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Agricultural Biotechnology: Background and Recent Issues

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

Agricultural Biotechnology: Background and Recent Issues

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Summary

Since the first genetically engineered (GE) crops (also called GM [genetically modified] crops, or GMOs, genetically modified organisms) became commercially available in the mid-1990s, U.S. soybean, cotton, and corn farmers have rapidly adopted them. As adoption has spread, there have been policy debates 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)—remain appropriate, particularly as newer applications (e.g., biopharmaceuticals—drugs manufactured with the use of GE crops or animals) emerge that did not exist when the current regulatory regime was established.

On August 18, 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. Nonetheless, the findings unsettled rice markets, threatened rice exports, and rekindled longtime criticisms that U.S. oversight of biotech should be strengthened.

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. This year, 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. Even though the EU says it has ended its moratorium (with its May 2004 approval of a GE variety of corn for import), U.S. agricultural interests are concerned that stricter EU rules for labeling and tracing GE products could continue to discriminate against U.S. exports. (Under U.S. rules, GE crops do not have to be distinguished from non-GE crops.) Also, there is debate over whether agricultural biotechnology will improve (according to proponents) or undermine (according to opponents) food security in developing countries.

Congress generally has been supportive of GE agricultural products, although some Members have expressed wariness about their adoption and regulation. The 109th Congress continues to follow trade developments, particularly the U.S.-EU dispute, the recent GE rice case, and U.S. regulatory mechanisms for approving biotech foods. This CRS report will be updated if significant policy changes occur.

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

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

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 "Biotech Rice,"below). The incident has 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, still adequate?

Current Applications

Crops

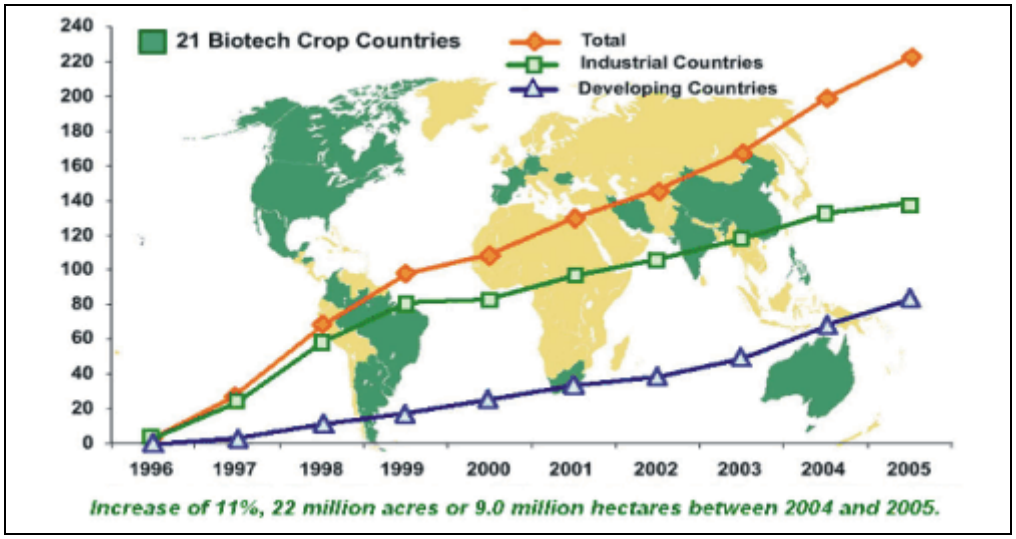
In 2005, GE crops were planted on an estimated 222 million acres worldwide. The total number of countries growing such crops had reached 21 by 2005, but most of the acreage was highly concentrated among four crops (soybeans, corn, cotton, and canola) and five countries. The United States had 55% of global acreage, and Argentina had 19%. Brazil (10%), Canada (7%), and China (4%) had the largest shares of the rest of all planted acres.[2]

[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] International Service for the Acquisition of Agri-biotech Applications (ISAAA), *Global Status of Commercialized Biotech/GM Crops: 2005*. Accessed at http://www.isaaa.org/. For information on developments in Brazil, where GM crops were planted illegally prior to 2003, see CRS Report RS21558, *Genetically Engineered Soybeans: Acceptance and Intellectual Property Rights Issues in South America*, by Randy Schnepf.

