Genetically Engineered Food

An Overview

food&water watch

About Food & Water Watch

Food & Water Watch is a non-profit organization working with grassroots organizations around the world to create an economically and environmentally viable future. Through research, public and policy-maker education, media and lobbying, we advocate policies that guarantee safe, wholesome food produced in a humane and sustainable manner and public, rather than private, control of water resources including oceans, rivers and groundwater. For more information, visit **www.foodandwaterwatch.org**.

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Since the 1996 introduction of genetically engineered crops — crops that are altered with inserted genetic material to exhibit a desired trait — U.S. agribusiness and policymakers have embraced biotechnology as a silver bullet for the food system. The industry promotes biotechnology as an environmentally responsible, profitable way for farmers to feed a growing global population. But despite all the hype, genetically engineered plants and animals do not perform better than their traditional counterparts, and they raise a slew of health, environmental and ethical concerns. The next wave of the "Green Revolution" promises increased technology to ensure food security and mitigate the effects of climate change, but it has not delivered. The only people who are experiencing security are the few, massive corporations that are controlling the food system at every step and seeing large profit margins.

Additionally, a lack of responsibility, collaboration or organization from three U.S. federal agencies — the Food & Drug Administration (FDA), U.S. Department of Agriculture (USDA), and Environmental Protection Agency (EPA) — has put human and environmental health at risk through inadequate review of genetically engineered (GE) foods, a lack of post-market oversight that has led to various cases of unintentional food contamination and to a failure to require labeling of these foods. Organic farming, which does not allow the use of GE, has been shown to be safer and more effective than using modified seed. Moreover, public opinion surveys indicate that people prefer food that has not been manipulated or at least want to know whether food has been modified.[1]

A Background on Genetic Engineering and Biotechnology

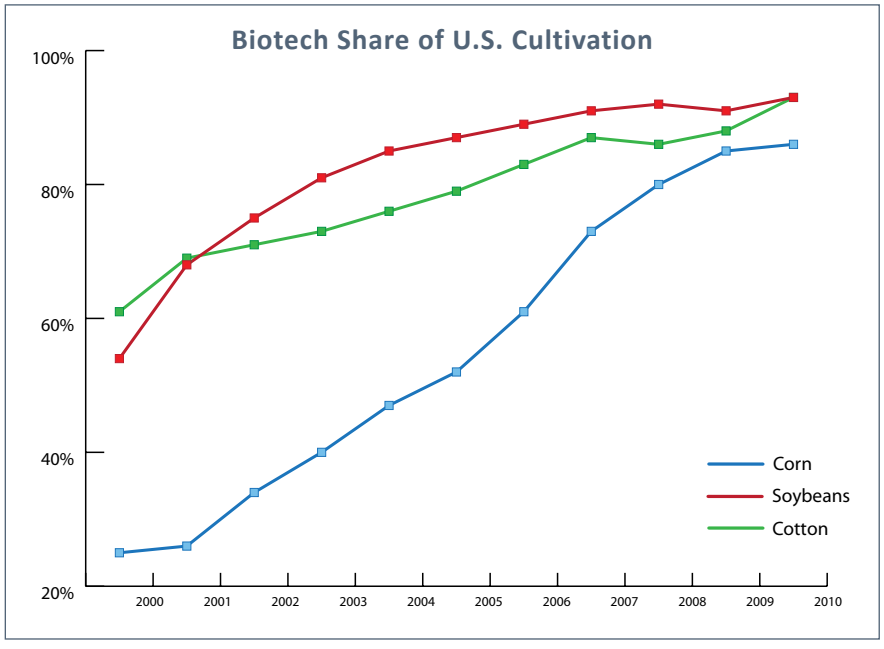
Biotechnology involves manipulating the genetic makeup of plants or animals to create new organisms. Proponents of the technology contend that these alterations are improvements because they add new desirable traits. Yet this manipulation may have considerable unintended consequences. Genetic engineering uses recombinant DNA technology to transfer genetic material from one organism to another to produce plants, animals, enzymes, drugs and vaccines.[2] GE crops became commercially available in the United States in 1996 and now constitute the vast majority of corn, cotton and soybean crops grown in the country.[3] More recently, biotechnology firms have developed genetically engineered animals, including food animals such as hogs and salmon.[4]

Genetic engineering modifies the genetic material of crops to display specific traits.[5] Most commercial biotech crops are developed to be either herbicide tolerant, allowing herbicides to kill weeds without harming crops, or insect resistant, which protects plants from destructive pests.[6] Although biotech firms have long promised additional traits such as high-yielding and drought-resistant GE seeds, to date these products are not commercially available.[7]

Farmers have bred their best livestock and saved seeds from their most productive crops for thousands of years. Selective crop breeding was accelerated by the development of crop hybridization, which cross-bred plants that had desirable traits and helped reverse the stagnating corn yields of the 1930s. By 1960, 95 percent of U.S. corn acreage was cultivated with hybrid seed.[8]

Biotechnology has challenged traditional breeding methods for desirable crop and livestock traits.[9] Hybrid seeds were bred within the same plant species until the discovery of the human genome in the 1950s. This breakthrough spurred the development of genetic engineering techniques, which allow breeders to splice genes from very different species.[10] Genetic engineering can insert a specific gene from any plant, animal or microorganism into the DNA of a host organism of a different species.[11] One GE tomato even used a fish gene to make the tomato frost-resistant.[12] However, splicing different organisms together could pose risks to consumers that have allergies to the added traits — in this case, consumers with seafood allergies could be exposed inadvertently to an allergen in the tomato.[13]

In 2010, more than 365 million acres of GE crops were cultivated in 29 countries — representing 10 percent of global cropland.[14] The United States is the world leader in GE crop production, with 165 million acres, or nearly half of global production.[15] U.S. GE cultivation grew rapidly from only 7 percent of soybean acres and 1 percent of corn acres in 1996, to 94 percent of soybean and 88 percent of corn acres in 2011.[16]



Source: USDA

Inserting desirable genetic traits from one organism into the embryo of another produces so-called "transgenic" animals.[17] Additionally, the technology of cloning creates artificially reproduced plants or animals that identically replicate the original animal without DNA modification. In the United States, cloning is used primarily to produce rodeo bulls and other non-food animals, but several hundred cloned food animals also are believed to exist in the country.[18] Today, cloning primarily duplicates conventional livestock animals, but in the future could be used to copy transgenic animals. Cloning could be used to replicate livestock that have superior meat or milk yields or to mass-produce animals with marketable traits such as lower cholesterol or fat content.[19] Although no meat or milk in the United States has been disclosed as coming from clones, cloned animals undoubtedly already have entered the food supply.[20]

Transgenic animals have been developed to promote faster growth, disease resistance or leaner meat, as well as to minimize the impact of animal waste.[21] By 2004, the largest biotech firms had filed 12 patents for GE animals.[22] As of this writing, no transgenic food animals had been approved in the United States, although some animal-derived products, such as pharmaceuticals, had been approved.[23] The USDA National Organic Program prohibits GE crops to be utilized in certified organic crops for food and animal feed.[24]

What Are the GE Crops?

The United States has approved a host of GE commodities, including fruits and vegetables. Bioengineered crops fall into three broad categories: crops with traits to deter pests and disease; crops with value-added traits to provide nutritional fortification; and crops with industrial traits for use in biofuels or pharmaceuticals.[25]

Herbicide-tolerant or insect-resistant commodities — corn, canola, cotton and soybeans — make up the overwhelming majority of GE crops.[26] Other GE crops that have been approved for field trials but are not commercially available include rice, sugar beet, melon, potato, apple, petunia, millet, switchgrass and tobacco.[27] GE papaya, flax, tomatoes, potatoes and squash have made it through the field trial approval

process, although they are not necessarily currently commercially available.[28]

Herbicide-tolerant and insect-resistant crops: Herbicide-tolerant crops are designed to withstand specific herbicides. Co-branded herbicides designed to work with specific herbicide-tolerant seeds kill weeds without damaging GE crops. Most of these crops are resistant to the herbicide glyphosate (sold commercially as Roundup and produced by the agrichemical company Monsanto).[29] In 2010, about 90 percent of U.S. soybeans and 70 percent of U.S. corn and cotton were "Roundup Ready" crops.[30] Other herbicide-tolerant crops include Bayer's Liberty Link corn and Calgene's BXN cotton.[31]

Insect-resistant crops contain genes that deter insects. The most common variety contains a *Bacillus thuringiensis* (*Bt*) soil bacterium gene that is designed to repel the European corn borer and several cotton bollworms.[32] However, key pests already have developed resistance to *Bt* crops. A University of Missouri entomologist found that corn rootworms could pass on *Bt* resistance to their offspring.[33] And University of Arizona researchers found that within seven years of *Bt* cotton introduction, cotton bollworms developed *Bt* resistance that they later passed on to offspring, meaning that the resistance was dominant and could evolve rapidly.[34]

Value-added crops: Some GE crops alter the nutritional quality of a food and are promoted by the biotech industry as solutions to malnutrition and disease. "Golden Rice" — rice enhanced with the organic compound beta-carotene — has been engineered to reduce the prevalence of vitamin A deficiency in the developing world.[35] GE canola and soybean oils are manipulated to have lower polyunsaturated fatty acid levels and higher monounsaturated fatty acid (oleic acid) content.[36] In 2010, the USDA approved a Pioneer-brand soybean that is modified to produce more oleic acid.[37] Because soybean oil is the most commonly consumed vegetable oil in the United States, the industry maintains that the reduced-fat oil could provide significant health benefits.[38]

Industrial and pharmaceutical crops: Other GE crops contain genes that are useful for the energy and pharmaceutical industries. The USDA has approved amylase corn, which produces an enzyme that is suitable for producing ethanol, a key biofuel.[39] Plants also are engineered to mass-produce certain vaccines or proteins that can be used in human drugs. For example, the USDA has approved field tests for a safflower variety that is engineered to produce a precursor to human insulin that can be used in the treatment of diabetes.[40]

The Next Frontier: Genetically Engineered Animals

There are fewer transgenic animals than GE crops, but the number of new GE animals that are awaiting government approval has accelerated. Genetically engineered animals and biotechnology livestock treatments are designed either to boost production or to insert traits that may compensate for the negative impacts of factory-farmed livestock.[79]

Dairy products were the first bioengineered animal products in the food supply.[80] In 1990, the FDA determined that chymosin, a cheese-manufacturing enzyme produced using a "safe" strain of genetically engineered E. coli bacteria, was "generally recognized as safe;" by 2001, the bioengineered enzymes were used to produce 60 percent of hard cheese in the United States.[81]

In 1993, the FDA approved the use of recombinant bovine somatotropin (rBST), also known as recombinant bovine growth hormone (rBGH), to increase milk production in cows.[82] Although dairy cows naturally produce BST, artificially elevating the hormone levels

Notable GE Crops

ALFALFA: The USDA first approved Monsanto's Roundup Ready alfalfa in 2005.[41] Alfalfa is an important forage crop for grazing animals and is also used for making hay that is distributed for livestock feed. In 2007, organic alfalfa producers challenged the USDA approval on grounds that GE alfalfa could contaminate and wipe out non-GE alfalfa.[42] Alfalfa is an open-pollinated crop, meaning that wind or insects can pollinate and contaminate conventional alfalfa fields.[43] Because this poses special risks for organic alfalfa and for organic dairy farms whose crops may be contaminated by GE alfalfa, a California district court ruled for a prohibition on GE alfalfa sales and plantings until the USDA performed an Environmental Impact Statement (EIS).[44] The USDA's 2010 EIS demonstrated the potential negative economic impacts for organic and conventional alfalfa farmers, including increased costs needed to prevent contamination, reduced demand, and lost markets due to contamination.[45] Nonetheless, the USDA decided to approve GE alfalfa without any planting restrictions in January 2011.[46]

CORN: In 2011, the USDA approved Syngenta's amylase corn, which produces an enzyme that facilitates production of ethanol.[47] Although the corn is intended specifically for ethanol use, the USDA determined that it was also safe for food and animal feed, allowing it to be planted alongside GE corn that is destined for the human and animal food supply.[48] Contamination of corn crops destined for the food supply is possible, especially in the absence of a buffer zone to minimize wind pollination.[49] Even the USDA admits that contamination of high-value organic, blue, and white corns may produce "undesirable effects" during cooking, such as darkened color or softened texture.[50]

PAPAYA: In 1999, the EPA approved two papaya varieties that are designed to be resistant to the papaya ringspot virus.[51] GE papayas constituted 30 percent of Hawaii's papaya cultivation in 1999, rising to 77 percent by 2009.[52] The USDA approved a third ringspot-resistant papaya in 2009.[53]

POTATO: In 1995, the EPA and FDA approved Monsanto's Colorado potato beetle-resistant NewLeaf potato.[54] Monsanto withdrew the potato from the market in 2001 but maintains it may return to potato research in the future.[55] In 2010, the European Union approved German chemical company BASF's Amflora potato for cultivation, although the crop is designed for industrial paper and textile use, not for food.[56] Amflora was the EU's first GE approval since 1998.[57]

RICE: In 1982, the Rockefeller Foundation launched the Golden Rice initiative to combat vitamin A deficiency, which annually causes blindness in a quarter-million malnourished children worldwide.[58] The first Golden Rice strain failed to deliver enough biofortified beta-carotene to address vitamin A deficiency.[59] In 2004, Syngenta field-tested Golden Rice 2 at Louisiana State University.[60] Golden Rice must undergo field tests and receive approval by Bangladesh and the Philippines' regulators before being released into target markets in the developing world.[61]

SAFFLOWER: In 2007, the USDA approved field tests for a safflower variety engineered by the Canadian company SemBioSys to produce proinsulin, a precursor to human insulin.[62] Although safflower primarily self-pollinates, insects could still cross-pollinate conventional safflower crops with GE pharmaceutical traits.[63] Gene flow also can occur if birds carry the GE seeds outside of the testing area.[64] Despite the contamination risk, SemBioSys has an application pending to bring the GE pharmaceutical to market and is continuing field trials in the United States.[65]

SUGAR BEET: USDA approved Monsanto's Roundup Ready sugar beet in 2005 after determining that cultivation poses no risks to other plants, animals or the environment.[66] In 2008, the Center for Food Safety and the Sierra Club challenged the approval in court on grounds that the USDA's Environmental Assessment (EA) ignored important environmental and economic impacts.[67] In 2009, a U.S. District Court directed the USDA to develop a more in-depth Environmental Impact Statement.[68] Nonetheless, the USDA allowed several seed companies to begin cultivation.[69] The court intervened, ordering Monsanto to dig up 256 acres of GE sugar beet plantings pending completion of the environmental review.[70] The USDA expects to finalize the EIS by April 2012 but issued a 2011 interim partial deregulation until then, allowing farmers to resume root production but not seed production plantings.[71]

