Agricultural Biotechnology: Background and Recent Issues

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Summary

U.S. soybean, cotton, and corn farmers have rapidly adopted GE varieties of these crops since their commercialization in the mid-1990s. In 2008, 25 countries worldwide planted GE crops on approximately 309 million acres. Today, GE varieties dominate soybean, cotton, and corn production in the United States, and they are expanding rapidly in other countries. As adoption has spread, policy debates have continued over the costs and benefits of GE products.

Issues include the impacts of GE crops on the environment and food safety, and whether GE foods should be specially labeled. Underlying these issues is the question of whether U.S. regulation and oversight of biotechnology—with responsibilities spread primarily among the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA)— are adequate, particularly as newer applications (e.g., biopharmaceuticals—drugs manufactured with the use of GE crops or animals) emerge that did not exist when the current regulatory regime was established.

Regulatory noncompliance incidents have continued to raise concerns about the adequacy of existing U.S. regulatory structures. About 16 major events have occurred since 1995 according to USDA's Animal and Plant Health Inspection Service (APHIS). Recent events include December 2008, when a small amount of unapproved GE cotton was harvested along with commercially available GE cotton; 2007, when the Scotts Company paid a civil penalty for failure to comply with performance standards for field trials of herbicide tolerant creeping bentgrass, and a U.S. District Court held that USDA's environmental analysis for a variety of GE alfalfa was inadequate; 2006, when trace amounts of an unapproved GE rice were found in sample of the 2005 crop of U.S. long-grain rice.

In October 2008, APHIS announced the first revision of its biotechnology regulations since their promulgation in 1987. Proposed changes include a multi-tiered permitting system, new risk categorizations for assessing environmental releases of GE organisms, regulation of GE plants that produce pharmaceutical and industrial compounds, and new standards for low-level presence of regulated GE products. Other recent issuances include FDA's January 2009 final guidance on regulation of GE animals and products and its January 2008 final guidance on the safety of meat and milk from cloned animals.

Some U.S. agricultural export markets, notably the European Union (EU), have taken a more restrictive approach to regulating agricultural biotechnology than the United States, presenting obstacles for U.S. farm exports. In 2006, a World Trade Organization (WTO) dispute panel ruled against the EU's de facto moratorium on approvals of new GE crops from 1998 to 2004. The parties (Canada and the United States) subsequently agreed to extend the time for EU compliance with the ruling to January 11, 2008. The EU missed that deadline. Positive action from the EU has been slow. U.S. agricultural interests remain concerned that stricter EU rules for labeling and tracing GE products will continue to discriminate against U.S. exports. Congress generally has been supportive of GE agricultural products, although some Members have expressed wariness about their adoption and regulation. The 110th Congress continued to follow trade developments, particularly the U.S.-EU dispute, the low-level appearance of regulated GE varieties in some food and feed, and U.S. regulatory mechanisms for approving biotech foods. Legislative activity in the 110th Congress was modest.

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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 trait (e.g., resistance to a pest or disease) from one organism, and inserting them into another, sometimes very different, organism, that can be raised for food, fiber, pharmaceutical, or industrial uses.

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, complained 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 incident 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].

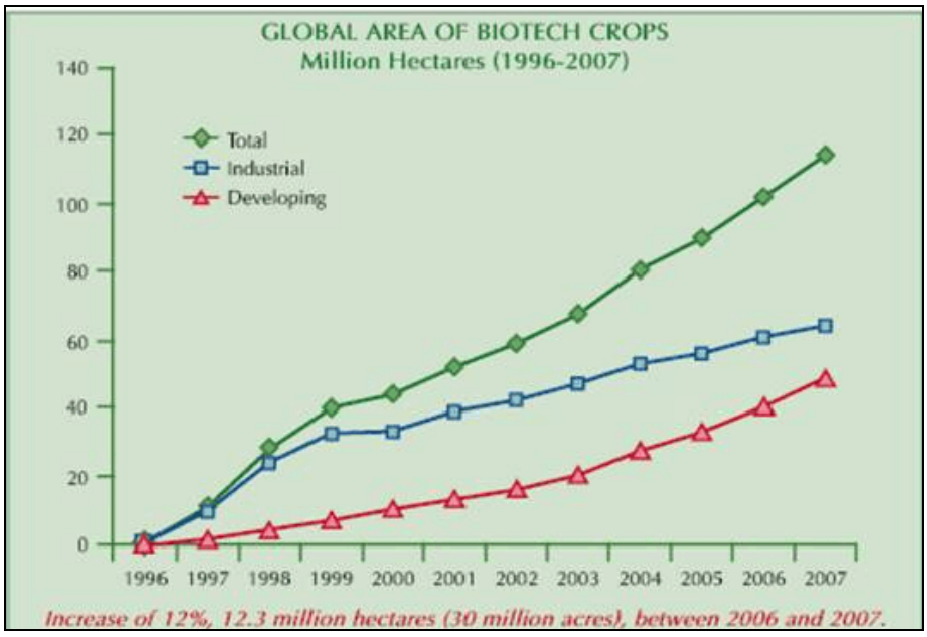
[3] FAO. *FAO Biotechnology Glossary*, [http://www.fao.org/biotech/index_glossary.asp].