Figure 1. Global Area of Biotech Crops

Million Acres (1996 to 2005)



Source: Clive James, 2005

In the United States, over 60 GE plant varieties were approved by APHIS for commercial use through early 2005. However, most of these varieties are within a relative handful of crop types—dominated by soybeans, cotton, and corn.[3] Eighty-nine percent of all U.S. soybean, 83% of all upland cotton, and 61% of all corn acres were planted with GE seed varieties in 2006, according to USDA's National Agricultural Statistics Service (NASS; see **Table 1**). Almost all current commercial applications benefit the production side of agriculture: weed and insect control are by far the most widespread uses of GE crops here (and abroad).

Herbicide-tolerant (HT) crops are engineered to tolerate herbicides that would otherwise kill them along with the targeted weeds. These include 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."

Insect-resistant crops effectively have the pesticide inserted into the plants themselves to control insect pests for the life of the crop. Many of these crops have been genetically engineered with *Bt* (*Bacillus thuringiensis*, a soil bacterium), which has a naturally occurring pesticide. 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.

[3] 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/.

Table 1. U.S. Acreage in Major GE Crops, 1996 and 2006

(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%
2006	66.7	89%	12.4	83%	48.4	61%

Source: USDA-NASS.

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 on the market or not widely planted. For example, Calgene's FlavrSavr tomato, first marketed to consumers from 1995 to 1997, was withdrawn after Calgene determined that the varieties being grown were not of consistently high quality. GE potato varieties may have peaked several years ago at 2%-3% of the market; 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 GE sugar beets, flax, and radicchio, have received government approval but have not been commercially marketed (and/or research has been discontinued), presumably due largely to perceived producer or consumer unease with them.

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 Department 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.[4]

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 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%). Several other scientifically emerging animal biotechnologies, while not yet commercialized, are believed by researchers to hold great promise (see "Future GE Applications," below).[5]

[4] ERS, *The First Decade of Genetically Engineered Crops in the United States*.

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

U.S. Food Products Containing GE Crops[6]

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.

Analysts say some farmers are wary of planting GE crop varieties because their customers may be worried about their safety. Biotechnology supporters contend that such concerns are unfounded because scientific 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[7]

"Input" Traits

For farmers, insect-resistant and herbicide-tolerant GE varieties are under development or have been developed for other crops, including 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. Currently awaiting government

[6] 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 January 21, 2005; 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*, at http://www.colostate.edu/programs/lifesciences/TransgenicCrops/index.html.

[7] 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*.

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.[8]

"Output" Traits

For processors and consumers, a range of GE products may be on the horizon, such as 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 to improve flavor; colored cotton; improved cotton fiber; delayed-ripening melons, bananas, strawberries, raspberries, and other produce (such tomatoes already are approved); and naturally decaffeinated coffee. Critics point out that, although biotechnology advocates have been forecasting the adoption of various "output" traits for some time, few are actually reaching the marketplace.

Plants being developed but not yet commercialized could become "factories" for pharmaceutical compounds. The compounds would be extracted and purified for human and animal health uses (among concerns are whether they could "contaminate" food crops; see "Plant-Based Pharmaceuticals from Biotechnology," 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.

Regulation and Oversight

Coordinated Framework for Regulation of Biotechnology

The basic federal guidance for regulating biotechnology products is the Coordinated Framework for Regulation of Biotechnology (51 *Fed. Reg.* 23302), published in 1986 by the White House Office of Science and Technology Policy (OSTP). A key principle is that genetically engineered products should continue to be regulated according to their characteristics and unique features, not their production method—that is, whether or not they were created through biotechnology. The framework provides a regulatory approach intended to ensure the safety of biotechnology research and products, using existing statutory authority and previous agency experience with traditional breeding techniques. The three lead agencies are USDA's Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA) 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

[8] 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.