TOMATO: In 1991, DNA Plant Technology Corporation used a gene from the winter flounder (a type of flatfish) to create a cold-tolerant tomato.[72] The crop was approved for field trials but was never approved for sale or commercialized.[73] In 1992, Calgene's Flavr Savr tomato, engineered to stay fresher longer, was the first GE food on the market.[74] It later was withdrawn from the market due to harvesting problems and lack of demand.[75]

WHEAT: In 2002, Monsanto petitioned the USDA to approve Roundup Ready red spring wheat, the first GE crop designed primarily for human food consumption rather than for livestock feed or for a processed food ingredient.[76] Given that Japan and the EU have different restrictions for GE food crops, the large-scale cultivation of GE wheat could damage options for U.S. wheat exports. A 2004 Iowa State study forecasted that approving GE wheat could lower U.S. wheat exports by 30 to 50 percent and depress prices for both GE and conventional wheat.[77] Because of export concerns, Monsanto abandoned GE wheat field trials before obtaining commercial approval, although the company resumed research in 2009.[78]

with rBGH injections can lead to increased milk production and significant animal health problems. Cows injected with rBGH can have significant health problems, including higher rates of mastitis, an udder infection that requires antibiotic treatment.[83] In turn, the use of antibiotics in industrial dairies contributes to the growth of antibiotic-resistant bacteria, a growing public health problem.[84]

rBGH injections also increase the production of the pasteurization-resistant growth hormone called IGF-1. The European Commission found that consumption of milk from rBGH-treated cows increases human intake of IGF-1.[85] IGF-1 has been linked to breast and prostate cancer.[86] RBGH has never been approved for commercial use in Canada or the EU due to concerns about the drug's impact on animal health.[87]

By 2007, the use of rBGH was on the wane, especially on small farms.[88] U.S. factory-farmed dairies with more than 500 cows are over four times as likely to use rBGH than small dairies with fewer than 50 cows.[89]

Genetically engineered livestock also have been developed in an attempt to mitigate the problems of manure pollution from factory farms. One Canadian university is developing transgenic Enviropigs that produce the phosphorus-absorbing enzyme phytase as a way to decrease the phosphorus levels from manure that commonly pollutes waterways.[90] The United States and China are potentially lucrative Enviropig markets, and researchers already have applied for FDA and Canadian Food Inspection Agency approval to market the pig.[91]

Yet changing the chemical content of the Enviropig's manure would not reduce total manure discharges from factory farms. An alternative solution to achieve the same phosphorus reduction in manure would be to use phytase as a feed supplement. In reality, the only beneficiaries of Enviropigs would be factory farms. Engineering livestock to fit the factory farm model fails to address the systemic problem of overcrowded, poorly regulated livestock operations that overwhelm the land's ability to utilize manure for crop production.

Researchers are developing transgenic animals that allegedly reduce the spread of disease in animals and humans as well. The University of Edinburgh has engineered chickens that cannot spread H5N1 avian flu to other birds.[92] The USDA has funded research that would prevent cattle from developing infectious prions that can cause bovine spongiform encephalopathy, or mad cow disease, which can be fatal to humans who eat the tainted beef.[93] And U.K. biotechnology company Oxitec has engineered sterile mosquitoes to combat the spread of dengue fever in the developing world.[94]

Yet genetically engineered livestock will merely treat the symptoms of a poorly regulated food safety system. They will not adequately combat disease. Moreover, current GE regulatory approval processes do not account for health impacts that may accompany the intended modifications.

A 2011 USDA Office of Inspector General (OIG) report on regulatory control over GE animals and insects urged the agency to revise its regulations and improve oversight of animal research.[95] Without a clear framework, research projects have led to breaches of the food supply and to untracked field releases.[96] The OIG reported that between 2001 and 2003, the University of Illinois allowed at least 386 GE pigs from a study to be slaughtered and sold for human consumption, even though GE pigs have never been approved for U.S. consumption.[97]

Genetic engineers commonly use fish as research subjects because their external eggs simplify the manipulation of DNA.[98] Transgenic fish are being produced for food, for use in pharmaceuticals, and to test water quality.[99] In 2010, the FDA considered approving the first GE fish for human consumption.[100] This is despite that fact that a 2004 National Research Council report concluded that GE seafood posed food safety risks either by the introduction of known or unknown allergens.[101]

The GE fish under consideration is Aquabounty's AquAdvantage salmon, which combines genes from the ocean pout (a member of the eel family) and the chinook salmon to create an Atlantic salmon that grows to market size twice as fast as non-GE salmon.[102] In its submission to the FDA, Aquabounty acknowledges that it cannot guarantee that its transgenic fish will not escape from salmon farms.[103]

Although the biotech salmon purportedly would be sterile, the large, voracious GE salmon could out-compete wild fish for food, habitat and mates but then fail to successfully reproduce, effectively driving wild salmon to extinction.[104] Moreover, carnivorous farmed fish eat pellets made from wild fish, among other ingredients.[105] GE salmon would require more wild-caught fishmeal feed than non-GE fish, putting more strain on ocean fish populations to provide feed.

Biotechnology Regulatory Timeline

1930: The Plant Patent Act of 1930 provided 17-year patent protection for plant varieties, including hybrids.[106]

1952: The Patent Act of 1952 extended broader patent rights to agricultural developments to "any new and useful […] composition of matter" including chemicals and processes.[107]

1961: The International Convention for the Protection of New Varieties of Plants established an intergovernmental organization that providing intellectual property rights to the breeders of new plant varieties.[108]

1970: The Plant Variety Protection Act of 1970 provided plant variety breeders with exclusive patent rights for 18 years.[109] It included a "farmer's exemption" that allowed farmers to save seed and to sell saved seeds to other farmers.[110]

1980: The U.S. Supreme Court decision *Diamond v. Chakrabarty* extended patent rights to genetically engineered oil-eating bacteria.[111] The Court ruled that laboratory-created living things were not "products of nature" under the 1952 Patent Act and were thus patentable. This watershed decision bestowed patent protection on GE plants, animals and bacteria.

1981: The first transgenic mice were produced for tissue manipulation and experimentation.[112]

1985-88: A series of rulings by the U.S. Patent and Trademark Office awarde patent protection to plants and nonhuman animals.[113]

1985: The first transgenic sheep and pigs were modified to display enhanced growth.[114]

1986: The Reagan White House determined that no new laws were necessary to regulate biotechnology since it did not pose any special or unique risks.[115]

1986: The Technology Transfer Act allowed the USDA to share publicly financed research and technology with private businesses.[116]

1987: The USDA authorizes field trials of GE plants.[117]

1992: The USDA approves the first GE commercial cultivation, Calgene's Flavr Savr tomato.[118]

1994: The United States ratified the International Convention for the Protection of New Varieties of Plants, which extended plant patents to 20 years for most crops and prohibited farmers from selling saved patented seed without the patent owner's permission.[119]

1995: The EPA registered the first pest-protected plant, Monsanto's NewLeaf potato.[120]

1996: The U.S government approved commercial cultivation of GE soybeans and *Bt* corn.[121]

2000: GE StarLink corn, approved for animal feed, unintentionally contaminated the human food system before being approved for human consumption.[122]

2001: FDA released guidance allowing food companies to voluntarily label GE or non-GE foods, provided that the labels are not false or misleading.[123]

2009: FDA announces that GE animals would be regulated as veterinary drugs instead of food (known as Guidance 187) and defined transgenic animals as veterinary drugs under the Federal Food, Drug and Cosmetics Act.[124]

Insufficient Protection

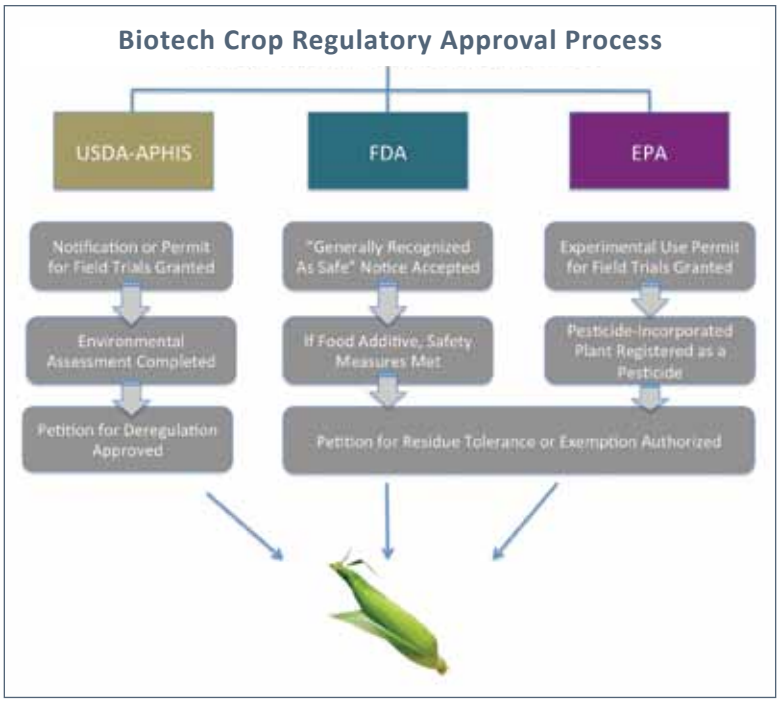
The patchwork of federal agencies that regulates genetically engineered crops and animals in the United States has failed to adequately oversee and monitor GE products. Lax enforcement, uncoordinated agency oversight and ambivalent post-approval monitoring of biotechnology have allowed risky GE plants and animals to slip through the regulatory cracks.

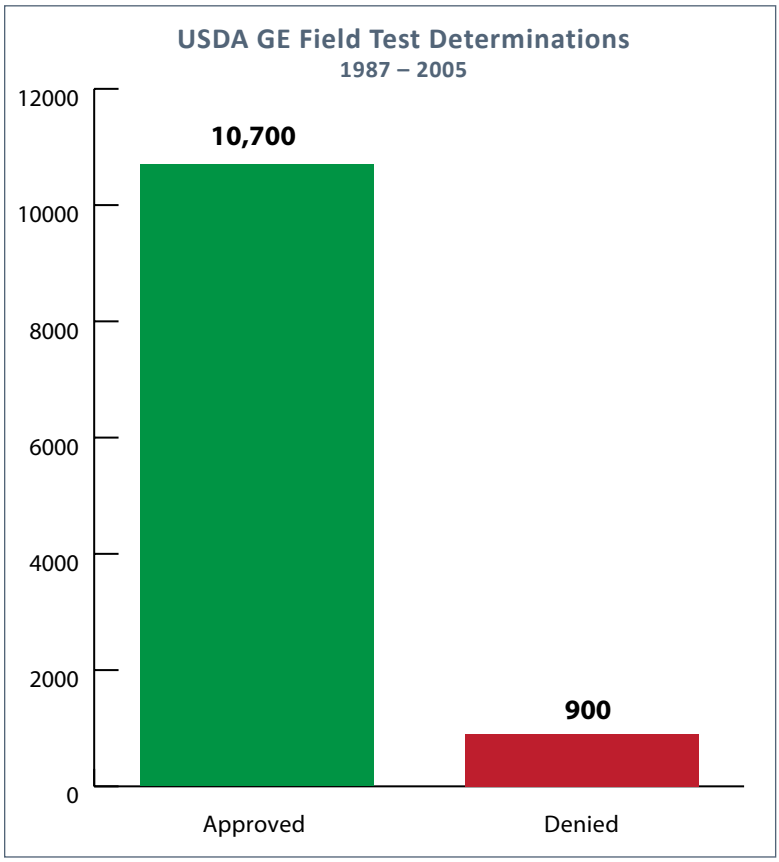
Federal regulators approve most applications for GE field trials, and no crops have been rejected for commercial cultivation.[125] Although some biotechnology companies have withdrawn pending applications, federal regulators approve most GE crops despite widespread concerns about the risk to consumers and the environment.[126] Nonetheless, the biotech industry has pressed for lighter regulatory oversight. Between 1999 and 2009, the top agricultural biotechnology firms spent more than $547 million on lobbying and campaign contributions to ease GE regulatory oversight, push for GE approvals and prevent GE labeling.[127]

The current laws and regulations to ensure the health and environmental safety of biotechnology products were established before genetic engineering techniques were even discovered.[128] The agencies responsible for regulating and approving biotechnology include the USDA, the Environmental Protection Agency (EPA), and the FDA. Although the missions of these agencies overlap in some areas, it is the responsibility of the USDA to ensure that GE crops are safe to grow, the EPA to ensure that GE products will not harm the environment and the FDA to ensure that GE food is safe to eat.

Safe to grow?

The USDA is responsible for protecting crops and the environment from agricultural pests, diseases and weeds, including biotech and conventional crops.[129] The Animal and Plant Health Inspection Service (APHIS) oversees the entire GE crop approval process, including allowing field testing, placing restrictions on imports and interstate





Source: USDA

shipping, approving commercial cultivation and monitoring approved GE crops.[130]

The USDA reviews permit applications and performs environmental assessments to decide whether GE plants will pose environmental risks before field trials may begin.[131] The USDA has approved most of the applications for biotech field releases it has received, giving the green light to 92 percent of all submitted applications between 1987 and 2005.[132] Once field trials are complete, the USDA can deregulate a crop, allowing it to be grown and sold without further oversight.[133] By 2008, the USDA had approved nearly 65 percent of new GE crop deregulation petitions.[134]

Safe for the environment?

The EPA regulates pesticides and herbicides, including GE crops that are designed to be insect resistant.[135] A pesticide is defined as a substance that "prevents, destroys, repels or mitigates a pest," and all pesticides that are sold and used in the United States fall under EPA jurisdiction.[136] The EPA also sets allowable levels of pesticide residues in food, including GE insect-resistant crops. Between 1995 and 2008, the EPA registered 29 GE pesticides engineered into corn, cotton and potatoes.[137]

Bioengineered pesticides are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), first enacted in 1947.[138] New pesticides — including those designed for insect-resistant GE crops — must demonstrate that they do not cause "unreasonable adverse effects on the environment," including polluting ecosystems and posing environmental and public health risks.[139] The EPA must approve and register new GE insect-resistant crop traits, just as the agency does with conventional pesticides.[140] Biotech companies must apply to field test new insect-resistant GE crop traits, establish permissible pesticide trait residue levels for food and register the pesticide trait for commercial production.[141]

Safe to eat?

The FDA is responsible for the safety of both conventional and GE food, animal feed and medicines. The agency regulates GE foods under the Food, Drug and Cosmetics Act, which also gives the FDA authority over the genetic manipulation of animals or products intended to affect animals.[142] GE foods, like non-GE foods, can pose risks

to consumers from potential allergens and toxins.[143] The FDA does not determine the safety of proposed GE foods; instead, it evaluates whether the GE product is similar to comparable non-GE products.[144]

The biotechnology industry self-regulates when it comes to the safety of GE foods. In seeking approval, a company participates in a voluntary consultation process with the FDA, and the agency classifies the GE substances either as "generally recognized as safe" (GRAS) or as a food additive. So far, only one GE product has ever been through the more rigorous "food-additive" process; the FDA has awarded GRAS status to almost all (95 percent) of foods and traits in food since 1998.[145] The FDA also enforces tolerances set by the EPA for pesticidal residues in food.[146] The FDA does no independent safety testing of its own and instead relies on data submitted by biotech companies.