Current Applications

Crops

In 2008, GE crops were planted on an estimated 308.8 million acres worldwide, a year-over-year increase of 26.4 million acres (**Figure 1**). The total number of countries growing such crops reached 25 in 2008. Most of the acreage was highly concentrated among four crops — soybeans, corn, cotton, and canola — and six countries. The United States has approximately 50% of global acreage (154.4 million acres), and Argentina had 16.8% (51.9 million acres). Brazil (12.6%, 39.0 million acres), Canada (6.1%, 18.8 million acres), India (6.1%, 18.8 million acres), and China (3.0%, 9.4 million acres) have the largest shares of the remaining planted acres.[4]

Figure 1. Global Acreage Planted to GE Crops, 1996-2007



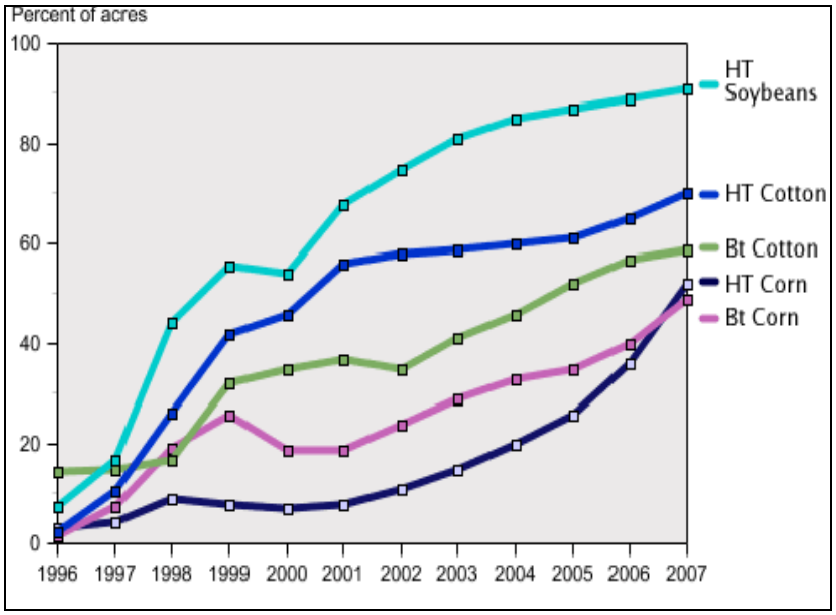
Source: International Service for the Acquisition of Agri-biotech Applications (ISAAA), Clive James, 2007 ISAAA Report on the Global Status of Biotech/GM Crops. Accessed January 2008 at [http://www.isaaa.org/resources/publications/briefs/37/executivesummary/default.html].

In the United States, over 60 GE plant varieties were approved by APHIS for commercial use through early 2005.[5] Ninety-two percent of all U.S. soybean, 86% of all upland cotton, and 80% of all corn acres were planted with GE seed varieties in 2007, according to USDA's National Agricultural Statistics Service (**Figure 2, Table 1**). Virtually all current commercial applications benefit the production side of agriculture, with weed and insect control by far the most widespread uses of GE crops in the United States and abroad.