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.[9]

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

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

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.[10]

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 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.[11]

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 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

[10] 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.

[11] 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 believe that new legislation could 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. Some critics view the recent findings of traces of an unapproved variety of GE rice in commercial U.S. rice supplies as indicative of the problem.

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 covers biotech adoption and regulation, and includes a discussion of the many outstanding policy issues. The AC21 report observes, 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."[12]

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 is adequate to ensure safety and public acceptance." Among other observations, the AC21 cited the lack of a "clear, comprehensive federal regulatory system to assess the environmental and food safety of transgenic animals before they are commercialized."

All sides of the debate appear to agree that whatever policy course is pursued in the future, it should provide for a clear, predictable, trusted regulatory process.[13]

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

[12] 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 representativates. Accessed on the internet at http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&contentid=AC21Reports.xml.

[13] 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/.

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.[14]

CFS in June 2006 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 is seeking the establishment of a mandatory, pre-market review system for all such foods.[15]

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).

APHIS also has been considering an overhaul of its existing biotechnology regulations. In the January 23, 2004, *Federal Register*, the agency published a notice of its intent to prepare an environmental impact statement (EIS) evaluating these regulations, and requesting public comment on a number of possible changes. These include whether to broaden APHIS's regulatory scope to cover GE plants that may pose a noxious weed risk or may be used as biological control agents; whether to establish new categories for field testing that delineate requirements based upon relative levels of potential risk; and whether to change (i.e., strengthen) its environmental reviews and permit conditions for GE plants producing pharmaceuticals and industrials. APHIS also solicited comments on ways that it might ease its requirements for lower-risk products. The agency received over 3,000 comments on its proposal.[16] As of this writing, APHIS had not yet issued a draft EIS, although the agency has stated that it intends to do so in 2006, with a proposed rule to follow sometime in 2007.

OIG Criticisms

In a December 2005 audit report, USDA's Office of Inspector General (OIG) criticized APHIS's biotech regulation. Noting the approval, so far, 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.[17]

More specifically, APHIS lacks 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

[14] 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.

[15] 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.

[16] Personal communication, APHIS Legislative and Public Affairs Office, August 2, 2004.

[17] USDA, OIG. *Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits*, accessed on the Internet at http://www.usda.gov/oig/webdocs/50601-08-TE.pdf.

for pharmaceutical or industrial uses—after testing ends, OIG stated. Where notifications (rather than permitting) are used, APHIS does not review applicants' containment protocols. APHIS site inspection requirements are vague and not always are fulfilled by inspectors, and the agency's guidance for containing GE crops and seeds needs strengthening, OIG noted, among other things.

Responding to the audit report, APHIS said that most of the OIG recommendations "reaffirm APHIS' decision to create BRS [see above] and devote greater resources toward regulating biotechnology. Most of the recommendations in the report are in line with changes that BRS has already enforced, is currently undertaking, or plans to implement."[18]

Global Trade Concerns

The U.S. approach to biotech 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 are still evolving. Meanwhile, some U.S. exports have been disrupted and trade tensions have grown, as discussed below.[19]

Biotech Rice

Although several GM varieties of rice have been approved for commercial use ("deregulated," in regulatory parlance), none are sold or presumably planted in the United States. On August 18, 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."[20]

[18] "BRS OIG Report Frequently Ask Questions," which responds in more detail to the OIG criticisms. It can be viewed on the Internet at http://www.aphis.usda.gov/brs/brs_oig.html.