The FDA also regulates genetically engineered animals as veterinary medicines. In 2009, the agency decided that the Food, Drug and Cosmetics Act definition of veterinary drugs as substances "intended to affect the structure of any function of the body of man or other animals" includes genetically altered animals.[147] As of spring 2011, only GE salmon and Enviropig have been considered for commercial approval, but no transgenic animals have been approved to enter the food supply.[148] *(See Appendix for more about the U.S. regulation of GE food.)*

Impact on Consumers

Uncertain Safety

Despite the FDA's approval of common GE crops, questions about the safety of eating these crops persist. GE corn and soybeans are the building blocks of the industrialized food supply, from livestock feed to hydrogenated vegetable oils to high-fructose corn syrup. Safety studies on GE foods are limited because biotechnology companies prohibit cultivation for research purposes in their seed licensing agreement.[158]

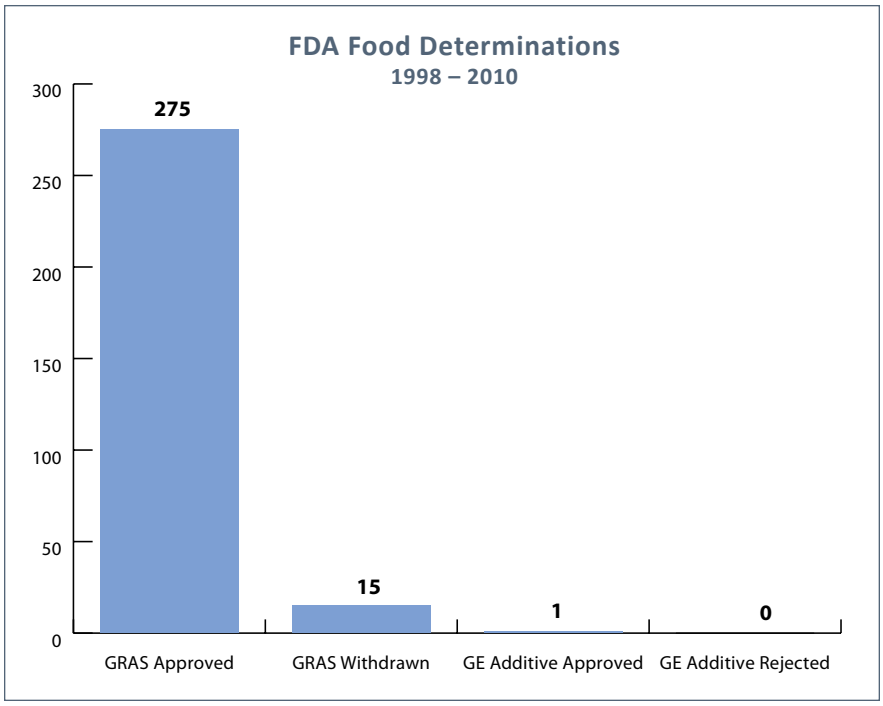
Some of the independent, peer-reviewed research that has been done on biotech crops has revealed some troubling health implications. A 2009 *International Journal of Biological Sciences* study found that rats that consumed GE corn for 90 days developed a deterioration of liver and kidney functioning.[159] Another study found irregularities in the livers of rats, suggesting higher metabolic rates resulting from a GE diet.[160] And a 2007 study found significant liver and kidney impairment of rats that were fed insect-resistant *Bt* corn, concluding that, "with the present data it cannot be concluded that GE corn MON863 is a safe product."[161] Research on mouse embryos showed that mice that were fed GE soybeans had impaired embryonic development.[162] Even GE livestock feed may have some impact on consumers of animal products: Italian researchers found biotech genes in the milk from dairy cows that were fed a GE diet, suggesting the ability of transgenes to survive pasteurization.[163]

EU Regulation

Biotechnology regulation in the European Union is far stricter than in the United States and operates under the "precautionary principle," assessing each food's safety before approving its commercialization.[149] The EU has approved more than 30 GE products for sale in the region, most of which is GE soy and corn (maize) in animal feed.[150] Only two GE crops are currently approved for cultivation in the EU: Monsanto's insect-resistant corn and BASF's high-starch potato.[151] Moreover, domestic GE production is very limited in Europe. In 2009, only 0.05 percent of European fields were growing GE crops, or less than 1 percent of global genetically modified cropland.[152]

Despite having separate regulation for novel food, EU biotechnology regulation still allows some GE products to fall through the cracks. EU law requires that all foods and feeds with any GE content bear labels, including those with more than 0.9 percent accidental biotech content. GE products considered "processing aids," like GE enzymes used to make cheese, are exempt from the labeling process.[153] In this way, the majority of GE use, including soy and corn imports, is hidden from consumers in unlabeled meat and milk from GE-fed livestock. European consumers, who have widely opposed GE foods, have been duped into believing that these products have been withdrawn from the food chain when consumers are in fact unwittingly supporting the GE industry via imported animal feed.[154]

European consumers are skeptical of the safety of GE foods. A 2010 biotechnology survey performed by the European Commission reported that 59 percent of Europeans think that GE food is unsafe for their health and that of their family, and 61 percent do not think that the development of GE food should be encouraged.[155] These opinions are reflected in the nearly one-quarter of EU member countries that are operating bans on GE products despite agribusiness and World Trade Organization pressure.[156] Under the EU's Deliberate Release Directive, which regulates GE crops that go on the market, a "safeguard clause" allows member countries to restrict or prohibit GE use or sale, provided there is evidence that the crop poses significant risks.[157]



Source: FDA

The Roundup Ready trait lowers the nutritional content of crops by inhibiting the absorption of nutrients including calcium, iron, magnesium and zinc, making plants more susceptible to disease.[164] Studies indicate that fusarium — a soil-borne pathogen that infects plant roots — becomes more prevalent when crops are treated with Roundup.[165]

Moreover, some evidence suggests that the most common GE-affiliated herbicide, glyphosate, may pose animal and human health risks. A 2010 study published in *Chemical Research in Toxicology* found that glyphosate-based herbicides caused highly abnormal deformities and neurological problems in vertebrates.[166] Another study found that glyphosate caused DNA damage to human cells even at lower exposure levels than those recommended by the herbicide's manufacturer.[167]Nevertheless, glyphosate use on Roundup Ready crops has grown steadily, with application doubling between 2001 and 2007.[168]

The potential long-term risks from eating GE food are unknown. The FDA contends that there is not sufficient scientific evidence demonstrating that ingesting these foods leads to chronic harm.[169] But GE varieties became the majority of the U.S. corn crop only in 2005 and the majority of the U.S. soybean crop only in 2000.[170] The potential cumulative, long-term risks have not been studied. These considerations should be critical in determining the safety of a product prior to approval, and not left to attempt to assess once the product is on the market.

GE insect-resistant crops may contain potential allergens. One harmless bean protein that was spliced onto pea crops to deter pests caused allergic lung damage and skin problems in mice.[171] Yet there are no definitive methods for assessing the potential allergenicity of bioengineered proteins in humans.[172] This gap in regulation has failed to ensure that potential allergenic GE crops are kept out of the food supply.

In 1998, the EPA approved restricted cultivation of Aventis' insect-resistant StarLink corn, but only for domestic animal feed and industrial purposes because the corn had not been tested for human allergenicity.[173] However, in 2000, StarLink traces were found in taco shells in U.S. supermarkets.[174] The EPA granted Aventis's request to cancel StarLink's registration, helping to remove the GE corn from the food supply.[175] The StarLink episode is a cautionary tale of the failure of the entire regulatory system to keep unapproved GE crops out of the human food supply.

Insufficient Labeling

The FDA governs the proper labeling of U.S. food products. However, because the agency views GE foods as indistinct from conventional foods, the FDA does not require the labeling of GE food products as such. The FDA does permit voluntary GE labeling as long as the information is not false or misleading.[176] Food manufacturers can either affirmatively label GE food or indicate that the food item does not contain GE ingredients (known as "absence labeling"). Virtually no companies disclose that they are using GE ingredients under this voluntary scheme. Moreover, consumers in the United States blindly consume foods that contain GE ingredients.[177]

For consumers to have the opportunity to make informed choices about their food, all GE foods should be labeled. A 2008 CBS/*New York Times* poll found that more than half of American consumers would choose not to buy GE foods, and 87 percent wanted all GE ingredients to be labeled.[178] A 2010 Consumers Union poll found that 95 percent of U.S. consumers favor mandatory labeling of meat and milk from GE animals.[179] Yet

despite this overwhelming support, the FDA will not require labeling of food that comes from genetically modified animals such as the AquaAdvantage salmon.[180]

Impact on the Food System

Superweeds

In the 15 years since herbicide-tolerant crops were first introduced, weeds already have become resistant to GE-affiliated herbicides. Ubiquitous application of Roundup has spawned glyphosate-resistant weeds, a problem that is driving farmers to apply more toxic herbicides and to reduce conservation tilling to combat weeds, according to a 2010 National Research Council report.[201]

At least eight weed species in the United States (and 15 worldwide) have been confirmed to be resistant to glyphosate,[202] including aggressive crop weeds such as ragweed, mare's tail and waterhemp.[203] A 2009 Purdue University study found that glyphosate-tolerant mare's tail could "reach staggering levels of infestation in about two years after it is first detected."[204] Even biotech company Syngenta predicts that glyphosate-resistant weeds will infest one-fourth of U.S. cropland by 2013.[205] Research shows that higher densities of glyphosate-resistant weeds reduce crop yields.[206] Purdue University scientists found that Roundup-resistant ragweed can cause 100 percent corn-crop losses.[207]

Biotech Industry Tries to Block Milk Labels

When the FDA approved the synthetic growth hormone rBGH to enhance milk production in cows, it stated that because there was no distinguishable difference between the milk that comes from cows treated with rBGH and milk that does not, it could not require any label on milk that was produced using the hormone.[181] Given the amount of controversy surrounding rBGH, this decision was surprising, and dairies that were not using the artificial hormone quickly began labeling their products as "rBGH-free."

However, the FDA made any attempts at labeling the absence of rBGH extremely difficult when it issued a 1994 guidance suggesting that the simple phrase "rBGH-free" was misleading.[182] The guidance also recommended that producers include on any rBGH-free label a lengthy qualifying sentence stating that: "No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows."[183]

Just days after the FDA released the document, Monsanto filed suit against two dairy farms that had labeled their milk "rBGH-free."[184] The FDA also got involved and sent warning letters to several dairies that had labeled their milk "hormone-free," stating that they were violating the federal Food, Drug, and Cosmetic Act for misbranding.[185] Monsanto even complained to the FDA and the Federal Trade Commission about allowing any rBGH-related labels to appear on milk, claiming that the practice was damaging its business.[186]

Ben & Jerry's was one company that made an immediate and significant push to label its products as free of rBGH. The Vermont-based ice cream manufacturer first included an rBGH-free label on its products in February 1994.[187] It aggressively defended that decision by continually modifying the label in order to withstand challenges,[188] as well as by suing the state of Illinois to protect its right to label its products.[189] Illinois was one of the first states to ban any labeling of an absence of rBGH, essentially making it impossible for Ben & Jerry's to market its products nationwide as not produced with rBGH.[190]

Varying state labeling requirements effectively prevent national dairy manufacturers and milk retailers from truthfully labeling their products as rBGH-free, since it is easier to have no label than to develop a different label for each state.[191] Ben & Jerry's settlement with the state of Illinois in 1997 enabled that company and others to market and label their products nationwide as not produced with rBGH provided that they include the disclaimer: "The FDA has said no significant difference has been shown and no test can now distinguish between milk from rBGH treated and untreated cows."[192]

In 2007 and 2008, several additional states, at the urging of groups backed by Monsanto,[193] made significant moves to restrict the type of rBGH-free labeling that could appear on dairy products. Some states, such as Utah,[194] developed proposals that were modeled after FDA guidelines, while others, including Ohio, issued more specific requirements regarding the type, size, and location of the FDA disclaimer.[195] Missouri and Pennsylvania went even further by attempting to ban any mention of an absence of rBGH.[196] In Pennsylvania, the Secretary of Agriculture attempted to create an outright ban on any rBGH labeling, but this was reversed in response to consumer backlash and was reduced to a rule that was similar to the original FDA proposal.[197] A bill introduced in Missouri was met with a similar reaction, and in response to consumer protest the original bill had to be modified[198] before eventually dying in committee.[199]

Despite years of grappling with the issue, most attempts made by state legislatures and agriculture departments to ban rBGH labeling have been unsuccessful. In 2010, the U.S. Court of Appeals for the Sixth Circuit threw out Ohio's restrictive limits on affirmative "rBGH-free" labeling.[200] As of the summer of 2011, the Ohio Department of Agriculture still had not revised its rules.

