 57% of the United States cotton seed industry.[72] D&PL has subsidiaries in 13 countries, including such major cotton producers as China, India, and Brazil. This proposed merger came under scrutiny by the Antitrust Division of the U.S. Department of Justice. In November 2008, the department issued a final judgment that required Monsanto to divest of certain assets and rights it acquired when it purchased D&PL.[73]

ISAAA estimated the 2006 global market value of GE seeds was approximately $6.3 billion, 21% of the estimated global seed market of approximately $30 billion.[74] Estimates of market value were based on the sale price of GE seed plus any applicable technology fees. ISAAA's estimate of the distribution of GE crop market value in 2006 was:

- $2.68 billion for GE soybeans;
- $2.39 billion for GE corn;
- $0.87 billion for GE cotton;
- $0.21 billion for GE canola.

With the expansion of acreage devoted to GE crops since 2006, the global market value of GE seed has risen accordingly.

## Anticompetitive Behavior

Anticompetitive practices are business or government actions that prevent or reduce competition in particular markets. Such practices may include the creation of barriers to entry for firms, dumping of products on markets below their cost of production, price fixing, linking products together to limit consumer choice, government-granted monopolies, and other business actions. Anticompetitive practices are argued to have negative effects on markets and, by extension, whole economies, through the creation of monopoly profits. The assumption is that a free and efficiently functioning market economy arises when many enterprises, each with limited market power, are permitted to buy and sell. Such markets are then assumed to produce lower prices to consumers as well as a wider range of products.

Some licensing practices and conditions pertaining to intellectual property rights may also restrain competition, have adverse effects on trade, and impede the transfer and dissemination of technology. Licensing practices or conditions that in particular cases constitute an abuse of intellectual property rights can have an adverse effect on competition in the relevant market.

Governments enact competition laws to prevent these and other anticompetitive practices. The realities of modern competitive markets, however, are arguably sometimes more complex than

[72] Bayer Crop Science, a top-10 seed company, accounted for about 25% of the U.S. cotton seed market in 2005.

[73] See Final Judgment, *United States v. Monsanto and Delta and Pine Land Company*, Civil Action No. 1:07-cv-00992, United States Court for the District of Columbia, November 6, 2008, http://www.justice.gov/atr/cases/f239400/239476.htm.

[74] International Service for the Acquisition of Agri-Biotech Application (ISAAA). *ISAAA Brief 35-2006: Global Status of Commercialized Biotech/GM Crops.* January 18, 2007. http://www.isaaa.org/resources/publications/briefs/35/executivesummary/default.html. Site accessed January, 2009.

simple theories of open market competition would suggest. Oligopolistic or quasi-monopolistic firms, for example, can achieve scale economies in production or marketing that would be difficult or impossible for smaller firms to accomplish. In these production sectors (e.g., airlines), the levels of capital investment are very high, and the firms' evolution into quasi-monopolies can be an effective strategy from the standpoint of a competitive economy.

This market dominance of GE seed noted above is reinforced by Monsanto's U.S. dominance of glyphosate herbicide. In September 2006, a class-action suit involving 100,000 farmers was filed against Monsanto, the world's largest seed company, in the U.S. District Court in Wilmington, DE.[75] Plaintiffs alleged that Monsanto, through its control of 80% of the U.S. market for glyphosate, had an effective monopoly. Monsanto has patents on seed lines of cotton, canola, and soybeans that are genetically engineered to be glyphosate tolerant. In their suit, the plaintiffs alleged that Monsanto retained product exclusivity "by acquiring seed companies that were developing modified seed technology, eliminating those products that could have led to the development of genetically modified seeds that could be used with non-glyphosate herbicide." These efforts to block the development of competing genetically modified seeds had a direct effect on Monsanto's glyphosate herbicide monopoly because had competing seeds been developed, farmers would have had a choice not only to buy competing seeds, but also to use different types of herbicides instead of glyphosate. Monsanto defeated the plaintiffs' motion for class certification in July 2007; the case was dismissed without prejudice, and was refiled in the Missouri courts.

The U.S. Department of Justice and USDA held five joint public workshops in 2010 to explore competition and regulatory issues in the agricultural industry. The workshops were the first joint USDA/Department of Justice workshops ever held to explore competition and regulatory issues in agriculture. Among the topics discussed was that of seed concentration. The workshops were transcribed and placed on the public record along with submissions and written comments received.[76]

## Contracts Between Seed Companies and Farmers

Some criticism has arisen regarding the licensing arrangements between the corporate owners of seeds with novel traits and the farmers who plant the seeds. Because these licensing practices stem from the firms' proprietary rights on the seed germplasm, those firms with large numbers of patents are often singled out for particular attention. While all firms have technology agreements with farmers who plant their seed, Monsanto has come under particular scrutiny for its technology agreement. Not only is Monsanto the world's largest seed company, it also has the largest number of plant biotechnology patents (647 in 2003). Monsanto's Technology Agreement gives the company significant control of the patented seed after the farmer has purchased, planted, and harvested the crop. If farmers fail to follow the terms of the agreement, they can be, and often are, the subject of enforcement actions brought by Monsanto. Even farmers who claim not to have knowingly planted genetically engineered seed can suffer financial penalties when their seed is found to contain Monsanto's patented genetic material. Although seed source contamination is common, farmers who are discovered with Monsanto's patented genetic material

[75] *Pullen Seeds and Soil v. Monsanto Company*, No. 06-599.