[4] International Service for the Acquisition of Agri-biotech Applications (ISAAA), ISAAA Brief 39-2008, *Executive Summary: The First Thirteen Years, 1996 to 2008 Report on the Global Status of Biotech/GM Crops*. Accessed January 2008 at [http://www.isaaa.org/resources/publications/briefs/39/executivesummary/default.html]

[5] 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/.

Figure 2. Adoption of Genetically Engineered Crops in the United States, 1996-2007



Source: USDA Economic Research Service

Notes: Data for each crop includes more recently developed varieties engineered with both herbicide tolerance and pest resistance. These multiple trait plants are referred to as "stacked trait" varieties.

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.

Insect-resistant crops effectively have the pesticide inserted 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.[6] 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.

[6] 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. U.S. Acreage in Major GE Crops, 1996 and 2008

(acres in millions)

	Soybeans		Upland Cotton (UC)		Corn	
	Acres	% of all soy acres	Acres	% of all UC acres	Acres	% of all corn acres
1996	4.2	7%	2.2	17%	2.9	4%
2008	68.6	92%	7.7	86%	69.9	80%

Source: USDA-NASS. *Acreage Report*, June 2008.

Other crops approved for commercialization have included varieties of flax, papaya, potatoes, radicchio, rapeseed, rice, squash, sugar beets, tobacco, and tomatoes. However, these are either 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 several years 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.

In contrast to abandoning certain approved GE products, a variety of white GE corn has recently begun to be 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—real or potential—has apparently subsided to the point that processors have cleared their growers to plant the GE variety.[7] 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.[8]

Nonetheless, 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.[9] 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.

[7] 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.

[8] 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 court filing may be accessed at [http://www.centerforfoodsafety.org/pubs/Final%20Complaint.pdf].

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

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%).[10] Several other emerging animal biotechnologies, while not yet commercialized, are believed by researchers to hold great promise (see "Future GE Applications," below).[11] In February 2009, FDA approved the first product from a transgenic animal, an anti - clotting protein derived from the milk of transgenic goats.[12] The animals are genetically engineered to produce a recombinant human antithrombin III protein in their milk.[13] 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.

U.S. Food Products Containing GE Crops[14]

An estimated 70% of all processed U.S. foods likely contain some GE material. That is largely because two such plants (corn and soybeans, where farmers have widely adopted GE varieties) are used in many different processed foods. U.S. biotechnology rules do not require segregation and labeling of GE crops and foods, as long as they are substantially equivalent to those produced by more conventional methods (see "Regulation and Oversight," below).

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

As noted earlier, because most other government-approved GE crops are not being grown commercially, few other GE-derived foods are reaching consumers.

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[10] Milk containing rBST may be falling out of favor in some places. Wal-Mart, the largest grocery retail outlet in the United States, has a private label milk (Great Value Milk) that will be 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.

[11] Also see CRS Report RL33334, *Biotechnology in Animal Agriculture: Status and Current Issues*, by Geoffrey S. Becker and Tadlock Cowan.

[12] "FDA approves drug product from transgenic goats." *Food Chemical News*, February 9, 2009.

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

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

Analysts say some farmers are 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 approved GE crop varieties to be safe, and that foreign governments are simply using such concerns to maintain barriers to imports.

Future GE Applications[15]

"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. Cloned cattle also have been developed to resist 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 are GE salmon that require as little as half the usual time to grow to market size. Other such fish could follow later.[16]

"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

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

[16] So far one GE fish, the "Glofish," has been marketed in the United States. It is an aquarium fish that is not approved for consumption. For more on genetically engineered fish, see CRS Report RL32974, *Genetically Engineered Fish and Seafood*, by Rachel Borgatti and Eugene H. Buck.

are whether they could "contaminate" food crops; see "Plant-Based Pharmaceuticals from Biotechnology," below). Some varieties of plants under development could also produce "bioindustrials," 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, although some have begun field trials.

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 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 regulates animal biologics (i.e., viruses, serums, toxins for animal vaccines) under the Virus, Serum, and Toxins Act (21 U.S.C. 151 *et seq.*). Specifically, GE plants that are or might be plant pests are considered "regulated articles" under APHIS regulations (7 CFR 340-340.9). APHIS authorization must be obtained prior to import, interstate movement, or environmental release, including field testing.