Patent Power and Seed Consolidation

Only a few biotechnology companies dominate the U.S. seed industry, which once relied on universities for most research.[208] Farmers depend on the few firms that sell seeds, and these companies have raised the prices of seed and affiliated agrochemicals as the market has become increasingly concentrated. High levels of concentration can raise seed prices for farmers.[209] Biotech corn seed prices increased 9 percent annually between 2002 and 2008, and soybean seed prices rose 7 percent annually.[210] Between 1996 and 2007, Monsanto acquired more than a dozen seed companies.[211] The two largest firms sold 58 percent of corn seeds in 2007 and 60 percent of soybean seeds in 2005.[212]

Biotechnology firms control how their patents are used, form joint ventures and impose stringent requirements on farmers who grow patented seeds. Mergers combined with patent restrictions have increased the market power of biotechnology companies.[213]

Strict patents protect genetically engineered seeds.[214] These seeds were not even considered patentable until the 1980s, when several court cases extended patent rights to GE organisms.[215] Biotech companies further leverage the limited patent monopoly of their seeds through joint ventures and cross-licensing agreements.[216] The patent owner controls how partnering companies use and combine the traits.[217] Consequently, although there are numerous seed companies, most of the available corn, soybean and cotton seeds include Monsanto-patented traits that have been cross-licensed to other seed companies.[218] By 2009, nearly all (93 percent) of the soybeans and four-fifths (80 percent) of the corn cultivated in the United States were grown from seeds covered by Monsanto patents.[219]

Farmers pay licensing fees and sign contracts for limited permission to plant GE seeds.[220] The licenses typically prohibit farmers from saving the seeds from harvested crops to plant the next season; they also delineate specific farming practices, mandate specific sales markets and allow the company to inspect farmers' fields.[221] Indeed, farmers must buy new seeds every year because they face patent infringement suits if they run afoul of GE seed-licensing agreements by saving seed.[222] And biotech companies zealously pursue farmers that allegedly violate their patents. Monsanto has hired private investigators to videotape farmers, infiltrate community meetings and interview informants about local farming activities.[223] By October 2007, Monsanto had filed 112 patent infringement lawsuits, recovering as much as $160.6 million from farmers.[224]

Impact on Farmers

Contamination

The USDA prohibits the use of GE material — including enzymes, seeds, or veterinary treatments — in any product that carries the agency's "certified organic" label.[225] Certified organic farmers can face significant economic hardship if biotech traits contaminate their organic crops or organic livestock feed. Contamination can occur either when GE seeds are inadvertently mixed with non-GE seeds during storage or distribution, or when GE crops cross-pollinate non-GE crops.[226] A Union of Concerned Scientists study found that 50 percent of non-GE corn and soybean and 83 percent of non-GE canola seeds in the United States were contaminated with low levels of GE residue.[227] It is well documented that a farmer's field can be inadvertently contaminated with GE material through cross-pollination and seed dispersal.[228] Even Monsanto admits that "a certain amount of incidental, trace level pollen movement occurs."[229]

Liability

Farmers who unintentionally grow GE-patented seeds or who harvest crops that are cross-pollinated with GE traits could face costly lawsuits by biotechnology firms for "seed piracy." Farmers who intentionally grow GE crops are not required to plant non-GE buffer zones to

prevent contamination unless this is stipulated in the farm's USDA permit.[230] Yet even the use of buffer zones has proven ineffective because these areas are usually not large enough to prevent contamination.[231]

The USDA's approval of Roundup Ready alfalfa in 2010 highlights the significant ramifications that contamination can have for organic producers. Alfalfa is the most important feed crop for dairy cows.[232] However, GE alfalfa can easily cross-pollinate organic alfalfa crops and cause organic farmers to lose their markets if testing reveals contamination.[233] Conventional alfalfa farmers could face seed piracy suits from Monsanto even if their crops are inadvertently pollinated by GE alfalfa. At least one farmer contends that he was sued when his canola fields were contaminated with GE crops from neighboring farms.[234]

Organic dairy farmers already face difficulty securing organic feed, and this challenge will only worsen if GE alfalfa begins to contaminate organic alfalfa.[235] Organic dairy farmers receive a price premium of $6.69 (44 percent) for their milk, but they also have production costs of $5 to $7 more per hundred pounds of milk — 38 percent higher than conventional dairies.[236] GE contamination could eliminate this premium that covers the higher organic production costs, making these farms unprofitable.

Organic and non-GE growers bear the financial burden of GE contamination and are fighting to make biotech companies liable for these consequences instead. In 2011, the Public Patent Foundation filed suit against Monsanto on behalf of farmers and organic businesses, asking the court to determine whether Monsanto has the legal authority to sue farmers for patent infringement if their GE traits contaminates a conventional or organic farm.[237] U.S. Agriculture Secretary Tom Vilsack has informally discussed creating an insurance fund to compensate organic growers that have faced economic harm due to transgenic contamination, but there is no telling how committed he is to this policy idea.[238]

Global Trade

Although the United States has readily approved GE crops and products, many countries, including key export markets, have not done so. Three-quarters of consumers in Japan, Italy, Germany and France are skeptical of the safety of GE foods.[239] Europe has been restrictive in its approval of biotech foods because of uncertainty about the safety of the products for human consumption.[240]

Unlike the United States, the EU regulatory framework specifically addresses the new properties and risks of biotech crops and affirmatively evaluates the safety of every GE crop.[241] EU member states currently allow animal feed imports to contain up to 0.1 percent of unapproved GE material.[242] Additionally, the EU requires all foods, animal feeds and processed products with biotech content to bear GE labels.[243] Six EU countries currently ban GE cultivation altogether: Austria, France, Germany, Greece, Hungary and Luxembourg.[244] Countries that ban GE foods typically impose strict rules to prevent unauthorized GE imports, which blocks or limits U.S. exports of corn and soybeans that are primarily GE crops. Japan does not grow GE crops and requires mandatory labeling of all GE foods.[245]

Despite the advanced grain-handling system in the United States, GE grains have contaminated non-GE shipments and devastated U.S. exports. The Government Accountability Office (GAO) identified six known unauthorized releases of GE crops between 2000 and 2008.[246] In 2000, Japan discovered GE StarLink corn,

which was not approved for human food, in 70 percent of tested samples, even though StarLink represented under 1 percent of total U.S. corn cultivation.[247] After the StarLink discovery, Europe banned all U.S. corn imports, costing U.S. farmers $300 million.[248] In August 2006, unapproved GE Liberty Link rice was found to have contaminated conventional rice stocks.[249] Japan halted all U.S. rice imports and Europe imposed heavy restrictions, costing the U.S. rice industry $1.2 billion.[250] In 2007, Ireland impounded imported U.S. livestock feed that tested positive for GE, unapproved in the country.[251]

The United States is aggressively seeking to force its trading partners to overturn their GE prohibitions. The U.S. Trade Representative is lobbying trading partners to remove "unjustified import bans and restrictions to U.S. biotech products" and is even pressing countries to eliminate GE labeling requirements.[252] The diplomatic push by U.S. biotech interests extends to developing countries as well: in recent years, the U.S. State Department has pressed African nations to lift GE restrictions.[253]

Debunking Monsanto's Myths

MONSANTO MYTH: *Everything Monsanto does helps to make agriculture more productive and more profitable for farmers.*[254]

Biotech companies such as Monsanto claim that their products strengthen farm productivity by improving yields and reducing costs.[255] Yet the cost savings are largely illusory, and the yield gains have been limited.

GE seeds and affiliated herbicides are typically more expensive than conventional products. For example, in 2009, Roundup Ready soybean seeds cost twice as much as non-GE seeds.[256] Although biotech companies contend that farmers save on affiliated herbicides, the herbicide savings are less than the increased seed costs. Soybean farmers were able to save between $3 and $20 per acre on reduced herbicide costs,[257] but GE soybean seed can cost $23 more per acre than conventional seed.[258] In 2008, biotech corn and soybean seeds cost 60 and 52 percent more, respectively, than non-biotech varieties.[259]

And these higher costs do not generate higher yields. A 2009 Union of Concerned Scientists survey found that herbicide-tolerant corn and soybeans showed no yield increase over non-GE crops, and insect-resistant corn had only a slight advantage over conventional corn.[260] A 2007 Kansas State University study found that non-GE soybeans had 10 percent higher yields than biotech soybeans.[261]

MONSANTO MYTH: *Monsanto will help to create more nutritious, vitamin-rich foods for consumers.*[262]

Some scientists and development advocates have promoted biotechnology as a means to combat malnutrition. Scientists in Spain, for example, are attempting to engineer beta-carotene, folate and vitamin C into African corn.[263] One well-known biofortification project, Golden Rice, adds beta-carotene to rice to help fight the vitamin A deficiency that causes blindness in a quarter million children annually.[264] Yet engineering crops with beta-carotene may not even reduce vitamin A deficiency because consumption alone does not ensure absorption.[265] Diets of malnourished people often lack the fats and oils crucial to absorbing vitamin A.[266] One of the few clinical trials on humans to examine Golden Rice's nutrition effects studied only five, healthy American volunteers, hardly representative of the target population.[267]

Development agencies, foundations such as the Bill and Melinda Gates Foundation, and biotech companies are investing in uncertain technological solutions to a problem that needs a more practical solution. Developing new biotech crops is expensive, challenging, time consuming and regionally specific. To date, no biofortified crops have been successfully commercialized.[268] Vitamin A deficiency can instead be combated by consuming conventionally grown orange-colored produce (sweet potatoes, carrots or mangos) and dark leafy green vegetables, supplemented with fats and oils.[269] Providing low-income rural families with the capacity to grow crops that provide balanced nutrition is a more practical approach than asking them to spend more money for seeds that may not have better yield or bear more nutritious food.

MONSANTO MYTH: *Monsanto will help farmers do more with less.*[270]

Most GE crops are designed to be tolerant of specially tailored herbicides, the most common of which is glyphosate, marketed by Monsanto under the brand name Roundup.[271] Farmers can spray the herbicide on their fields, killing the weeds without harming their GE crops. Monsanto's Roundup Ready (herbicide-tolerant) corn, soybeans and cotton were planted on 150 mil-

lion U.S. acres in 2009.[272] Glyphosate use on Roundup Ready crops has grown steadily. Between 2001 and 2007, annual U.S. glyphosate use doubled to 185 million pounds.[273]

Ubiquitous Roundup application has spawned glyphosate-resistant weeds, driving farmers to apply even more toxic herbicides, according to a *2010 National Research Council report*.[274] Farmers may resort to other herbicides to combat superweeds, including 2,4-D (an Agent Orange component) and atrazine, which have been associated with health risks including endocrine disruption and developmental abnormalities.[275]

Monsanto's solution to the emerging Roundup-resistant weeds has been to offer certain farmers "residual control" rebates of up to $20 per acre to apply additional herbicides after Roundup fails.[276] Biotech companies also are developing seeds that are tolerant of multiple herbicides to cope with weed resistance. Dow has developed a GE corn variety that is tolerant of 2,4-D and glufosinate[277] — which could be dangerous to eat because a metabolite of 2,4-D is known to cause skin sores, liver damage and sometimes death in animals.[278] Monsanto, meanwhile, has developed a dicamba-tolerant soybean.[279]

MONSANTO MYTH: *Monsanto squeezes more food from a raindrop.*[280]

Biotechnology proponents contend that high-tech solutions can reduce poverty and hunger in the developing world, but high-priced seeds and herbicides are ill suited to poor farmers in the developing world. The prestigious 2009 *International Assessment of Agriculture Knowledge, Science and Technology for Development*, a report written by more than 400 scientists and sponsored by the United Nations and World Bank, concluded that the high costs for seeds and chemicals, uncertain yields, and potential to undermine local food security makes biotechnology a poor choice for the developing world.[281]

Monsanto uses cotton expansion in India as an example of improving food security.[282] Indian farmers, wooed by Monsanto's marketing, have widely adopted GE cotton.[283] Many take out high-interest loans to afford the GE seeds, which can be twice as expensive as conventional seeds.[284] Half of all pesticides applied in India are now used on cotton, and some farmers significantly over-apply the chemicals, making agricultural workers highly vulnerable to health problems.[285] More than half of Indian farmers lack access to irrigation, leaving them dependent on a punctual rainy season for a good crop.[286] And when GE cotton crops fail, farmers are often unable to repay the substantial debt. The steeper treadmill of debt with GE crops contributes to a rising number of farmer suicides in India — exceeding 17,000 in 2009.[287]

By contrast, a 2006 study published in *Environmental Science and Technology* found that low-input farms in developing countries had significant yield gains.[288] And a 2007 University of Michigan study found that organic farming in the developing world had higher yield gains than conventional production and could feed the global population without increasing the amount of cultivated land.[289] Despite the huge public relations campaigns, biotechnology is not solving our sustainability problems — it's making them worse and creating more.

MONSANTO MYTH: *Monsanto will help to mitigate climate change impacts by enabling farmers to adapt to the changing environment.*[290]

Global warming, drought and catastrophic weather events will affect agriculture for decades to come.[291] Biotech firms have promised high-yield and drought-resistant GE seeds, but these traits are not presently commercially available.[292] Crop research has yet to achieve the complex interactions between genes that are necessary for plants to endure environmental stressors such as drought.[293] As of summer 2011, no drought-tolerant GE crops had been approved.[294]

Traditional methods of breeding for stress tolerance produce crops that are more resilient to disruption and climate change than GE crops because these crops complement and thrive in nutrient-rich and biodiverse soil.[295] Even if research succeeded in developing drought-tolerant crops, biotechnology companies would control any viable seeds, potentially putting new seeds out of reach for poor farmers.

MONSANTO MYTH: *Monsanto makes the most efficient use of important resources in order to help farmers sustain our planet.*[296]

Expanding thirsty GE crops to more arid developing countries will exacerbate water scarcity. The developing world faces the most pronounced environmental degradation.[297] Global agriculture uses nearly 2 *quadrillion* gallons of rainwater and irrigation water annually — enough to flood the entire United States with two feet of water.[298] In the developing world, 85 percent of water withdrawals go toward agriculture.[299]

Already, parts of northern India pump 50 percent more water than the aquifers can refill.[300] Even Nobel Laureate

Norman Borlaug, the godfather of the Green Revolution, noted that the rapid rise of ill-planned irrigation schemes to accommodate new crops in Asia often led to waterlogged or salty fields, which reduced agricultural productivity.[301]

In the United States, irrigated corn acreage increased 23 percent and irrigated soybean acreage increased 32 percent between 2003 and 2008.[302] The rising U.S. cultivation of GE corn and soybeans further threatens the strained High Plains Aquifer, which runs beneath eight western states and provides nearly a third of all groundwater used for U.S. irrigation.[303] Ninety-seven percent of High Plains water withdrawals go to agriculture, and these withdrawals now far exceed the recharge rate across much of the aquifer.[304] The worldwide expansion of industrial-scale cultivation of water-intensive GE commodity crops on marginal land could magnify the pressure on already overstretched water resources. But these are the crops the biotech industry has to offer.

Conclusion

The U.S. experiment with GE food has been a failure. Impacts on the environment, food system and public health are not fully documented but are clearly not worth it. It is time for a new approach to biotechnology in the food system.

Recommendations

- **Enact a moratorium on new U.S. approvals of genetically engineered plants and animals.**
- **Institute the precautionary principle for GE foods:** Currently in the United States, most GE foods, donor organisms and host organisms are generally considered safe for consumption and the environment until proven otherwise.[305] The United States should enact policy that would more rigorously evaluate the potentially harmful effects of GE crops before their commercialization to ensure the safety of the public.
- **Develop new regulatory framework for biotech foods:** Congress should establish regulations specifically suited to GE foods.
- **Improve agency coordination and increase post-market regulation:** The EPA, USDA and FDA should create mechanisms for coordinating information and policy decisions to correct major regulatory deficiencies highlighted by the GAO.[306] Additionally, the agencies should adequately monitor the post-market status of GE plants, animals and food.
- **Require mandatory labeling of GE foods:** An affirmative label should be present on all GE foods, ingredients and animal products.
- **Shift liability of GE contamination to seed patent holders:** The financial responsibility of contamination should be on the patent holders of the GE technology, rather than on those who are economically harmed. The patent-holding biotechnology company should financially compensate farmers whose crops are contaminated.