[19] See also CRS Report RL31970, *U.S. Agricultural Biotechnology in Global Markets: An Introduction*, by Geoffrey S. Becker and Charles E. Hanrahan. This report does not discuss the trade challenges encountered by the biotechnology companies themselves. Among other problems, besides foreign resistance to agricultural biotechnology in general, these companies also face often divergent laws on international property rights (IPR), where their patent or plant breeding rights in one country may be nonexistent in another. In the developing world in particular, the policy challenge is to find a balance between companies' IPR and the ability to use the new technologies. For details, see International Food Policy Research Institute, *Biotechnology and Genetic Resource Policies*, Briefs 1-6, January 2003; and CRS Report RL31568, *Plants, Patents, and Seed Innovation in the Agricultural Industry*, by John R. Thomas.

[20] "Statement by Agriculture Secretary Mike Johanns Regarding Genetically Engineered Rice," August 18, 2006. LL
(continued...)

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

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

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

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%).[21]

USDA officials, during the week of August 21, 2006, 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

(...continued)

stands for "Liberty Link." Liberty is a herbicide, and LL crops are engineered to resist the herbicide, making for more effective weed control.

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

samples were grown or how they entered the food supply. One group, the Center for Food Safety, has called for a moratorium on all new field testing permits until oversight can be improved.[22]

Biotech Wheat

Such trade concerns have been 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-dependent North Dakota that their country would not import any U.S. wheat products if the Monsanto application was approved.[23]

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 on May 10, 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.

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

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

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

rules, and that the EU failed to ensure that its approval procedures were conducted without "undue delay." The final ruling was circulated to the parties in May 2006 and was expected to be made public in September 2006.[24]

The dispute panel's interim ruling appeared to dismiss 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, reportedly directs the EU to bring its practices in line with WTO rules.

EU officials have long asserted that their cautious approach to regulating agricultural biotechnology has been necessary to restore confidence among European consumers, who have become much more wary of changes in food production, after a series of major food safety crises that were not related to GE crops. At the same time, EU officials contended that they in fact had shown good faith in moving as quickly as possible to restart the approval process.

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 WTO case does 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 (meat and livestock products generally are exempt). GE-based products also must be segregated from non-GE products, with documentation. U.S. agricultural interests argue that, even if 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.[25]

The Biosafety Protocol

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

The protocol, which 134 other nations had ratified as of August 25, 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 United States objects to implementing measures approved during an international conference in Kuala Lumpur in February 2004. According to the

[24] Source: *Inside U.S. Trade*, various issues.

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

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. These and other rules can disrupt U.S. exports, U.S. government and industry officials believe.[26]

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. China has been researching GMOs since 1986. It could soon approve commercial varieties of GE rice, 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.[27]

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.

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. President Bush, for example, has stated that EU governments, because of their policies on GE products, are hindering the cause of ending hunger in Africa.[28] The United States maintains that genetically modified crops are safe to eat and that there is little likelihood of GE corn entering the food supply of African countries for several reasons, including the fact that bioengineered varieties of corn are not well adapted to African growing conditions.

The Food and Agriculture Organization (FAO) of the United Nations has offered a qualified endorsement of agricultural biotechnology, stating that it "can benefit the poor when appropriate

[26] 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.

[27] "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.

[28] U.N. Wire, "Bush, EU Spar Over Genetically Modified Foods," accessed June 24, 2003, at http://www.unwire.org/.

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."[29]

Other Selected Issues

Food Safety and Labeling

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

In July 2004, the Institute of Medicine and the National Research Council (IOM/NRC) of the National Academies of Science released a report generally supporting the proponents' view. The IOM/NRC found that food safety should be assessed based on the composition of the altered food (e.g. whether it contains new compounds, unusually high levels of nutrients, or other significant traits) rather than how the food was produced (by genetic engineering or conventional methods). However, the IOM/NRC determined that the safety of modified foods should be assessed on a case-by-case basis and cautioned that scientists' current ability to predict adverse consequences of genetic changes is limited.[30]

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

[29] 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.

[30] 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.

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.[31]

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.