More specifically, a "regulated" plant cannot be introduced into the environment, 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 post 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) and has public comment periods before deciding whether to approve the developer's request for "non-regulated status."

Food and Drug Administration (FDA)

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

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

1992 FDA policy statement 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]

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 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 January 15, 2008, by FDA. The documents generally echoed the FDA's December 28, 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

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

[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.

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 the U.S. Department of Agriculture (USDA) did ask that it be continued for products from clones (but not from the offspring of clones).[19]

Environmental Protection Agency (EPA)

EPA must approve the use of all pesticides, including those genetically engineered into plants, which it terms "plant-incorporated protectants" (PIPs). EPA essentially determines a PIP's environmental safety through its authority under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA; 7 U.S.C. §136 *et seq.*). Also, under the FFDCA, the EPA establishes tolerances (i.e., safe levels) for pesticides in foods. Pre-commercial regulation is through a system of notifications for small-scale field tests or experimental use permits for larger field tests. As for any pesticide, EPA requires the manufacturer of a PIP to obtain a registration through a regulatory process intended to ensure its safe use environmentally.

In practice, all three agencies have more detailed procedures than 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 the biotechnology process poses no unique or special risks; therefore it demands no new laws beyond those that already govern the health, safety, efficacy, and environmental impacts of more traditional production methods.

Assessments of Current Policy

The biotechnology industry, prominent U.S. agricultural 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 evidence that current GE crops have harmed the environment or human health.[20]

These reports generally conclude 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 is adequate. However, the reports have also suggested a number of administrative or regulatory changes that might be adopted to improve oversight.

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

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

[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*.

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.

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.

Another court case involving the deregulation of 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]

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

[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].

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."

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]

Views on the FDA Guidance

The recent FDA guidance on early food safety evaluations for new plant varieties (issued in June 2006; see page 6) 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 AP. 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 AP.[25]

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

APHIS Oversight

USDA's APHIS has taken a number of actions over the past several years intended to improve regulatory oversight (like FDA, utilizing its current legislative authorities). These have included consolidation of its activities under a new Biotechnology Regulatory Services (BRS) office; development of a compliance and enforcement unit to ensure GE developers' adherence to the rules, and the publication of more stringent permit conditions for GE-derived plants for pharmaceuticals and industrials (see "Plant-Based Pharmaceuticals from Biotechnology," below).

In the January 23, 2004, *Federal Register*, the agency published a notice of its intent to prepare an 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

[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] 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.

[26] 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].

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 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.[27]

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."[28]

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.[29]

APHIS Regulatory Changes

In July 2007, APHIS published a draft environmental impact statement (EIS) as part of the evaluation of its regulatory structure. In October 2008, APHIS proposed a revision of its regulations regarding the importation, interstate movement, and environmental release of certain GE organisms. [30] The public comment period ended November 24, 2008, and the final rule has not yet been published. These 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

[27] 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[.

[28] "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.

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

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

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.[31] The proposed regulations will 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 but retaining the permitting procedure. The proposed regulations would also establish a new petition procedure for APHIS to approve a new conditional exemptions 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 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 revisions were mixed. The Biotechnology Industry Organization and the Grocery Manufacturers Association generally supported the revisions. The Center for Food Safety (CFS) denounced the proposal 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.[32]

Global Trade Concerns

The U.S. approach to biotechnology regulation contrasts with that of many major trading partners. For example, the European Union (EU), Japan, South Korea, New Zealand, and Australia either have or are establishing separate mandatory labeling requirements for products containing genetically modified ingredients; in many of these countries, consumer and official attitudes toward GE foods are more skeptical. Differing regulatory approaches have arisen at least partly because widely accepted international standards continue to evolve. Incidents, such as those discussed below, have been disrupted U.S. exports and contributed to trade tensions.[33]

[31] 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.

[32] Food Chemical News. "USDA proposed biotech regulatory overhaul to mixed reviews." Vol. 50, No. 34, October 13, 2008.

[33] See also CRS Report RL31970, *U.S. Agricultural Biotechnology in Global Markets: An Introduction*, by Geoffrey S. (continued...)