Appendix: The U.S. Regulatory System for GE Food

USDA

The USDA is responsible for protecting crops and the environment from agricultural pests and weeds, including biotech and conventional crops. The Animal and Plant Health Inspection Service (APHIS) oversees the entire GE crop approval process, from field tests to commercial cultivation.[307]

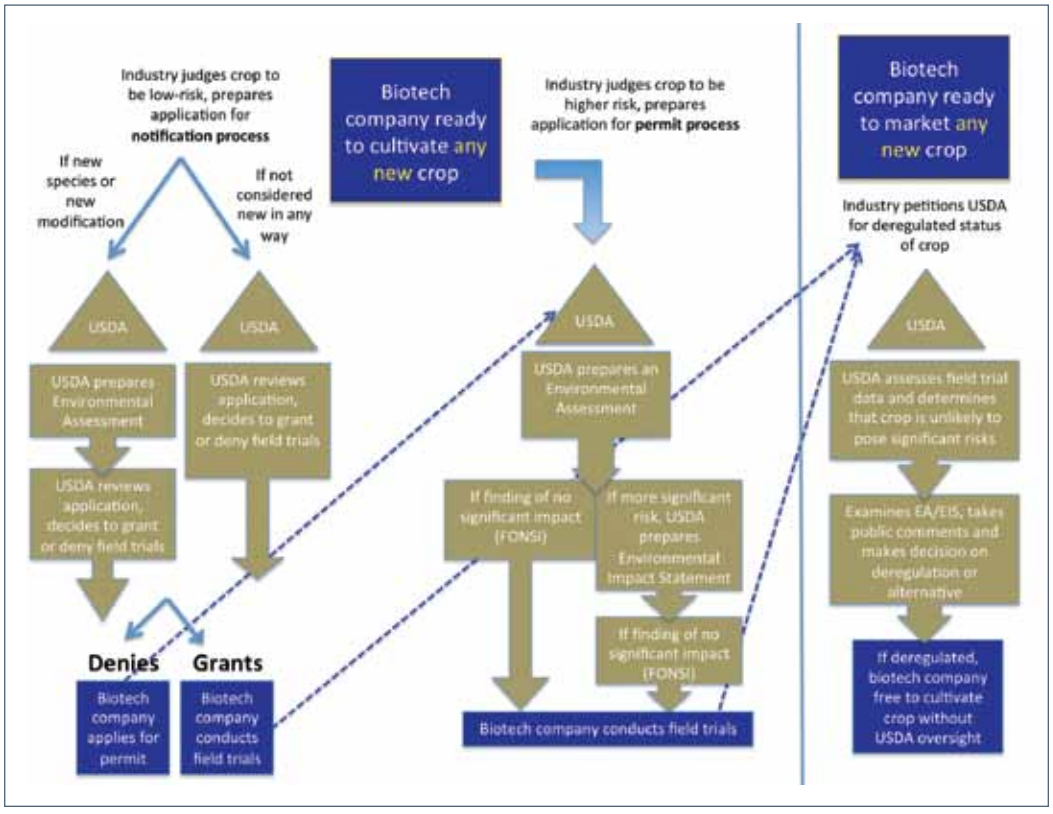
Biotech companies must either enter a "notification" or "permit" process before GE field trials begin.[308] Under the streamlined notification process, companies submit data showing that the new GE plant will not harm agriculture, the environment or non-target organisms, and the USDA either approves or denies the field-testing application within one month.[309] If the USDA denies the notification application, the company can re-apply under the more involved permit process.[310] The notification process does not require either an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) for GE crops that are neither new species nor new modifications.[311]

Under the more rigorous permit application process, the USDA determines if the GE field trial poses significant environmental impact before issuing a permit.[312] The USDA reviews scientific submissions for four months before granting or denying the field test permit request.[313] If approved, the permit imposes restrictions on planting or transportation to prevent the GE plant material from escaping and posing risks to human health or the environment.[314] The USDA approved the vast majority — 92 percent — of the applications for biotech field releases between 1987 and 2005.[315] The applying company is required to submit field-trial data to the USDA within six months of the test, demonstrating that the crop poses no harm to plants, non-target organisms or the environment.[316] If the applicant violates the permit, the USDA can withdraw it.[317]

The USDA must complete an EA and/or EIS before approving any new crop release (including biotech crops) that will affect the environment under the National Environmental Policy Act.[318] The EA determines whether the GE crop will pose significant risks to human health or the environment if cultivated.[319] If there is no significant risk, the USDA issues a "finding of no significant impact" (FONSI).[320] But if the USDA finds more significant environmental implications, it must also perform a more thorough EIS.[321]

The USDA already relies on company-supplied data for many of its EAs, but a 2011 proposed pilot project threatens to further compromise the scientific rigor of the process. The two-year pilot project allows consultants that are funded by a cooperative services agreement between the biotech company and APHIS to perform EAs, giving firms more influence over the safety designation of their own products. [322]

If a field trial does not reveal significant risks, the company can petition for nonregulated status, allowing the crop to be cultivated and sold commercially without fur-



ther oversight.[323] The USDA solicits public comments on the deregulation for 60 days.[324] After reviewing available data, the USDA makes a final decision within six months.[325] By 2008, the USDA had approved nearly 65 percent (73 of 113) of new GE crop deregulation petitions, according to the Government Accountability Office, the investigative arm of Congress.[326]

After GE crops are approved, the USDA performs almost no post-release oversight and has no program for monitoring approved GE plants.[327] Instead, the USDA's primary post-market role with GE crops is through the Agricultural Marketing Service (AMS), which helps facilitate the export of transgenic crops by verifying their genetic identity.[328] The AMS does not test for GE presence in grains; it only works with interested shippers who participate in a voluntary verification program.[329]

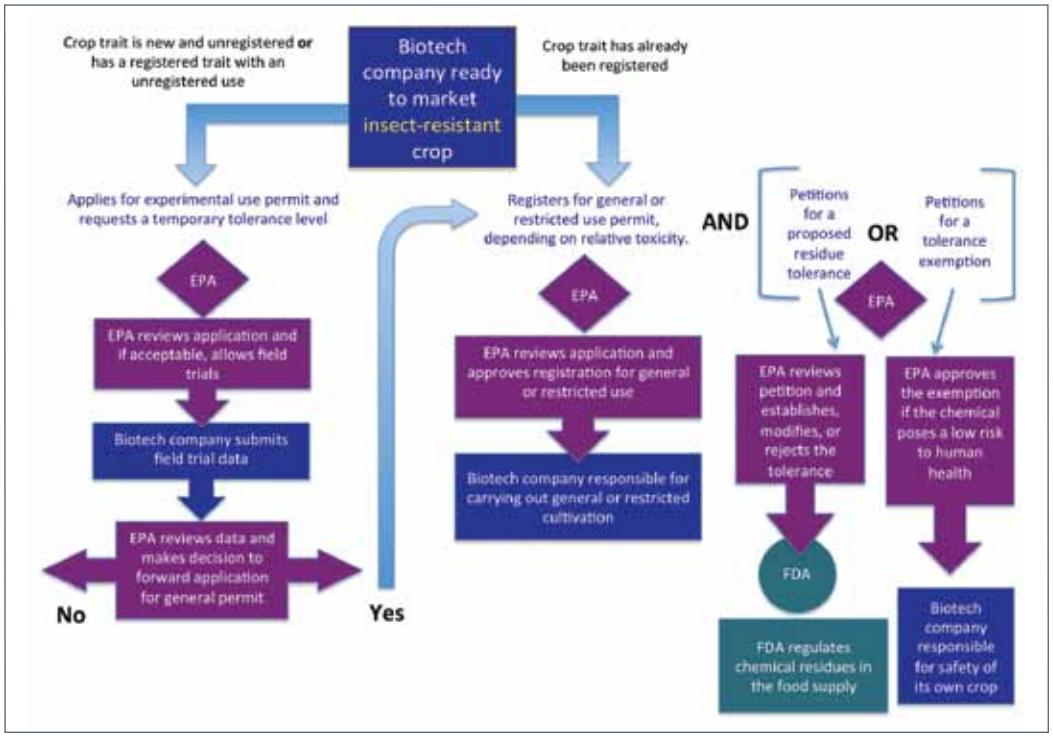
EPA

Pesticide residue standards: The EPA establishes allowable pesticide residue limits for food or feed crops and is required to meet all food and feed safety standards enforced by the FDA.[330] These tolerance levels, or safe levels of pesticide residues, are based both on immediate exposure risks and on the potential accumulated risk from consuming pesticide residues over time.[331]

The EPA pesticide tolerances appear generous. A 2010 National Institutes of Health cancer risk study reported criticism by environmental health professionals and advocates that agribusiness influence at EPA deterred the agency from establishing sufficiently strong pesticide limits.[332] The EPA can even exempt pesticides from establishing tolerances if it finds a low probability of risk to public health.[333] Theoretically, tolerance exemptions allow food to contain any amount of that pesticide residue.[334]

Field trials and final approval: The EPA considers any substance that "prevents, destroys, repels or mitigates a pest" a pesticide, including insect-resistant crops, which the agency terms "plant incorporated protectants."[335] All new pesticides must be registered with the EPA.[336] Additionally, the EPA reviews and grants experimental use permits for field tests of unregistered pesticides or of registered pesticides tested for an unregistered use.[337] Biotech companies must apply for an experimental use permit for insect-resistant GE crops if they are grown on more than 10 acres of land.[338] Experimental use permits typically limit field trials to one year.[339] Biotech companies must submit all test data detailing a plant's toxicity and environmental risk to the EPA within six months of the field trial's completion.[340] If the test demonstrates that the crop poses acceptable risks, the company can apply to register the new crop for commercial distribution. The EPA may solicit expert scientific input as well as public comment on pending applications.[341]

Applications for permit registration must include management plans that describe any limitation on cultivating the new insect-resistant GE crops.[342] The management plans often require the designation of a non-insect-resistant seed buffer refuge along the border of the GE crop.[343] This "refuge" is intended to give pests access to non-pesticidal plants so that a pest does not develop resistance to the pesticide.[344] Biotech seed companies are responsible for ensuring that farmers follow these management plans. For example, in 2010, the EPA imposed a $2.5



million fine on Monsanto for selling GE seed between 2002 and 2007 without informing Texas farmers about EPA-mandated planting restrictions.[345]

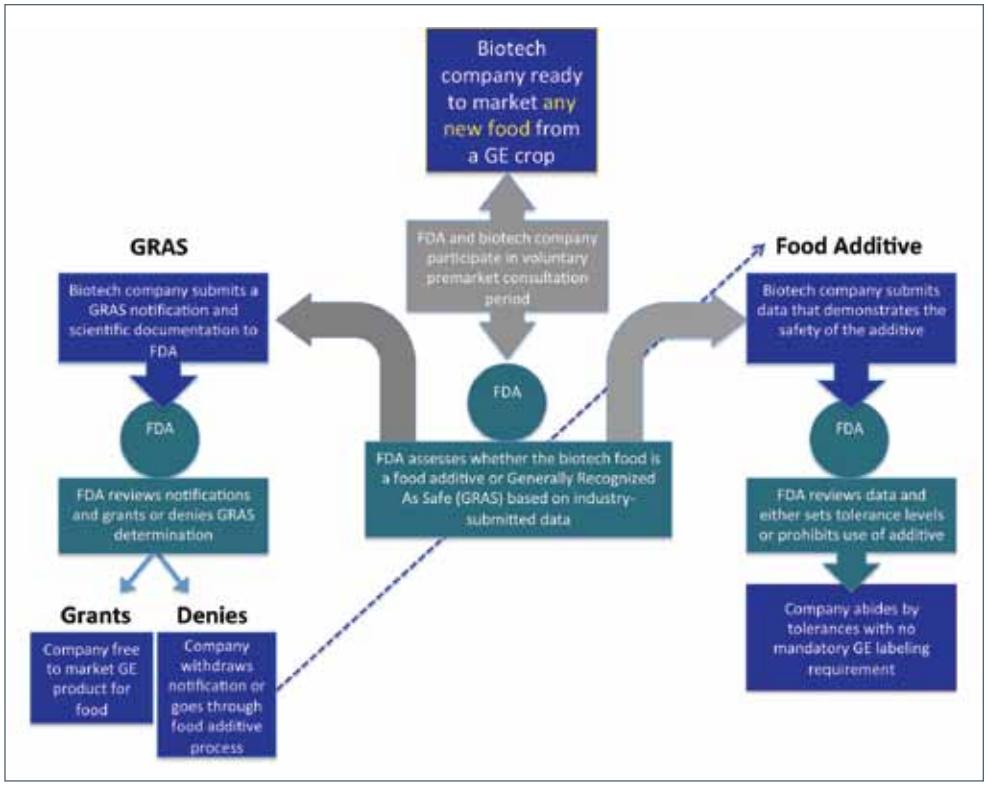
FDA

In most cases, the biotechnology industry self-regulates when it comes to the safety of genetically engineered foods. In 1992, the FDA issued guidance that gave the biotech industry responsibility for ensuring that new GE foods are safe and compliant with the federal Food, Drug and Cosmetics Act.[346] In 2001, the FDA proposed a rule requiring companies to submit data and information on new biotech-derived foods 120 days before commercialization.[347] As of mid-2011, the decade-old rule still had not been finalized and the industry data submissions remained voluntary.