[76] The transcripts of the workshops and comments can be accessed at the following U.S. Department of Justice site: http://www.justice.gov/atr/public/workshops/ag2010/index.html.

may find themselves in legal jeopardy.[77] While these actions on the part of Monsanto have been the subject of much discussion and criticism, to date, they have not been challenged in the courts.

## Monsanto Patent Expiration

The patent on Monsanto's Roundup Ready (RR) transgenic soybeans will expire in 2014. Implications of patent expiration are difficult to assess at this point because this will be the first widely disseminated biotechnology crop to lose its patent protection. RR soybeans are, in fact, the most widely disseminated biotechnology trait in the world. One might assume that patent expiration in plant biotechnology cases would follow the model of patent expiration in other areas: When the patent expires, the patent owner no longer holds monopoly rights over the invention, and the invention passes into the public realm. Anyone then can make use of the invention without being required to pay royalties to the patent holder. In the pharmaceutical industry, for example, when a patent expires on a particular drug, the drug becomes a generic pharmaceutical that any company can adopt and market under its own brand. A common practice for many pharmaceutical companies with an expiring patent is to patent a new drug that is a slight variant of the drug with the expiring patent.[78]

In 1980, the U.S. Supreme Court ruled in *Diamond v. Chakrabarty* that isolated genes were patentable under the Patent Act of 1952. Since that decision, lower courts and the U.S. Patent and Trademark Office (USPTO) have generally regarded genetic materials and related technologies as patentable inventions.[79] Most plant biotechnology inventions today are protected under utility patents and not as plant patents. Utility patents make protection of plant genes possible, as well as allowing plant breeders to protect the use of the genetic material of a number of plants, and to protect for multiple uses.

Plant biotechnology inventions may be divided into three major categories. (1) *Method inventions* refers to process technologies (e.g., methods of manufacture, plant breeding, or genetic engineering technologies. (2) *Gene inventions* refers to biological information, mainly isolated or recombinant genes or proteins, but also includes unicellular microorganisms, such as bacteria. (3) *Variety inventions* refers to specific plant varieties, such as corn and soybean varieties engineered to be resistant to various herbicides (e.g., RR soybeans, cotton) or to be resistant to certain plant pests (e.g., Bt resistant corn).[80]

---

[77] Center for Food Safety. *Monsanto vs. U.S. Farmers*. 2005.

http://www.centerforfoodsafety.org/Monsantovsusfarmersreport.cfm. Accessed January 2009.

[78] The U.S. Food and Drug Administration (FDA) has authority for approving generic chemical drugs under the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417). The bill is often referred to as the Hatch-Waxman Act. The law permits the generic company to establish that its drug is chemically the same as the already approved drug. This allows the generic company to rely on FDA's previous finding of the safety and effectiveness of the approved drug. For a detailed discussion of the FDA regulatory process for a certain class of pharmaceuticals (biologics), see CRS Report RL34045, *FDA Regulation of Follow-On Biologics*, by Judith A. Johnson.

[79] For an overview of the patent process, see CRS Report R40681, *Current Issues in Patentable Subject Matter: Business Methods, Tax Planning Methods, and Genetic Materials*, by John R. Thomas.

[80] G. Graff, G. Rausser, and A. Small, "Agricultural biotechnology's complementary intellectual assets," *Review of Economics and Statistics*, 85(2), pp. 349-363. Plant variety patents are awarded only for asexually reproduced plants. Such patents are awarded only in the United States, Japan, and Australia. Sexually reproduced plants may receive patent-like protection—"breeder's rights"—for up to 25 years through certificates issued under the Plant Variety Protection Act of 1970. "Breeder's rights" refers to a specific variety (which must physically exist), while utility patents may refer to genes, cells, plants, seeds or (where allowed) the varieties as such. Another important difference is (continued...)