GE Rice

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

Owner Bayer CropScience had not asked APHIS to deregulate this particular line, called LLRICE601, which had been field tested between 1998 and 2001. Two other Bayer GE rice varieties, known as LLRICE62 and LLRICE06, had received commercial approval but have not been commercialized, USDA stated. Also, "[t]he protein in LLRICE601 is approved for use in other products" and "has been repeatedly and thoroughly scientifically reviewed and used safely in food and feed, cultivation, import and breeding in the United States, as well as nearly a dozen other countries around the world."[34]

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

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

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

(...continued)

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.

[34] "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.

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, Arkansas, 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%).[35]

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.[36] 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.

GE Wheat

Trade concerns were apparent in the debate over whether to introduce (commercialize) GE herbicide-tolerant 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 had petitioned the Administration to conduct a more thorough assessment of the environmental impacts of the Monsanto request; 27 farm, religious, and consumer advocacy organizations endorsed the petition in early 2004. Underlining these concerns, Japanese consumer groups in March 2004 reportedly told U.S. officials in wheat-

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

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

dependent North Dakota that their country would not import any U.S. wheat products if the Monsanto application was approved.[37]

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 GM 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.[38]

GE Alfalfa

As noted above, a U.S. District Court held in 2007 that APHIS failed to properly consider the environmental effects of 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. 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 were 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.

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

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

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

"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.[39] 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.

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

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

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.[40]

GMOs in the Developing World

In Asia, particularly China and India, governments view GMOs 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. It has, however, been reluctant to approve commercial varieties of GE, which have been under development there. 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.[41]

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.[42]

According to a recent report published by the International Service for the Acquisition of Agri-biotech Applications, 12 developing nations planted GE crops in 2007. Of the total 114.3 million

[40] 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.

[41] "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.

[42] 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/]

hectares of GE crops cultivated worldwide, 43% of the global GE crop area is in developing countries.

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.

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."[43] Other groups have been more pointed in criticizing GE crops, arguing that they can have hidden costs that are inadequately examined by biotechnology advocates.[44]

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

[43] 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.

[44] 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]

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.[45]

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 the region 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 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.[46] 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 2**).

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

[46] 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.

Table 2. World's Largest Seed Companies

Company	Seed Sales (Millions)
Monsanto (United States)	$6,700[a]
Dupont/Pioneer (United States)	$6,400
Syngenta (Swizerland)	$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 2**) 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.

The Antitrust Division of the U.S. Department of Justice 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 4 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.[47] In 2004, Monsanto's GE seed and/or its patented trait technology accounted for

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

175.7 million acres, approximately 88% of the total global GE crop area.[48] Monsanto has 41% of the global GE corn seed and 25% of global GE soybean seed sales.[49] **Table 3** shows Monsanto's dominance of GE commodity crops.

Table 3. 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 4**).

Table 4. 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

Monsanto also announced in August 2006 its intention to buy Delta and Pine Land (D&PL), the world's largest seed cotton company. Together, DP&L and Monsanto account for 57% of the United States cotton seed industry.[50] DP&L has subsidiaries in 13 countries, including such major cotton producers as China, India, and Brazil. This proposed merger is under scrutiny by the Antitrust Division of the U.S. Department of Justice.

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.[51] Estimates of market value

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

[49] Ibid., page 5.

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

[51] 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.

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 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.

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 and 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 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 Delaware.[52] 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

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

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. .

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 may find themselves in legal jeopardy.[53] 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.

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

[53] Center for Food Safety. *Monsanto vs. U.S. Farmers*. 2005.
[http://www.centerforfoodsafety.org/Monsantovsusfarmersreport.cfm]. Accessed January 2009.

case-by-case basis and cautioned that scientists' current ability to predict adverse consequences of genetic changes is limited.[54]

U.S. policy also does not require GE-derived foods to be so labeled as long as they are substantially the same as their more conventional counterparts. Nonetheless, some consumer groups continue to seek mandatory labeling of all GE foods. These groups argue that U.S. consumers, like their EU counterparts, should have an opportunity to see all relevant information on a label so that they can make food choices based on their own views about its perceived quality or safety. The food industry generally opposes compulsory 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").

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.[55] Over the objections of the United States, Canada, and several Latin American countries Argentina, 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.[56]

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) 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. Another related question is how to assess liability if such mixing does occur, or if GE plants prove harmful to the environment. For example, to what extent if any should biotechnology companies share liability with producers and others who use their products?

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.

[54] 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.