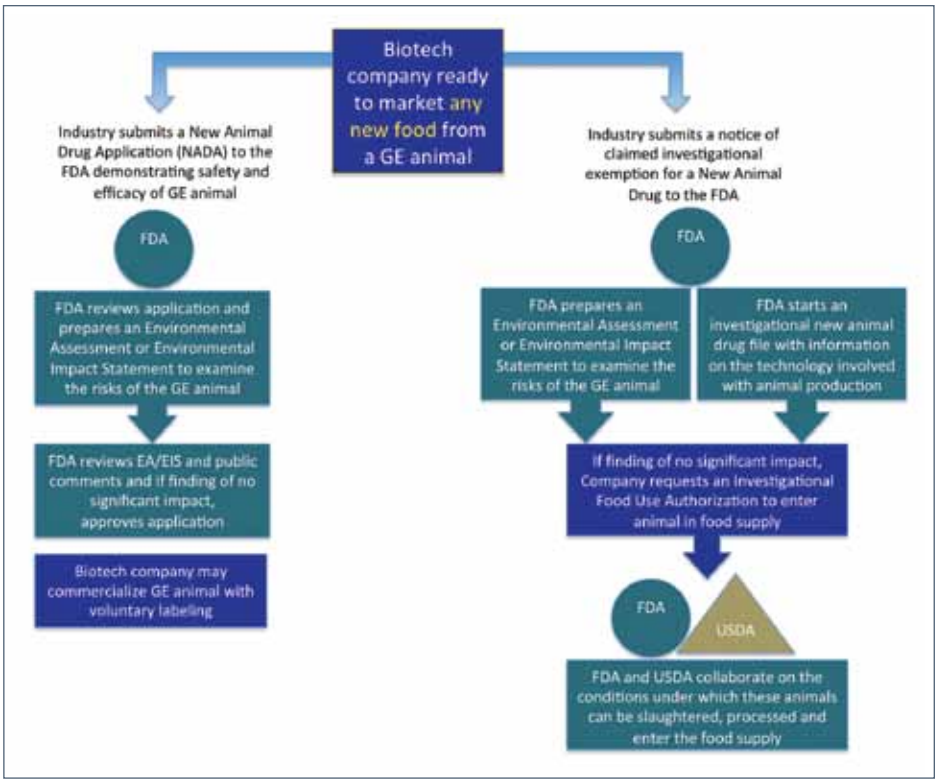
For whole foods (intact foods such as a whole apple or potato), safety responsibility is on the manufacturer and no FDA premarket approval is necessary.[348] However, for substances added to food, such as biotech traits, the FDA classifies them as "generally recognized as safe" (GRAS) or as food additives.[349] The FDA grants GRAS determinations to GE-derived foods that are considered equivalent to the structure, function or composition of food that is currently considered safe.[350] A company may voluntarily submit a GRAS notification and scientific documentation to the FDA, but it is not a requirement.[351] If the FDA determines that the GE food or ingredient is GRAS, it is not required to make a pre-market safety determination to approve the substance the way it would for a food additive.[352] The FDA has awarded "generally recognized as safe" status to almost all —95 percent — of the GRAS applications submitted for food since 1998, according to the agency's GRAS Notice Inventory.[353]

By contrast, the FDA must pre-approve food additives before they can be sold. However, the FDA trusts biotechnology companies to certify that their new GE foods and traits are the same as foods currently on the market. The company may send information on the source of the genetic traits (i.e., which plants or organisms are being combined) and on the digestibility and nutritional and compositional profile of the food, as well as documentation that demonstrates the similarity of the new GE substance to a comparable conventional food.[354] The FDA evaluates company-submitted data and does not do safety testing of its own.[355] The agency can approve the GE substance, establish certain regulatory conditions (such as setting tolerance levels) or prohibit or discontinue the use of the additive entirely.[356] The FDA evaluates the safety of all additives, but it has evaluated only one GE crop trait as an additive, the first commercialized GE crop, Flavr Savr tomatoes.[357]

Once a GE food product has been approved and is on the market (either by GRAS designation or as a food additive), the FDA is responsible for its safety. Until recently, the agency could ask companies to recall dangerous food products only voluntarily; however, the Food Safety Modernization Act of 2011 recently granted the FDA mandatory recall authority.[358] Generally, the FDA has awaited outbreaks of foodborne illness before taking action, rather than vigorously monitoring and inspecting food manufacturers.[359] This reactive approach has been ineffective in preventing foodborne illnesses. The FDA did pressure a company to recall one GE food product



— StarLink corn, which was unapproved for human consumption — when it entered the food supply.[360] The FDA's lack of post-market monitoring can expose the public to unapproved GE traits in the food supply.



GE Animals

The federal government regulates genetically engineered animals the same as veterinary medicines. In 2009, the FDA decided that the Food, Drug and Cosmetics Act definition of veterinary drugs as substances "intended to affect the structure of any function of the body of man or other animals" includes genetically altered animals.[361] This allows the FDA's Center for Veterinary Medicine to approve GE animals under a procedure that is unsuited for the complex interactions of transgenic animals with other livestock and the environment. This regulatory interpretation (known as Guidance 187) was released in the same year as some companies publicly announced their intentions to bring transgenic food animals to market.[362]

The FDA must approve a New Animal Drug application before it can be commercialized. The application must demonstrate the GE animals' safety and efficacy as well as contain methods for detecting residues in food-producing animals, a description of manufacturing practices, and any proposed tolerance levels.[363] Veterinary drug manufacturers that are introducing their products for investigational use are exempt from new animal drug approval requirements.[364]

A transgenic investigational animal or animal product requires an investigational food-use authorization from both the FDA and the USDA in order to enter the food supply.[365] The biotech company must also prepare an Environmental Assessment for investigational GE animals.[366] In 2009, the FDA used the investigational use process to approve the first commercial biologic from a GE animal, the anticlotting agent ATryn produced with transgenic goat milk.[367] Many of the FDA's processes involving drugs are exempt from disclosure, making it difficult for the public to participate fully in regulatory decisions concerning GE animals. [368]

Once the FDA approves the production of experimental GE animals, the USDA must consider if and under what restrictions these animals can be slaughtered, processed and enter the food supply.[369] As of the summer of 2011, GE salmon and Enviropig had been considered for commercial approval, but no transgenic animals had been approved to enter the food supply.

It seems unlikely that the USDA will keep meat products derived from GE livestock out of the food supply, based on the FDA's tacit approval of food from cloned livestock. In 2008, the FDA determined that there are no risks associated with eating meat from cloned livestock or meat from the offspring of clones.[370] The USDA then asked producers of cloned animals, several hundred of which were believed to be on the market at the time, to abide by a voluntary moratorium on selling meat or milk from cloned animals.[371] The moratorium was supposed to allow time for a proposed USDA study on the potential economic impacts of cloned animals on U.S. agriculture and international trade.[372] As of the summer of 2011, that study had not been completed, and there are no known FDA efforts to ensure that owners of cloned animals comply with the moratorium on sales of meat or milk.

ENDNOTES

1 Pew Initiative on Food and Biotechnology. "Review of Public Opinion Research." November 16, 2006 at 9-10.

2 Pew Initiative on Food and Biotechnology. "Guide to U.S. Regulation of Genetically Modified Food and Agricultural Biotechnology Products." September 2001 at i; Vogt, Donna and Mickey Parish. Congressional Research Service. "Food Biotechnology in the United States: Science, Regulation, and Issues." (RL 30198). January 2001 at 2.

3 U.S. Department of Agriculture (USDA). Economic Research Service (ERS). "Adoption of Bioengineered Crops." Available at http://www.ers.usda.gov/Data/BiotechCrops/ and on file. Accessed September 9, 2009.

4 University of Guelph. "EnviropigTM" Available at http://www.uoguelph.ca/enviropig/ and on file. Accessed March 3, 2011; AquaBounty Technologies. "Press Room." Available at http://www.aquabounty.com/PressRoom/. Accessed on February 8, 2011.

5 Fernandez-Cornejo, Jorge and Margriet Caswell. USDA ERS. "The First Decade of Genetically Engineered Crops in the United States." EIB No. 11. April 2006 at 1.

6 Shoemaker, Robbin (Ed). USDA ERS. "Economic Issues in Agricultural Biotechnology." AIB-762. 2001 at 9.

7 To date, the United States has only approved herbicide tolerant and insect tolerant canola, corn, cotton and soybeans as well as virus resistant squash and papayas. Fernandez-Cornejo, Jorge. "Rapid growth in adoption of genetically engineered crops continues in U.S." *Amber Waves*. Vol. 6, Iss. 4. September 2008 at 6; International Service for the Acquisition of Agri-Biotech Applications (ISAAA). "Biotech crops poised for second wave of growth." [Press release]. February 11, 2009.

8 Fernandez-Cornejo, Jorge. USDA, Economic Research Service. "The Seed Industry in U.S. Agriculture." AIB-786. January 2004 at 2.

9 *Ibid*.

10 National Research Council. "Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects." 2004 at 19, Figure 1-1.

11 57 Fed. Reg. 22984, (May 29, 1992).

12 Lemaux, Peggy G. "Genetically engineered plants and foods: A Scientist's Analysis of the Issues (Part I). *Annu. Rev. Plant Biol.* Iss. 59. 2008 at 780.

13 National Research Council (2004) at 117-118.

14 James, Clive. ISAAA. "ISAAA Brief 42-2010: Global Status of Commercialized Biotech/GM Crops: 2010." 2011 at 7 of Executive Summary.

15 *Ibid*. at Table 1 of Executive Summary.

16 USDA. Office of Inspector General, Southwest Region. "USDA's Role in the Export of Genetically Engineered Agricultural Commodities." Audit Report No 50601-14-Te. February 2009 at 7; USDA ERS. "Adoption of Genetically Engineered Crops in the U.S." From Corn and Soybean spreadsheets. Accessed July 6, 2011. Available at http://www.ers.usda.gov/Data/BiotechCrops/. Updated July 1, 2011.

17 Cowan, Tadlock. Congressional Research Service. "Biotechnology in Animal Agriculture: Status and Current Issues." (RL33334). September 2010 at 3.

18 ViaGen. "Bovine." Available at http://www.viagen.com/benefits/bovine/. Accessed on January 31, 2011; Weiss, Rick. "FDA Says Clones Are Safe to Eat." *Washington Post*. December 29, 2006.

19 Vogt and Parish (2001) at 4.

20 Martin, Andrew and Andrew Pollack. "F.D.A. Says Food From Cloned Animals Is Safe." *New York Times*. December 29, 2006; Doering, Christopher. "Clones' offspring may be in food supply: FDA." *Reuters*. September 2, 2008.

21 Cowan (September 10, 2010) at 3.

22 USDA ERS. "Agricultural Biotechnology Intellectual Property: Utility patents held by U.S. companies (excluding subsidiaries), by technology class and subclass." Available online at http://www.ers.usda.gov/Data/AgBiotechIP/Data/Table12_Top100USNonUSCompSummarySubs.htm. Updated May 27, 2004. Accessed April 26, 2011.

23 U.S. Food and Drug Administration (FDA). "Consumer Q&A." Accessed on January 4, 2011. Available at http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113672.htm.

24 7 CFR 205.105, §§205.2 see "excluded methods."

25 Fernandez-Cornejo and Caswell (2006) at 1.

26 Shoemaker (2001) at 10.

27 USDA. "Petitions for Nonregulated Status Granted or Pending by APHIS as of July 18, 2011." Available at http://www.aphis.usda.gov/biotechnology/not_reg.html. Accessed on July 26, 2011.; USDA. Public Data of Permit Information. April 28, 2011. On file and available at http://www.aphis.usda.gov/biotechnology/status.shtml.

28 *Ibid*.

29 Fernandez-Cornejo (2004) at 4.

30 Neuman, Williams and Andrew Pollack. "Farmers Cope with Roundup-Resistant Weeds." *New York Times*. May 3, 2010.

31 Shoemaker (2001) at 10.

32 Fernandez-Cornejo (2004) at 4.

33 Wenzel, Wayne. "Refuge Angst." *Farm Journal*. October 5, 2007.

34 "Insect shows resistance to Bt crops." *Appropriate Technology*. Vol. 35, No. 1. March 2008 at 49.

35 Ye, Xudong et al. "Engineering the Provitamin A (β-carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm." Science, vol. 287. Jan 14, 2000 at 303.

36 World Health Organization (WHO). "Safety aspects of genetically modified foods of plant origin." Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology. 2000 at 8.

37 75 Fed. Reg. 32356. (Jun. 8, 2010).

38 U.S. General Accounting Office (GAO). "Genetically Modified Foods: Experts View Regimen of Safety Tests as Adequate, but FDA's Evaluation Process Could Be Enhanced." Report to Congressional Requesters. (GAO-02-566). May 2002 at 6.

39 76 Fed. Reg. 8708. (February 15, 2011).

40 73 Fed. Reg. 8847-8848. (Feb. 15, 2008); SemBioSys. "Our Solution for Diabetes." 2010. Available at http://www.sembiosys.com/Products/Diabetes.aspx. Accessed on December 17, 2010.

41 76 Fed. Reg. 5780-5781. (Feb. 2, 2011).

42 Geertson Seed Farms et al., v. USDA. Memorandum and Order. United States District Court for the Northern District of California. No. C 06-01075 CRB. February 13, 2007 at 1, 3.

43 USDA. "Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status." Record of Decision. January 27, 2011 at 9.

44 Geertson Seed Farms et al., v. USDA. Memorandum and Order. United States District Court for the Northern District of California. No. C 06-01075 CRB. February 13, 2007 at 1,3.

45 USDA. "Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status." Final Environmental Impact Statement. December 2010 at S-39-41.

46 76 Fed. Reg. 5780-5781, (Feb. 2, 2011); USDA. "Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status." 2011 at 5, 7-8.

47 76 Fed. Reg. 8708. (February 15, 2011).

48 USDA. "Syngenta Seeds, Inc. Alpha-Amylase Maize Event 3272, Draft Environmental Assessment." November 6, 2008 at 34-35; USDA. "National Environmental Policy Act Decision and Finding of No Significant Impact, Syngenta Seeds Inc., Alpha-Amylase Maize, Event 3272." 2011 at 10.

49 USDA. "Syngenta Seeds, Inc. Alpha-Amylase Maize Event 3272, Draft Environmental Assessment." 2008 at 21.

50 *Ibid*. at 32-33.

51 Fernandez-Cornejo and Caswell (2006) at Table 2; Manshardt, Richard M. University of Hawaii, College of Tropic Agriculture & Human Resources. "'UH Rainbow' Papaya: A High-Quality Hybrid with Genetically Engineered Disease Resistance." July 1999 at 1.

52 Fernandez-Cornejo and Caswell (2006) at Table 2; Manshardt (1999) at 1; USDA-NASS. "Hawaii Papayas." October 27, 2009 at 6. Available at http://www.nass.usda.gov/Statistics_by_State/Hawaii/Publications/Fruits_and_Nuts/papaya.pdf

53 74 Fed. Reg. 45163. (September 1, 2009).

54 Monsanto. "The NewLeaf Potato." 2010. Available at http://www.monsanto.com/newsviews/Pages/new-leaf-potato.aspx. Accessed on January 3, 2011.

55 *Ibid*.

56 BASF. "European Commission approves Amflora starch potato." [Press Release]. March 2, 2010. Available at http://www.basf.com/group/pressrelease/P-10-179

57 Voosen, Paul. "E.U. Approves First Modified Crop for Planting in 12 Years." *New York Times*. March 2, 2010.

58 Ye et al. (2000) at 303; Golden Rice Humanitarian Board. "Frequently Asked Questions." 2010.

59 Brown, Paul. "GM rice promoters 'have gone too far'" *Guardian*. February 10, 2001.

60 Schultz, Bruce. LSU AgCenter. "'Golden Rice' Could Help Malnutrition." News Release. October 13, 2004.

61 International Rice Research Institute. Golden Rice Project Brief. April 2011.

62 73 Fed. Reg. 8847-8848. (Feb. 15, 2008).

63 USDA. "Environmental Assessment: In response to permit application (06-363-103r), received from SemBioSys, Inc. for a field-test to produce human proinsulin (line 4438-5A) in genetically engineered safflower (*Carthamus tinctorius*) seeds." 2007 at 10-11.

64 Cummings, John L. et al. "Dispersal of viable row-crop seeds of commercial agriculture by farmland birds: implication for genetically modified crops." *Environ. Biosafety Res.*, Vol. 7, 2008 at 248.