To be awarded a patent in the United States, an invention must be "novel and non-obvious." Normally, a patent is enforceable for a maximum of 20 years. Monsanto's RR soybeans met these criteria, and the USPTO granted the corporation a patent in 1994.[81] When the patent expires, RR soybeans will become a generic commodity that Monsanto no longer exclusively controls. The original trait of Roundup resistance will enter the public domain and become available to soybean farmers and breeders. Heretofore, Monsanto required growers to sign agreements that they would not save seed year-over-year. This meant that growers had to purchase their soybean seed anew each year. Monsanto rigorously enforced these technology licensing agreements with growers. When RR soybeans become a generic commodity, after 2014, these licensing agreements will no longer be enforceable.

In a December 15, 2009, letter to the American Soybean Association (ASA), Monsanto described how it intends to proceed with the post-patent process.[82] This letter came as a result of significant concern expressed by ASA about how Monsanto intended to handle the post-patent process for its RR soybeans. Originally, Monsanto had planned not to renew licenses for the expiring RR1 trait and to require growers to destroy or return all soybean seed. This would have forced growers who wanted to plant RR soybeans to transition to the new trademarked Genuity Roundup Ready 2 Yield trait (RR2Y) soybean seed.[83] In its letter to the ASA, however, Monsanto stated that it would not prevent farmers from continuing to grow its RR1 soybeans. Monsanto also stated that it will maintain full global regulatory support for RR1 technology through 2017. This will permit RR1 soybeans from the 2014 crop to be sold and processed. Monsanto further stated that it will also work with appropriate stakeholders after 2017 on any needed extension of regulatory support.

Not only does Monsanto market its own RR seed, approximately 200 independent seed companies license the RR trait from Monsanto. Monsanto receives royalties from the seed companies for use of its RR trait. This arrangement permits the seed companies to use the RR trait in their own varieties of soybean seed that they sell under their own brand names. This approach made the RR trait widely available, and also permitted growers to buy seed from companies of their choice. These licensing agreements between Monsanto and the seed companies also control what other genetics competing companies can combine with the RR trait.[84] Monsanto stated in its letter to the ASA that it will stop collecting royalties from seed companies on the RR1 trait beginning in 2015. As Monsanto begins to use its newly patented

(...continued)

that the breeder's rights system generally allows farmers to re-use the seeds they have obtained. Plant variety patents generally exclude this right.

[81] Roundup is Monsanto's trademarked brand of the broad-spectrum herbicide glyphosate. The patented soybean is tolerant of glyphosate, thereby enabling growers to apply the herbicide widely in fields to kill weeds without at the same time harming the soybean plant. Roundup-Ready soybeans now account for over 90% of all soybeans grown—and nearly the same proportion of upland cotton—in the United States. The Roundup trait has also been genetically engineered for various corn varieties, alfalfa, canola, potatoes, and sugar beets.

[82] The letter is available at http://accordingtomonsanto.files.wordpress.com/2009/12/stakeholder-letter00011.pdf.

[83] In 2009, Monsanto introduced its trademarked Genuity Roundup Ready 2 Yield trait. The new RR2Y trait is located at a different site in the soybean plant genome from that of the RR1 trait. Monsanto has stated that it plans to offer more than 65 new varieties of Genuity Roundup Ready 2 Yield soybeans for planting in 2010. The four new traits (dicamba tolerance, intrinsic yield, improved oil quality, and Omega 3) will be stacked on the Genuity Roundup Ready 2 Yield platform; that is, a single seed will be engineered to include four new traits along with the RR2Y trait.

[84] In 2008, Monsanto sued Pioneer, a major seed company, for "stacking" its RR trait with another trait.

RR2Y trait in future seed development, the RR2Y trait will become the platform for future licensing to seed companies.[85]

Monsanto's letter to the ASA suggests how Monsanto and other plant biotechnology firms might manage the post-patent process as other plant varieties lose their patent protection. As noted above, Monsanto considered not renewing licenses in the final year of its RR1 patent protection and requiring growers and seed company license holders to destroy all remaining RR1. This would have ensured that growers and seed companies who wanted the RR trait would have to pay royalties based on the newly patented RR2Y trait. Had Monsanto pursued this course, it is conceivable that access to the RR1 trait as a generic trait would have been curtailed. Monsanto might have been able to pursue contract violations with growers and seed companies if they had continued to market seed containing the RR1 trait, thereby potentially circumventing the new generic status of RR1. Because Monsanto was under review by the Department of Justice's Anti-Trust Division for its dominance in the seed business, Monsanto may have considered the course it chose with regard to the expiration of RR1 to be the more prudent one

# Other Selected Issues

## Food Safety and 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 defend the current system. They counter that additional testing and oversight are unnecessary because all foods must meet the same rigorous federal safety standards regardless of whether or not they are genetically engineered.