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 AP question for GE plant material. Questions include whether such presence should be exempt from regulation, what thresholds (levels) of AP might be acceptable, and under what conditions. Major grain and biotechnology industry organizations responded by urging the FDA, EPA and APHIS to establish a policy governing AP.

[31] "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.

Environmental Concerns

Biotechnology advocates claim that GE crops offer environmental advantages over conventionally produced organisms. They note that the technology is more precise than traditional methods like crossbreeding. The latter methods transfer unwanted and unanticipated characteristics along with the desired new traits from one organism to another. Biotechnology also has made it possible to apply fewer and less toxic chemical herbicides and insecticides and to reduce soil tillage (thereby decreasing erosion and improving soil fertility), supporters of the technology assert.

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

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

A more recent NAS/NRC report cited studies to conclude that some GE organisms are viable in natural ecosystems and can breed with wild relatives. The report urged developers of GE organisms to consider biological techniques such as induced sterility in order to prevent transgenic plants and animals from escaping into the environment. "Because no single bioconfinement method is likely to be 100% effective," and because few are well-developed, such developers should create a redundant system by using more than one method of containment. The report called for more research to improve both containment methods and public confidence in regulation.[32] 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.[33] 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.[34]

[32] 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.

[33] "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.

[34] 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/
(continued...)

Plant-Based Pharmaceuticals from Biotechnology

Worldwide, hundreds of GE plants are under development for use as "factories" for pharmaceuticals (and other industrial compounds). GE pharmaceuticals might include, for example, vaccines or medicines for forms of cancer, infectious diseases, cardiovascular and nervous system diseases, metabolic disorders, and agents of biowarfare. Proponents believe plant-based pharmaceuticals will provide a far more cost-effective alternative to conventional pharmaceutical production, which now requires major investments both in large volumes of purified culture mediums and in manufacturing plants. Plant-based pharmaceuticals, on the other hand, could be easily incorporated into the existing agricultural infrastructure, providing a significant new source of farm income, they believe.[35]

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.

Nonetheless, concerns persist among both consumer groups and the food manufacturing industry about producing GE plant-made pharmaceuticals in food crops. Some want 100% prevention systems in place before the first product is commercialized. Some of these groups suggest that only non-food crops should be used for GE plant-made pharmaceuticals, or that, at a minimum, pharmaceutical crops should be banned from agricultural areas where food and feed crops are produced. Other potential issues include whether manufacturers of plant-based pharmaceuticals will be able to maintain consistency in dosages and overall quality, and unanticipated environmental problems (e.g., threatening endangered species).[36]

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)

(...continued)

10.1073/pnas.0405154101.

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

[36] 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.

more record-keeping and training requirements. APHIS issued a letter on January 14, 2004, aimed at clarifying and updating its previous guidance on permits.[37]

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 lawsuit was brought by several environmental advocacy organizations. Possible remedies were to be discussed before the court later in the month.[38]

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. **In the 108th Congress**, after the Administration launched its formal challenge of the EU GM moratorium, the Senate on May 23, 2003, passed by unanimous consent a resolution (S.Res. 154) in support of the action. A similar House measure (H.Res. 252) was passed on June 10, 2003, by a suspension vote of 339-80. 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.

In the 109th Congress, members have continued to follow trade developments, particularly the U.S.-EU dispute, and now the GE rice case, as well as U.S. regulatory mechanisms for approving biotech foods. However, there appear to be fewer proposed bills to date. 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 are H.R. 5266, H.R. 5267, H.R. 5268, H.R. 5269, H.R. 5270, and H.R. 5271.

Congress continues to fund a variety of biotechnology-related activities at USDA, primarily through regular annual appropriations. USDA spending for biotechnology related programs now

[37] 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.

[38] As reported by *Food Chemical News Daily*, August 16, 2006.

exceeds $300 million yearly. More than two-thirds of the total 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 FY2006 is $10.5 million, supporting a staff of about 70. Other USDA agencies also have received lesser amounts for various biotechnology activities.

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