65 SemBioSys (2010); USDA-APHIS-Biotechnology Regulatory Services. Public Permit Data. April 28, 2011.

66 70 Fed. Reg. 13007-13008. (March 17, 2005).

67 *Center for Food Safety v. Thomas J. Vilsack*. No. C 10-04038 JSW 15 (N.D. Cal 2010).

68 USDA. Animal and Plant Health Inspection Service (APHIS). "Questions and Answers: Environmental Impact Statement on GE Sugar Beets." Factsheet. June 2010.

69 USDA. "USDA Announces Next Steps on Sugar Beets." [Press Release]. September 1, 2010.

70 *Center for Food Safety v. Thomas J. Vilsack* (2010); "Judge orders Monsanto to uproot genetically modified sugar beets." *Los Angeles Times*. December 1, 2010.

71 USDA APHIS (2010); USDA. "APHIS Determination Decision regarding the Petition for Partial Non-Regulated status for Monsanto/KWS glyphosate tolerant (Roundup Ready) H7-1 sugar beets (a "Partial, i.e., Conditional, Deregulation)." February 4, 2011 at 3-4.

72 USDA. "Environmental Assessment and Finding of No Significant Impact." Permit Number 91-079-01. 1991. Accessed on February 8, 2011. Available at http://www.isb.vt.edu/documents/ea/9107901r.ea.pdf

73 USDA. Biotechnology Regulatory Services. "All Release Permit Applications." Accessed on February 8, 2011. Available at http://www.aphis.usda.gov/brs/status/relday.html; USDA. "Petitions for Nonregulated Status Granted or Pending by APHIS as of July 18, 2011."

74 Shoemaker (2001) at 21.

75 *Ibid*.

76 Waters Bass, Gwenell L. Congressional Research Service. "Status of Genetically Engineered Wheat in North America." Report. November 4, 2004 at 3; Gillis, Justin. "Monsanto Pulls Plan to Commercialize Gene-Altered Wheat." *Washington Post*. May 11, 2004.

77 Wisner, Robert. Iowa State University. "Round-Up® Ready Spring Wheat: It's potential short-term impacts on U.S. wheat export markets and prices." October 2004 at Executive Summary.

78 Wisner, Robert. Iowa State University. "Round-Up® Ready Spring Wheat: It's potential short-term impacts on U.S. wheat export markets and prices." October 2004 at 1; Monsanto. "Frequently Asked Questions about Monsanto and Wheat." Available at http://www.monsanto.com/products/Pages/wheat-faq.aspx. Accessed on February 7, 2011.

79 Vogt and Parish (2001) at 1; University of Guelph. "Enviropig."

80 Vogt and Parish (2001) at 5.

81 *Ibid*.

82 "Monsanto's BST barely beat tomato to market." *Chicago Sun-Times*. March 20, 1994 at 28.

83 Dohoo, Ian, DesCouteaux, Luc, Leslie, Ken, Shewfelt, Wayne, et al. Health Canada, Drug and Health Products. "Report of the Canadian Veterinary Medical Association expert panel on rBST." November 1998.

84 Pew Commission on Industrial Farm Animal Production. "Putting Meat on the Table." 2008.

85 European Commission. Directorate General for Health and Consumer Protection. "Report on Public Health Aspects of the Use of Bovine Somatotrophin." In *Food Safety—From Farm to Fork*. March 1999.

86 Yu, H., and T. Rohan. Review: Role of the Insulin-like Growth Factor Family in Cancer Development and Progression. *Journal of the National Canter Institute* 92:1472-89. 2000.

87 Dohoo et al. (1998) at section 7; Groves, Martha. "Canada Rejects Hormone that Boosts Cows' Milk Output." *Los Angeles Times*. January 15, 1999; European Commission (1999).

88 USDA APHIS. "Dairy 2007: Part I: Reference of Dairy Cattle Health and Management Practices in the United States, 2007." October 2007 at 79.

89 *Ibid*.

90 University of Guelph. "Enviropig-Commercialization and Regulatory." Available at http://www.uoguelph.ca/enviropig/# and on file. Acccessed November 29, 2010.

91 *Ibid*.

92 Jha, Alok. "GM chickens created that could prevent the spread of bird flu." *The Guardian* (United Kingdom). January 13, 2011.

93 Richt, Jurgen A. et al. "Production of cattle lacking prion protein." *Nature Biotechnology*. Vol. 25, January, 2007 at 132; USDA FSIS. "Bovine Spongiform Encephalopathy - Mad Cow Disease." March 2005. Available at http://www.fsis.usda.gov/factsheets/bovine_spongiform_encephalopathy_mad_cow_disease/index.asp and on file. Accessed August 15, 2010.

94 Connor, Steve. "GM mosquitoes deployed to control Asia's dengue fever." *The Independent* (London). January 27, 2011.

95 USDA Office of Inspector General. "Controls over Genetically Engineered Animals and Insect Research." Audit Report. May 2011 at 3.

96 *Ibid*. at 14.

97 *Ibid*.

98 Borgatti, Rachel and Eugene Buck. Congressional Research Service. "Genetically Engineered Fish and Seafood." 2004 at 2.

99 *Ibid*.

100 Pollack, Andrew. "Genetically Altered Salmon Get Closer to the Table." *New York Times*. June 25, 2010.

101 National Research Council (2004) at 117-119.

102 "AquaBounty Technologies Admission to Trading on AIM." March 15, 2006. Pages 18 and 124.

103 AquaBounty. "Environmental Assessment." 2010 at 72.

104 Muir, William and Richard Howard. "Possible Ecological Risks of Transgenic Organism Release When Transgenes Affect Mating Success: Sexual Selection and the Trojan Gene Hypothesis." Ecology. November 1999; Muir, Bill, "Transgenic fish could threaten wild populations." Purdue News. April 2000. Accessed October 18, 2010, available at http://news.uns.purdue.edu/html4ever/0002.Muir.trojan.html

105 Tacon, Albert et al. "Use of Fishery Resources as Feed Inputs to Aquaculture Development: Trends and Policy Implications." FAO Fisheries Circular No. 1018, Food and Agriculture Organization of the United Nations, Rome, 2006 at v.

106 Fernandez-Cornejo (2004) at 19.

107 *Ibid*.; 35 U.S.C. 101

108 Fernandez-Cornejo (2004) at 19.

109 7 U.S.C. 2483; USDA. "Plant Variety Protection Act and Regulations and Rules of Practice." 2005 at 14, note 30.

110 7 U.S.C. 2543; USDA. "Plant Variety Protection Act and Regulations and Rules of Practice." 2005 at 19.

111 447 U.S. 303. (1980).

112 Costantini, Franklin and Elizabeth Lacy. "Introduction of a rabbit B-globin gene into the mouse germ line." *Nature*. 294, Vol. 5. November 1981 at 91-93.

113 Fernandez-Cornejo (2004) at 19.

114 Hammer, Robert et al. "Production of transgenic rabbits, sheep and pigs by microinjection." *Nature* Vol. 315. June, 1985 at 680.

115 51 Fed. Reg. 23302. (June 26, 1986).

116 Shoemaker (2001) at 7.

117 USDA APHIS. "Biotechnology Regulatory History." Available at http://www.aphis.usda.gov/biotechnology/about_history.shtml. Accessed on January 4, 2010.

118 Shoemaker (2001) at 21; USDA APHIS. "Biotechnology Regulatory History."

119 Fernandez-Cornejo (2004) at 19; Shoemaker (2001) at 9.

120 USDA APHIS. "Biotechnology Regulatory History."

121 Gurian-Sherman, Doug. Union of Concerned Scientists. "Failure to Yield." April 2009 at 15.

122 U.S. Environmental Protection Agency (EPA). Draft White Paper. Concerning dietary exposure to CRY9C protein produced by StarlinkÒ corn and the potential risks associated with such exposure. October 16, 2007.

123 FDA. Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance. 2001. Available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059098.htm. Accessed December 15, 2010.

124 FDA. Center for Veterinary Medicine. "Guidance for Industry 187: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs." Final Guidance. January 15, 2009 at 5.

125 USDA. Public Data of Permit Information. April 28, 2011; USDA. "Petitions for Nonregulated Status Granted or Pending by APHIS as of July 18, 2011."

126 USDA. Public Data of Permit Information.

127 Food & Water Watch analysis of Center for Responsive Politics data, available at www.opensecrets.org. See Food & Water Watch. "Food and Agriculture Biotechnology Industry Spends More Than Half a Billion Dollars to Influence Congress." Issue Brief. November 2010 at 1.

128 Pew Initiative on Food and Biotechnology (2001) at 2.

129 USDA. Biotechnology Regulatory Services. "APHIS Biotechnology: Permitting Progress Into Tomorrow." Factsheet. February 2006 at 1.

130 7 U.S.C. §7701(3) (2000); USDA Biotechnology Regulatory Services (2006) at 1-4.

131 7 CFR §372.5 (b)(3) (1995).

132 Fernandez-Cornejo and Caswell (2006) at 3.

133 7 CFR §340.6(a) (2008); Pew Initiative on Food and Biotechnology (2001) at 11-12.

134 U.S. Government Accountability Office (GAO). "Genetically Engineered Crops: Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring." Report to the Committee on Agriculture, Nutrition, and Forestry, U.S. Senate. (GAO-09-60). Nov. 2008 at 11.

135 7 U.S.C. 136(u)(1); 40 CFR 174.3. See "plant-incorporated protectant."

136 7 U.S.C. 136(u)(1).

137 GAO (2008) at 11.

138 7. U.S.C. prec. 121; EPA. "FIFRA Amendments of 1988." [Press Release]. October 26, 1988.

139 7 U.S.C. 136a(c)(5).

140 40 CFR 152.1(a).

141 40 CFR 172.3(a), 40 CFR 180, 40 CFR 152.1(a); Pew Initiative on Food and Biotechnology (2001) at 13-14.

142 21 U.S.C. 301 (2002); Pew Initiative on Food and Biotechnology (2001) at 15.

143 GAO (2002) at 9.

144 21 CFR 170.35(c)(1)(iii); Pew Initiative on Food and Biotechnology (2001) at 20-21.

145 Pew Initiative (2001) at 21, note 15.; FDA. GRAS Notice Inventory. Accessed April 28, 2011. Data on file and available at http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing

146 EPA (2007) at 6.

147 FDA Center for Veterinary Medicine (2009) at 4-5.

148 Biotechnology Industry Organization. "Genetically Engineered Animals Frequently Asked Questions." October 22, 2009 at 2-4.

149 European Parliament and the Council. "Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC." *Official Journal of the European Communities*. March 12, 2001 at 7,25.

150 Europa-European Commission."EU Register of Genetically Modified Food and Feed." 2011. See http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

151 *Ibid*.

152 European Commission. "Agriculture in the EU: Statistical and Economic Information Report 2010." March 2011 at 43, 381; Clive (2010) at 3, 7.

153 European Parliament and Council. "Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed." *Official Journal of the European Union*. October 18, 2003 at Article 12.2.

154 Pew Global Attitudes Project. "Broad opposition to genetically modified foods." June 20, 2003.

155 Special Eurobarometer 341/Wave 73.1. "Biotechnology." Report. October 2010 at 18.

156 Europa-European Commission. "Rules on GMOs in the EU- Ban on GMOs Cultivation." Available at http://ec.europa.eu/food/food/biotechnology/gmo_ban_cultivation_en.htm; Ivanova, Irina. "Bulgaria parliament bans GMO crops to soothe fears." *Reuters*. March 18, 2010; Kovalyova, Svetlana. "Italy regions push minister for official GM ban." *Reuters*. September 30, 2010.

157 European Parliament and the Council (2001) at L 106/13, Article 23.

158 Pollack, Andrew. "Crop Scientists Say Biotechnology Seed Companies Are Thwarting Research." *New York Times*. February 20, 2009.

159 de Vendomois, Joel Spiroux et al. "A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health." *International Journal of Biological Sciences*, vol. 5, iss. 7. 2009 at 716-718.

160 Malatesta, Manuela et al. "Ultrastructural Morphometrical and Immunocytochemical Analyses of Hepatocyte Nuclei from Mice Fed on Genetically Modified Soybean." *Cell Structure and Function*. Volume 27, 2002 at Abstract.

161 Séralini, Gilles-Eric, Dominique Cellier and Joël Spiroux de Vendomois. "New Analysis of a Rat Feeding Study with a Genetically Modified Maize Reveals Signs of Hepatorenal Toxicity." *Archives of Environmental Contamination and Toxicology*. Vol. 52. 2007 at 596 and 601.

162 Cisterna, B. et al. "Can a genetically-modified organism-containing diet influence embryo development? A preliminary study on pre-implantation mouse embryos." *European Journal of Histochemistry*. 2008 at 263.

163 Agodi, Antonella et al. "Detection of genetically modified DNA sequences in milk from the Italian market." *International Journal of Hygiene and Environmental Health*. January 10, 2006 at Abstract.

164 Huber, Don M. "Ag Chemical and Crop Nutrient Interactions- Current Update." Proceedings Fluid Fertilizer Forum (Scottsdale, Ariz.). Vol. 27. Fluid Fertilizer Foundation. February 14-16 2010 at 3.

165 *Ibid*. at 8; Johal, G.S. and D.M. Huber. "Glyphosate effects on diseases of plants." European Journal of Agronomy, Vol. 31. 2009 at 144.; Kremer, Robert J. and Nathan E. Means. "Glyphosate and glyphosate-resistant crop interactions with rhizosphere microorganisms." *European Journal of Agronomy*, Vol. 31. 2009 at 153.

166 Paganelli, Alejandra et al. "Glyphosate-Based Herbicides Produce Teratogenic Effects on Vertebrates by Impairing Reinoic Acid Signaling." *Chem. Res. Toxicol*. Vol. 23, August 2010 at 1586.

167 Benachour, Nora and Gilles-Eric Seralini. "Glyphosate Formulations Induce Apoptosis and Necrosis in Human Umbilical, Embryonic, and Placental Cells." *Chem. Res. Toxicol*. Vol 22. 2009 at 97.

168 Aspelin, Arnold L. EPA. "Pesticides Industry Sales and Usage: 1994 and 1995 Estimates." August 1997 at Table 8; Grube et al. EPA. "Pesticides Industry Sales and Usage: 2006 and 2007 Market Estimates." February 2011 at Table 3.6

169 GAO (2002) at 30.

170 USDA ERS. "Adoption of Genetically Engineered Crops in the U.S." Updated July 1, 2011.

171 Young, Emma. "GM pea causes allergic damage in mice." *New Scientist*. November 21, 2005.

172 EPA (2007) at 7.

173 *Ibid*. at 9.

174 *Ibid*. at 10.

175 *Ibid*. at 1.

176 FDA (2001).

177 Fernandez-Cornejo and Caswell (2006) at 1.

178 CBS News Poll Database. "CBS News/*New York Times* Poll, Apr. 2008." Available online at http://www.cbsnews.com/stories/2007/10/12/politics/main3362530.shtml?tag=cbsnewsLeadStoriesArea. Updated April 2008. Accessed May 6, 2011.