In July 2004, the Institute of Medicine and the National Research Council (IOM/NRC) of the National Academies of Science released a report generally supporting the proponents' view. The IOM/NRC found that food safety should be assessed based on the composition of the altered food (e.g., whether it contains new compounds, unusually high levels of nutrients, or other significant traits) rather than how the food was produced (by genetic engineering or conventional methods). However, the IOM/NRC determined that the safety of modified foods should be assessed on a case-by-case basis and cautioned that scientists' current ability to predict adverse consequences of genetic changes is limited.[86]

U.S. policy also does not require GE-derived foods to be so labeled as long as they are substantially the same as their more conventional counterparts. Nonetheless, some consumer groups continue to seek mandatory labeling of all GE foods. These groups argue that U.S.

[85] Allegations that the RR trait is dominated by a single supplier have prompted the Department of Justice to issue a civil investigation demand to Monsanto for information on its soybean traits business.

[86] Press release, "Composition of Altered Food Products, Not Method Used to Create Them, Should Be Basis for Federal Safety Assessment," The National Academies, July 27, 2004.

consumers, like their EU counterparts, should have an opportunity to see all relevant information on a label so that they can make food choices based on their own views about its perceived quality or safety. The food industry generally opposes compulsory labeling. It contends that consumers might interpret GE labels as "warning labels" implying that the foods are less safe or nutritious than conventional foods, when the industry believes the preponderance of science indicates otherwise. The industry also has asserted that mandatory labeling would require development of a costly and possibly unattainable system to ensure that GE and non-GE foods remain segregated from the farm to the store, with no added benefit to the consumer. The industry has asserted that if consumers want to purchase GE-free products, the market will support a voluntary system, as exists for organic foods (where rules already prohibit GE foods from being called "organic").[87]

At the international level, the Codex Committee on Food Labeling in May 2006 agreed to continue work on draft guidelines for biotech labeling, which has been under discussion for approximately 10 years. Committee members asked a work group co-chaired by Norway, Argentina, and Ghana to examine member countries' biotech labeling policies, their rationale, and experiences, among other questions.[88] Over the objections of the United States, Canada, and several Latin American countries, the Codex Committee will continue work on biotechnology labeling. At an April 2008 meeting of Codex in Ottawa, the EU, most Asian nations, and African countries defended their mandatory labeling regimes as necessary to protect consumers.[89]

In September 2010, the Sixth Circuit Court of Appeals stuck down a state ban in Ohio on labels regarding the use of GE bovine somatotropin (rBST) in dairy products.[90] The Ohio rule banned statements such as "rBGH free" or "rBST free." The court, however, relying on evidence of the compositional difference between milk from cows treated with rBST and milk from untreated cows, found that consumers would not be misled by labels on foods containing rBST. The FDA also has concluded that "rBST free" is not a false or misleading label. Earlier labels that stated "does not contain bovine growth hormone" was misleading because all cow's milk contains naturally occurring bovine somatrotropin.

In fall 2012, Californians voted on Proposition 37, which would have required labeling of all foods containing GE material. Given the high proportion of processed foods containing GE soy or corn, it would have been virtually impossible to ensure a food labeled as non-GE actually did not contain any GE material. Opponents to labeling, including many large food companies and grocery outlets, spent heavily to defeat the proposal. The proposal was defeated, although proponents have vowed to continue to advocate for labeling. In its consideration to approve GE salmon, FDA is considering requiring labeling. If this were to occur, it could give an impetus to proponents to require mandatory labeling of other GE foods. Under current practices, it seems unlikely that FDA would require labeling, unless there were statutory changes to the Food, Drug, and Cosmetic Act that required such labeling. There were bills in the 112th Congress to require

[87] An industry group—the Non-GMO Project—concerned that GMOs may be commingling with organic and "natural" foods has begun a campaign to test products and label them if they contain GMOs. Whole Foods Market, one of the participants, plans to place its seal on hundreds of products it markets under its "365" brand.

[88] "Report of the Thirty-fourth Session of the Codex Committee on Food Labeling," Ottawa, Canada, 1-5 May 2006, as presented to the Codex Alimentarius Commission Twenty-ninth Session, Geneva, Switzerland, 3-7 July 2006.

[89] *Food Chemical News*. "Codex panel continues work on biotech labeling." Vol. 50, No.11, May 5, 2008.

[90] International Dairy Foods Association v. Robert Boggs, U.S. Court of Appeals for the Sixth Court, 09-3515, http://courtlistener.com/ca6/Uoz/international-dairy-foods-assn-v-robert-boggs/.

labeling foods containing GE material, and there are current bills before Congress that would require labeling of GE salmon (H.R. 584 and S. 248).

## Adventitious Presence

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 Dispute," 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 2007, APHIS published a *Federal Register* notice describing how the agency responds when LLP of regulated GE materials occur in commercial seed or grain that may be used for food or feed.[91] In the proposed APHIS regulation revisions discussed above, APHIS has 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. In the 2012 House farm bill (H.R. 5973), a provision would require that USDA begin developing an LLP standard.