[55] "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.

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

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 such standards, 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, the new EU regulation sets a tolerance level for non-GM foods, feeds, and processed products at 0.9%. All products with more than 0.9% must be labeled as GM. U.S. agricultural interests consider the EU regulation in particular to be unworkable and discriminatory. EU officials counter that their standards not only are reasonable but also are being demanded by consumers. (See also "U.S.-EU Dispute," above.)

In its January 23, 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 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.[57] In the proposed 2008 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.

Environmental Concerns

Two main issues continue to drive the science and public debate on the environmental impacts of GMOs. One issue is the transfer of the introduced genes to wild plants and non-GM crops, i.e., gene flow from GE plants. The second 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. There is evidence that some weeds have begun to show resistance to glyphosate/Roundup. Several varieties of rye grass, Palmer amaranth (pigweed), common waterhemp, and now giant ragweed are showing signs of resistance to glyphosate, in addition to the common ragweed.[58]

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.

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

[58] "Glyphosate resistant weeds a growing concern." *Minnesota Farm Guide.* April 25, 2008. Accessed at [http://www.minnesotafarmguide.com/articles/2008/04/25/ag_news/production_news/pro11.txt]

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

A 2002 NAS/NRC report stated that it could find no new distinctions between the types of environmental risks posed by GE plants and those posed by more conventionally bred crops (and that, in fact, there is a need to re-evaluate the potential environmental effects of the latter). The study concluded that the current APHIS regulatory system for biotechnology 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.[59] 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.[60] 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.[61]

The implications of gene flow continue to be an important source of environmental concern. Controlling genetic drift from GE planted fields to non-GE planted fields is a concern to those producers who wish to avoid GE crops. With the commercialization of GE sugar beets, concerns recently have been raised by farmers operating in areas where new GE sugar beet seed is being produced. In Oregon's Willamette Valley — one of the largest sugar beet seed production areas in the United States — organic farmers are worried that the GE sugar beet pollen can cross-fertilize table beets and Swiss chard plants.

[59] 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.

[60] "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.

[61] 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.

Plant-Based Pharmaceuticals from Biotechnology

Worldwide, hundreds of GE plants are under development for use as "factories" for pharmaceuticals (and other industrial compounds). Between 2004-2007 approximately 485 acres in the United States were planted to regulated GE plants for filed testing of plants producing pharmaceuticals, industrial compounds, and value-added chemicals for human consumption or phytoremediation.[62] 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.[63] 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.

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.[64]

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

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

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

[64] Also see CRS Report RS21418, *Regulation of Plant-Based Pharmaceuticals*, by Geoffrey S. Becker and Donna U. Vogt.

maintain consistency in dosages and overall quality, and unanticipated environmental problems (e.g., threatening endangered species).[65]

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.[66] 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. It is not the highest risk category. APHIS equated the biopharmed plants with a poplar engineered to produce enzymes for heavy metal remediation.[67]

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.

Emerging Policy 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. In some respects, the policy and regulatory issues may not be fundamentally new or different from the biotechnology issues of the past twenty years. Rather, certain issues may increase in importance as the industry matures and these longer-

[65] 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.

[66] 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.

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

standing regulatory issues take new forms. While not exhaustive, some of these issues might include:

- Evolving technologies: The introduction of new "stacked trait" varieties — plant varieties with multiple genetically engineered traits — 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;
- Environmental risk assessment;
- 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; testing and measurement issues; traceability and labeling of GE products;

In Congress

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 Cooperative State Research, Education, and Extension Service). APHIS's BRS budget in FY2008 was $11.7 million, supporting a staff of 70. For FY2009, funding for the BRS is estimated at $16.3 million and a staff of 95. Most of this proposed increase will support APHIS Biotechnology Quality Management System, a new voluntary, audit-based compliance assistance program. Other USDA agencies also have received lesser amounts for various biotechnology activities.

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. **In the 110th Congress**, Representative Kucinich introduced a series of biotechnology-related bills: (1) H.R. 6635, Genetically Engineered Safety Act, 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; (2) H.R. 6636, Genetically Engineered Food Right to Know Act, would require foods that contained GE material to be so labeled; and (3) H.R. 6637, Genetically Engineered Technology Farmer Protection Act, which 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 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 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.

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