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

## 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. Aside from the contamination issue to producers who do not want to plant GE crops, there is the concern that introduced genes can lead to herbicide and pesticide resistance in non-target species.[92] Weeds resistant to glyphosate/Roundup now affect as many as 10 million acres in the United States alone. Several varieties of rye grass, Palmer amaranth (pigweed), common waterhemp, and giant ragweed show clear signs of resistance to glyphosate, in addition to the common ragweed.[93] This pest and weed resistance is growing, and already leading to the development of "stacked-trait" GE varieties that are tolerant of as many as three different herbicides.

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 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

[92] Australian farmers grow non-GE imadiazolone-tolerant canola and non-GE triazine-tolerant canola. It is possible that if GE glyphosate-tolerant canola and GE glufosinate ammonium-tolerant canola are introduced, contamination could result in canola plants being unintentionally bred to be resistant to all four chemicals, glyphosate, gluphosinate ammonium, triazine, and imadizolone. The canola plants would be considered a "super weed."

[93] "Glyphosate Resistant Weeds a Growing Concern," *Minnesota Farm Guide,* April 25, 2008, at http://www.minnesotafarmguide.com/articles/2008/04/25/ag_news/production_news/pro11.txt. On July 28, 2010, the House Committee on Oversight and Government Reform's Domestic Policy Oversight Subcommittee held a hearing on the emergence of herbicide resistant weeds, with a particular focus on glyphosate-resistant weeds.

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.[94] 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.[95] 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.[96]

## 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.[97] 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.

A National Research Council Report in 2004 recognized that "biopharm crops pose a wholly different order" of environmental and human health risks.[98] APHIS announced in 2007 that an environmental impact statement was being prepared for field trials of a transgenic sunflower that in engineered to produce human proinsulin, which tests have shown to be structurally, chemically, and functionally the same as pharmaceutical grade human insulin.

---

[94] 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.

[95] "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.

[96] 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.

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

[98] National Research Council. Biological Confinement of Genetically Engineered Organisms. Washington , D.C., 2004.

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).[99]

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.[100] The proposed APHIS revisions for 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.

[99] 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.

[100] The latest version of this guidance (*Draft Guidance for APHIS Permits for Field Testing or Movement of Organisms with Pharmaceutical or Industrial Intent*, March 31, 2006) is available at http://www.aphis.usda.gov/brs/pdf/Pharma_Guidance.pdf.

It is not the highest risk category. APHIS equated the biopharmed plants with a poplar engineered to produce enzymes for heavy metal remediation.[101]

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..

## Current Legislative Issues

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 several years, legislative activity has been relatively subdued. 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 FY2013 is $16.7 million. This was approximately $1.4 million less than in FY2012. The CR enacted on March 26, 2013, authorizes the same amount for FY2013 as for FY2012—$18.1 million.

In the 113th Congress, three GE-related bills were reintroduced: the Seed Availability and Competition Act (H.R. 193); a bill to require labeling of GE fish (H.R. 584/S. 248); and a bill (S. 246) to prohibit interstate and foreign sales of GE salmon. On March 24, 2013, a Senate budget resolution also approved an amendment favoring mandatory labeling of GE fish.

New biotechnology developments, continuing opposition by consumer groups and environmentalists, and perceived inadequacies of federal regulation have begun putting increased strain on the existing General Framework for Biotechnology Regulation established in 1986 (discussed above). The laws governing biotechnology regulation were, after all, written for other purposes. The Food, Drug, and Cosmetic Act targeted adulterated foods and tainted or dangerous drugs. FDA regulates genetically engineered animals and insects under its New Animal Drug Application process, yet APHIS has jurisdiction over GE animals and insects that are animal pests under the Animal Health Protection Act. The EPA regulates pesticides, which gives the agency

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

jurisdiction over the soil bacterium, *B. thurengiensis*, genetically engineered into the plant to resistant plant pests, although APHIS has jurisdiction over the whole plant organism. APHIS regulates GE plants under the Plant Protection Act (PPA) because the bacterium used to engineer a new gene into an existing plant creates a disease in plants called crown gall. Therefore, the GE plant is presumed to be a potential plant pest (as defined by the PPA) until analysis confirms that it is not a plant pest. With the General Framework, now nearly 30 years old, the fragmentation of the existing regulatory structure that governs federal biotechnology policy today may create future controversy as the examples below might suggest.

## FDA Approval of Genetically Engineered Salmon

On August 25, 2010, FDA announced that it had begun the regulatory approval process of a GE salmon—called AquAdvantage 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.[102] 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 ends 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 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, a bill requiring the labeling of all GE salmon entering or sold in the state.[103] 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

[102] *Federal Register*, vol. 75, no. 165, August 26, 2010. Accessible at http://edocket.access.gpo.gov/2010/pdf/2010-21245.pdf.

[103] A summary of the California bill can be found at http://www.environmentcalifornia.org/uploads/e7/64/e764a13989bd42c8c10ffc20bc8b1db8/Fact-Sheet—GE-Salmon-Labeling—AB-88.pdf.

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.[104]

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.[105] 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.[106] 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.

In February 2011, the House introduced H.R. 521, a companion to S. 230, which would prevent FDA from approving the GE salmon. The bills would have amended the Federal Food, Drug, and Cosmetic Act to state that GE fish "shall be deemed unsafe." The bills were referred to committee and no subsequent action was taken in the 112th Congress. In June 2011, the House passed its FY2012 Agriculture, Rural Development, Food and Drug Administration and Related Agencies appropriations bill (H.R. 2112, Section 744). The bill included an amendment offered by Representative Don Young and Representative Lynn Woolsey that would have prohibited FDA from approving GE salmon. A bill was also introduced in the 112th Congress (S. 1717) that would have prohibited the interstate and foreign sale of GE salmon. H.R. 520 and S. 229 would also have required labeling GE salmon should FDA approve it. No further action was taken on these bills in the 112th Congress. However, in the 113th Congress, the bills to require labeling GE salmon (H.R. 584/S. 248) and to prohibit the interstate and foreign sales of GE salmon (S. 246) were reintroduced.

---

[104] Research published in the *Proceedings of the National Academy of Sciences* notes that a release of just 60 GE salmon into a wild population of 60,000 would lead to the extinction of the wild population in less than 40 generations. W. M. Muir and R. D. Howard, "Possible ecological risks of transgenic organism release when transgenes affect mating success: Sexual selection and the Trojan gene hypothesis," *Proceedings of the National Academy of Sciences*, 96: 13853-13856 (1999).

[105] The letter may be viewed at http://stopgefish.files.wordpress.com/2010/09/house-fda-ge-salmon-09-10.pdf.

[106] A list of the endorsing organizations may be found at http://stopgefish.files.wordpress.com/2010/09/list-of-endorsers-for-rep-defazio-sen-begich-dear-colleague-letters-9-28-10.pdf.

## 2013 Continuing Resolution (H.R. 933): Section 735

Section 735 of the FY2013 Continuing Resolution enacted March 26, 2013 (H.R. 933), sometimes referred to in the popular press as the "Monsanto Rider," or the "Farmer Assurance Provision," is a legislative response to the court challenges to APHIS's deregulation of GE alfalfa, discussed above.[107] After vacating APHIS's decision to deregulate GE alfalfa on the basis of its "Finding of No Significant Impact," a subsequent petition to the same court also resulted in an injunction against planting the bioengineered alfalfa after March 2007, and prohibited the sale of bioengineered alfalfa seed. The applicants appealed this injunction to the Supreme Court, which ruled that the lower court erred in granting the injunction.[108]

Senator Tester, joined by Senators Boxer, Gillibrand, and Leahy, had introduced an amendment to strike the rider from the Continuing Resolution before it was passed March 26, 2013. In floor comments, Senator Tester stated that the provision "ignores the Constitution's idea of separation of powers." The amendment failed to pass. Agriculture Secretary Vilsack has asked USDA's Office of General Counsel to review the provision "as it appears to preempt judicial review of a deregulatory action which may make the provision unenforceable."[109]

Section 735 goes directly to the court's decision to enjoin the planting of bioengineered alfalfa while the EIS was being completed (a four-year process). Section 735 requires USDA to immediately grant to a grower of a bioengineered plant whose non-regulated status has been invalidated by a court the right to continue growing and shipping the plant while other regulatory procedures are completed or court challenges resolved (e.g., an EIS). While the farmer may move, plant, and cultivate the bioengineered plant variety, Section 735 also states that the Secretary retains authority under the Plant Protection Act (PPA) to impose any "necessary and appropriate conditions consistent with section 411(a) or 412(c) of the PPA." With that language, it would seem that the conditions of cultivating or transporting a bioengineered plant whose non-regulated status was invalidated could be similar, less stringent, or more stringent, to conditions imposed by APHIS during field testing, that is, while the plant remains a "regulated article."

Section 735 requires USDA, upon request by a farmer, to partially (and temporarily) deregulate the bioengineered plant while the challenges to the original decision to grant non-regulated status to the plant are addressed. The essential condition authorized by Section 735 is the limitation of any authority APHIS has to completely prohibit the "movement, introduction, continued cultivation, commercialization, and other specifically enumerated activities" of a bioengineered plant whose determination of non-regulated status has been vacated, while other regulatory review procedures are conducted (e.g., an EIS). In granting such temporary and partial permits, the authority of USDA under the PPA to impose any "necessary and appropriate conditions" on the partial deregulation of the contested plant would remain the same as it is under current law.

The provision will expire at the end of FY2013.

---

[107] Section 735 contains the same language as Section 733 in the General Provisions title of the FY2013 Agriculture Appropriations bill (H.R. 5973) as reported by the House Appropriations Committee on June 20, 2012.

[108] For a detailed analysis of the GE alfalfa and sugar beet cases, see CRS Report R41395, *Deregulating Genetically Engineered Alfalfa and Sugar Beets: Legal and Administrative Responses*, by Tadlock Cowan and Kristina Alexander.

[109] "USDA Scrutinizing Biotech 'Rider' in CR." *Agri-Pulse*, Volume 9, Number 14, April 3, 2013.

## Provisions of the 2012 House Farm Bill (H.R. 6083)

H.R. 6083, the House farm bill introduced in the 112th Congress, contained a provision (Section 10012) that also may be seen, in part, as a legislative response to the court challenges to APHIS's Environmental Assessments under the National Environmental Policy Act. The provision would amend the Plant Protection Act, inserting a new section that would permit an applicant to petition the Secretary for a determination that an organism subject to regulation as a plant pest under the Plant Protection Act is not a plant pest. The new provision would set the terms of assessment and analysis required. The review process would be significantly expedited over current practice, requiring a determination within one year, with the potential for a six-month extension. After that time, unless APHIS determines that the plant is a potential pest, the default decision would be that it is not a plant pest, and the regulated organism would be deregulated. Perhaps the most important change in the proposed provision would be giving APHIS the exclusive role of assessing the organism's environmental effects and conducting a risk assessment. The language is specific:

> Notwithstanding any other provision of law, the environmental analysis required under subsection (b)(1) and as specifically described in such subsection shall be the only analysis or procedure regarding the effects on the environment of an organism that is the subject of a petition submitted under subsection (a) required or authorized by law with respect to reviewing and taking action on such a petition.

Were the provision to be enacted, no other federal law (e.g., the National Environmental Policy Act, Endangered Species Act) governing potential environmental effects could be invoked in APHIS's deregulation process. As with the Section 735 provision discussed above, language here may be seen to preempt judicial review of APHIS's deregulation process.

A subsequent provision in the House farm bill (Section 10015) directs USDA, in consultation with the Department of Health and Human Services and the Environmental Protection Agency, to submit a report to Congress on biotechnology regulation that addresses efforts by USDA to reduce "regulatory burdens on research conducted by academic institutions, small businesses, and public entities in developing lower-cost plant and animal sources of food, feed, fuel, and fiber developed through biotechnology," identify categories of products developed through biotechnology for which a history of safe use has been established, and provide expedited review periods, reduced data requirements, and exemptions from regulation for these products. The report also directs the Secretary to develop and implement a comprehensive national policy for low-level presence of bioengineered materials in grains and commodity crops, for food, feed, and processing.

## Future Issues

In the coming decade, several policy issues are likely to be at the center of attention by industry, consumer groups, and policy makers. 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 is a major source of conflict in the decision to deregulate GE alfalfa and will be a continuing concern if GE sugar beets are ultimately deregulated. 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 and these longer-standing regulatory issues take new forms. While not exhaustive, some of these issues 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);
- transgenic animals and the food and industrial/pharmaceutical products derived from them; animal welfare concerns;
- importation of GE products;
- low-level presence of unapproved GE materials in food and feed products;
- legal challenges to environmental assessments;
- 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.[110] The environmental effects of the increasing herbicide resistance and the resort to other herbicides may become policy issues as companies commercialize these new varieties.

[110] A new dicamba-resistant soybean is expected to be available in 2013. See http://deltafarmpress.com/dicamba-resistant-soybeans-2013. Dow AgroScience is currently developing a 2,4 D tolerant variety of corn. See http://www.dowagro.com/newsroom/corporatenews/2010/20100303a.htm.

# Appendix. In Congress: A Review of Biotechnology Legislation, 2003-2012

Over the past decade, a variety of biotechnology–related bills have been introduced in Congress. Labeling issues have been particularly prominent, as have bills that address issues surrounding new biotechnology developments. None of these bills were enacted, although several were reintroduced in subsequent congresses. The following paragraphs briefly discuss the extent of legislative activity over the past five congresses (108th Congress through the 112th Congress).

In the **112th Congress**, seven biotechnology-related bills were introduced or reintroduced in the 112th Congress: H.R. 521/S. 230 to prevent FDA from approving GE fish; H.R. 520/S. 229 to require labeling of GE fish; S. 1717 to prohibit selling or transporting GE salmon in interstate and foreign trade; H.R. 3553 to require labeling of any food containing GE material; H.R. 3554 to prohibit open-air cultivation of GE pharmaceutical and industrial crops; H.R. 3555 to assign liability for injuries caused by GE organisms; and H.R. 307, the Seed Availability and Competition Act. These bills were referred to committee and no further action was taken in the 112th Congress.

The House farm bill (H.R. 6083) contained provisions that would significantly modify current regulations for GE plants under the Plant Protection Act. The Senate farm bill did not contain these provisions. The House FY2013 agriculture appropriation bill (H.R. 5973) contained a provision (Section 733) to require USDA to issue permits to growers to plant and market a GE plant even though a court may have vacated the deregulation decision and ordered further review, as happened with GE alfalfa and sugar beets. Similar language was included in the Senate Continuing Resolution (H.R. 933, Section 735) which was enacted on March 26, 2013. Section 735 expires at the end of FY2013. Senator Begich introduced S. 230 to amend the Food, Drug, and Cosmetic Act (Section 512(a)) to prohibit the approval of GE fish. The bill was referred to the Committee on Health, Education, Labor, and Pensions. A companion bill (H.R. 521) was introduced by Representative Don Young and referred to the House Committee on Energy and Commerce. The House-passed FY2012 Department of Agriculture, Rural Development, Food and Drug Administration and Related Agencies appropriations bill (H.R. 2112, Section 744) included an amendment that would prohibit FDA from approving GE salmon.

Representative Kaptur introduced H.R. 307, the Seed Availability and Competition Act. This bill would require persons who retain seed harvested from patented seed to register with the Secretary of Agriculture and pay fees set by the Secretary for retaining the patented seed. An account would be established in the U.S. Treasury (the Patented Seed Fund) from which the collected fees would be used to pay the patent holders of the seed.

Animal cloning, although not involving transgenic animals to date, has been an area of some interest. In the **111th Congress**, Representative Fortenberry introduced H.R. 110, the Human Cloning Prohibition Act of 2009. Representative Kucinich introduced H.R. 5578, the Genetically Engineered Safety Act, which would prohibit open-air cultivation of GE pharmaceutical and industrial crops and the use of common human food or animal feed as the host plant for a genetically engineered pharmaceutical or industrial chemical. Representative Kucinich also introduced H.R. 5579, the Genetically Engineered Technology Farmer Protection Act. The bill would provide various legal protections for farmers and ranchers that may be harmed

economically by GE seeds. The bill also would assign liability for injury caused by GE organisms.

In the **110th Congress**, Representative Kucinich also introduced the same bills he reintroduced in the 111th Congress: H.R. 6635, Genetically Engineered Safety Act; and H.R. 6637, Genetically Engineered Technology Farmer Protection Act. He also introduced H.R. 6636, Genetically Engineered Food Right to Know Act, which would require foods that contained GE material to be so labeled.

In the **109th Congress**, Members continued to follow trade developments, particularly the U.S.-EU dispute, and GE rice case, as well as U.S. regulatory mechanisms for approving biotech foods. However, there were few proposed bills. In May 2006, Representative Kucinich again introduced a series of bills, like those he offered in the 108th Congress, to provide what he called "a comprehensive regulatory framework" for GE plants, animals, and other organisms. The bills were H.R. 5266, H.R. 5267, H.R. 5268, H.R. 5269, H.R. 5270, and H.R. 5271.

In the **108th Congress**, after the Administration launched a formal challenge of the EU GMO moratorium, the Senate on May 23, 2003, passed by unanimous consent a resolution (S.Res. 154) in support of the action. A similar House measure (H.Res. 252) was passed on June 10, 2003, by a suspension vote of 339-80. Also in the 108th Congress, Representative Nick Smith introduced bills (H.R. 2447, H.R. 3472, H.R. 4651) to create an interagency task force to promote the benefits of agricultural biotechnology. Both bills were referred to the House Agriculture Committee, but no subsequent action was taken on them. Other members took a different approach in proposing bills related to food and agricultural biotechnology.

Representative Kucinich also introduced a series of bills during the **108th Congress** (H.R. 2916, H.R. 2917, H.R. 2918, H.R. 2919, H.R. 2920, H.R. 2921) that would have prescribed a variety of legislative changes intended to mandate labeling of GE-based foods, broaden FDA oversight, protect producers from any potential legal and environmental risks from agricultural biotechnology, prohibit unapproved U.S. exports of GE plants and animals, and tighten rules for producing and handling GE pharmaceutical and industrial crops, among other things. Senator Durbin introduced a bill, S. 2546, to require premarket consultation and approval for GE foods at the FDA. These bills were referred to various committees, but no further action was taken on them by the 108th Congress.

## Author Contact Information

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

## Acknowledgments

This report was originally written in collaboration with Geoffrey S. Becker, CRS Specialist in Agricultural Policy.