179 Consumers Union. "FDA will not require labeling of meat or fish from genetically engineered animals." [Press Release]. January 15, 2009.

180 *Ibid*.; FDA Center for Veterinary Medicine. Guidance for Industry. "Regulation of genetically engineered animals containing heritable recombinant DNA constructs." January 15, 2009 at 23.

181 "Interim guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin." 59 Fed. Reg. 6279. (February 10, 1994).

182 *Ibid*.

183 *Ibid*.

184 Rosenfeld, Steven P. "Dairy cooperative says it will fight Monsanto suit." *Associated Press*. February 21, 1994.

185 FDA. "FDA Warns Milk Producers to remove 'hormone free' claims from the labeling of dairy products." [Press release]. September 12, 2003.

186 Hedges, Stephen J. "Monsanto having a cow in milk label dispute." *Chicago Tribune*. April 15, 2007 at C1.

187 McCarthy, Colman. "Monsanto's cash cow trips milk alarm." *Washington Post*. March 1, 1994 at D20.

188 Gilgoff, Henry. "Dairy labels go sour; it's hard to milk antihormone sentiment." *New York Newsday*. March 24, 1994 at A49.

189 Wu, Olivia. "Dairy companies sue Illinois to allow change in labels." *Chicago Sun-Times*. May 8, 1996 at A14; Berselli, Beth. "Settlement reached in hormone labeling case." *Washington Post*. August 15, 1997 at A22.

190 *Ibid*.

191 "Ben and Jerry's, state in accord on growth hormone statement." *Chicago Tribune*. August 14, 1997 at BU4; Berselli (1997).

192 Berselli (1997).

193 Melcer, Rachel. "Lawmakers consider bill to restrict labels on milk containers." *St. Louis Post-Dispatch*. April 17, 2008 at B1.

194 "Utah proposes rules on milk labels." *Associated Press* State & Local Wire. February 28, 2008.

195 Lewis, Zachary. "State eases label rule for hormone in cows." *Cleveland Plain Dealer*. March 27, 2008 at C1.

196 Melcer (2008); Avril, Tom. "Hormone labeling of Pa. milk to end." *Philadelphia Inquirer*. December 23, 2007 at A01.

197 Malloy, Daniel. "State reverses on dairy labeling, allows hormone claims." *Pittsburgh Post-Gazette*. January 18, 2008 at A1.

198 Melcer (2008).

199 Actions on Missiouri SB 1279 (2008). Available at: http://www.senate.mo.gov/08info/BTS_Web/Actions.aspx?SessionType=R&BillID=154026. Accessed April 1, 2009.

200 International Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 632 (2010).

201 National Research Council. "The impact of genetically engineered crops on farm sustainability in the United States." April 13, 2010 at S-3 and S-13. (Pre-Publication Copy).

202 Clapp, Stephen. "Canadian Researchers find suspected glyphosate-resistant weed." *Food Chemical News*. May 18, 2009.

203 Clapp. May 18, 2009; Wilson, Mike. "Multiple-resistance weeds coming to a field near you?" *Western Farmer Stockman*. February 28, 2008.

204 Clapp, Stephen. "Herbicide diversity called critical to keep Roundup effective. *Food Chemical News*. July 20, 2009.

205 Syngenta. "Leading the fight against glyphosate resistance." 2009. On file and available at http://www.syngentaebiz.com/DotNetEBiz/ImageLIbrary/WR%203%20Leading%20the%20Fight.pdf

206 Clapp, Stephen. "Study says farmers relying on Roundup may weaken benefits." *Food Chemical News*. April 20, 2009.

207 *Ibid*.

208 Howard, Phil. Michigan State University. "Seed Industry Structure, 1996-2008." 2009. Available online at https://www.msu.edu/~howardp/seedindustry.html and on file. Accessed September 8, 2009; Fernandez-Cornejo (2004) at 25-26 and Table 18.

209 Howard Phil. Michigan State University. "Seed Industry Structure, Cross-Licensing Agreements for Genetically Engineered Traits." 2009; Fernandez-Cornejo (2004) at 40.

210 Food and Water Watch Analysis of data from USDA National Agricultural Statistics Service (NASS). 2000-2008 Price Paid for Corn, Cotton, and Soybeans. Data available at http://www.nass.usda.gov/.

211 Organization for Competitive Markets. "Monsanto Transgenic Trait Dominance in US Market, 1996-2007." June 2008; Fernandez-Cornejo (2004) at 34 .

212 Hendrickson, Mary and Bill Heffernan. Department of Rural Sociology, University of Missouri-Columbia. "Concentration of Agricultural Markets." April 2007.

213 Shoemaker (2001) at v.

214 Harl, Neil E. Charles F. Curtiss Distinguished Professor of Agriculture and Professor of Economics, Iowa State University. "The Structural Transformation of Agriculture." Presentation at 2003 Master Farmer Ceremony, West Des Moines, Iowa. March 20, 2003 at 10.

215 Fernandez-Cornejo (2004) at 19.

216 Ross, Douglas. "Antitrust enforcement and agriculture." Address before the American Farm Bureau Policy Development Meeting. Kansas City, Missouri. August 20, 2002 at 9.

217 Monsanto Inc. "Monsanto Challenges Unauthorized Use of Roundup Ready® Technology by DuPont." [Press Release]. May 5, 2009; Monsanto Inc. "Monsanto — Why we're suing DuPont." Available at http://www.monsanto.com/dupontlawsuit/ and on file. Accessed December 8, 2009.

218 Monsanto, Inc. Securities and Exchange Commission. 10K Filing. October 27, 2009 at 6; Schimmelpfennig, David E. et al, "The impact of seed industry concentration on innovation: A study of U.S. biotech market leaders." *Agricultural Economics*. Vol. 30, Iss. 2. March 2004 at 159.

219 Whoriskey, Peter. "Monsanto's dominance draws antitrust inquiry." *Washington Post*. November 29, 2009.

220 Fernandez-Cornejo (2004 at 21.

221 Farmers' Legal Action Group (FLAG). "Farmers' Guide to GMOs." February 2009 at 9.

222 Pollack, Andrew. "As Patent Ends, a Seed's Use Will Survive." *New York Times*. December 18, 2009; Cowan, Tadlock. Congressional Research Service (CRS). "Agricultural Biotechnology: Background and Recent Issues." (RL32809). September 2, 2010 at 27; Monsanto. "Technology Use Guide: 2011." 2011 at 2. Available at http://www.monsanto.com/SiteCollectionDocuments/Technology-Use-Guide.pdf

223 Barlett, Donald L. and James B. Steele. "Monsanto's harvest of fear." *Vanity Fair*. May 2008.

224 Center for Food Safety. "Monsanto vs. U.S. Farmers." November 2007 at 1-2.

225 7 CFR 205.2.

226 Union of Concerned Scientists (UCS). "Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply." 2004 at 28.

227 *Ibid*. at 24.

228 FLAG at page 29-31; Ellstrand, Norman. "Going to Great Lengths to Prevent the Escape of Genes That Produce Specialty Chemicals." *Plant Physiology*. August 2003.

229 Monsanto. "Technology Use Guide: 2011" at 7.

230 7 CFR 205.2; Conner, David S. "Pesticides and Genetic Drift: Alternative Property Rights Scenario." *Choices*. First Quarter 2003 at 5.

231 Conner (2003) at 5.

232 Mallory-Smith, Carol and Maria Zapiola. "Gene flow from glyphosate-resistant crops." *Pest Management Science*. Vol. 64, 2008 at 434.

233 *Ibid*.

234 FLAG at page 29-31; Ellstrand (2003).

235 Dimitri, Carolyn and Lydia Oberholtzer. USDA ERS. "Marketing U.S. Organic Foods: Recent Trends From Farms to Consumers." Bulletin Number 58, September 2009 at Abstract.

236 McBride, William D. and Catherine Greene. USDA ERS. "A Comparison of Conventional and Organic Milk Production Systems in the U.S." Prepared for presentation at the American Agricultural Economics Association Annual Meeting (Portland, Ore.). July 29-August 1, 2007 at 13, 17; Food & Water Watch analysis of average consumer price data from the U.S. Bureau of Labor Statistics, Consumer Price Index—Average Price Data. Farmgate prices from USDA NASS Agricultural Prices Annual Summary.

237 *Organic Seed Growers and Trade Association et al. v. Monsanto Co.* United States District Court, Southern District of New York. Complaint. March 29, 2011 at 2, 5.

238 Hagstrom, Jerry. "Vilsack idea: Insurance to compensate organic producers for GMO seed drift." *The Hagstrom Report*. April 7, 2011.

239 Pew Global Attitudes Project. "Views of a Changing World." June 2003 at 90-91.

240 European Parliament and Council. Regulation (EC) No 1829/2003. October 18, 2003 at L 268/9.

241 Shoemaker (2001) at 32.

242 Henshaw, Caroline. "EU to Admit GM Material in Animal Feed." *Wall Street Journal*. February 22, 2011.

243 European Parliament and Council. Regulation (EC) No 1829/2003 at Article 12.2.

244 European Commission. "GMOs in a nutshell." *See* "Which EU countries ban the cultivation of GMOs?" Accessed March 9, 2011. Available at http://ec.europa.eu/food/food/biotechnology/qanda/d4_en.htm#d

245 Dr. Sato, Suguro. USDA Foreign Agricultural Service, Global Agriculture Information Network. "Japan Biotechnology Annual Report 2008." July 15, 2008 at 3.

246 GAO (2008) at 14.

247 EPA (2007); Pollock, Kevin. "Aventis Gives Up License To Sell Bioengineered Corn." *New York Times*. October 13, 2000; GAO (2008) at 16; Carter, Colin A. Professor, Department of Agricultural and Resource Economics, University of California, Davis. Statement before the Domestic Policy Subcommittee of the U.S. House Oversight and Government Reform Committee. March 13, 2008 at 2.

248 Leake, Todd. Dakota Resource Council Statement before the Domestic Policy Subcommittee of the U.S. House Oversight and Government Reform Committee. March 13, 2008 at 2.

249 Howington, Harvey. Vice President U.S. Rice Producers Association. Statement before the Domestic Policy Subcommittee of the U.S. House Oversight and Government Reform Committee. March 13, 2008 at 1.

250 *Ibid*. at 3.

251 McConnell, Sean. "Animal feed containing illegal GM maize impounded." *The Irish Times*. May 21, 2007.

252 Office of the U.S. Trade Representative. "2010 Report on Sanitary and Phytosanitary Measures." 2010 at 20.

253 Gathura, Gatonye. "US pushed for passing Biosafety Act." *The Daily Nation* (Kenya). March 13, 2011.

254 Monsanto. "Research and Development Pipeline." Brochure. 2011 at 2. Available at http://www.monsanto.com/products/Documents/pipeline-brochures/pipeline_2011.pdf

255 Monsanto. "Do GM Crops Increase Yield?" 2009. Available at http://www.monsanto.com/newsviews/Pages/do-gm-crops-increase-yield.aspx. Accessed February 26, 2011.

256 "Non-biotech soybean acreage increasing in the United States." *Food Chemical News*. August 17, 2009.

257 Price, Gregory K., William Lin et al. USDA ERS. "Size and Distribution of Market Benefits from Adopting Biotech Crops." Technical Bulletin No. 1906. November 2003 at 3.

258 *Food Chemical News*. August 17, 2009; Whigham, Kieth, Iowa State University. "How to lower soybean seed costs." *Integrated Crop Management.* IC-480(23). October 12, 1998; it takes about 1.3 bags of soybean seeds per acre (assuming the most common 3,000 seeds per pound and a target 200,000 seeds per acre).

259 USDA NASS. Quickstats: Price Paid for Row Crops, Biotech and Non-Biotech Corn and Soybean. On file and available at http://www.nass.usda.gov/Statistics_by_Subject/index.php?sector=ECONOMICS.

260 Gurian-Sherman (2009) at 22 and 33.

261 Gordon, Barney. "Manganese nutrition of glyphosate-resistant and conventional soybeans." *Better Crops*. Vol. 91, No. 4. 2007 at 12.

262 Monsanto. "Nutrition." Available at http://www.producemoreconservemore.com. Accessed February 26, 2011.

263 Naqvi et al. "Transgenic multivaitamin corn through biofortification of endosperm with three vitamins representing three distinct metabolic pathways." *Proceedings of the National Academy of Sciences*. Vol. 106, No. 19. May 12, 2009 at 7762.

264 Ye et al. (2000) at 303.

265 Krawinkel, Michael. "β-Carotene from rice for human nutrition?" *Am J Clin Nutr.* Vol. 90. 2009 at 696.

266 *Ibid*. at 696; Burgess, Ann and Peter Glasauer. Food and Agriculture Organization of the United Nations (FAO). "Family Nutrition Guide." 2004 at 22.

267 Krawinkel (2009) at 696; Tang et al. "Golden Rice is an effective source of Vitamin A." *Am J Clin Nutr.* Vol. 89. 2009 at 1776-1778.

268 USDA. "Petitions for Nonregulated Status Granted or Pending by APHIS as of July 18, 2011."

269 Burgess and Glasauer (2004) at 22.

270 Monsanto. "Do GM Crops Increase Yield?" 2009. Available at http://www.monsanto.com/newsviews/Pages/do-gm-crops-increase-yield.aspx. Accessed February 26, 2011.

271 Monsanto. "Monsanto Biotechnology Trait Acreage: Fiscal Years 1996-2009." 2009. On file and available at http://www.monsanto.com/investors/documents/2009/q4_biotech_acres.pdf; USDA NASS Quick Stats, Acres Planted, Corn and Soybeans; Monsanto. Roundup Power Max Herbicide. Brochure. 2008 at 4.

272 Monsanto. "Monsanto Biotechnology Trait Acreage: Fiscal Years 1996-2009." 2009.

273 Aspelin, Arnold L. EPA. "Pesticides Industry Sales and Usage: 1994 and 1995 Estimates." August 1997 at Table 8; Grube et al. EPA. "Pesticides Industry Sales and Usage: 2006 and 2007 Market Estimates." February 2011 at Table 3.6.

274 National Research Council (2010) at S-3 and S-13.

275 Ibrahim et al. "Weight of the Evidence on the Human Carcinogenicity of 2,4-D." *Environmental Health Perspectives*. Vol. 96. 1991 at 213; Hayes, Tyrone et al. "Hermaphroditic, demasculinized frogs after exposure to the herbicide atrazine at low ecologically relevant doses." *Proceedings of the National Academy of Sciences*. Vol. 99, No. 8. April 2002 at 5476; Stoker, Tammy E. et al. "Maternal exposure to atrazine during lactation suppresses suckling-induced prolactin release and results in prostatitis in the adult offspring." *Toxicological Sciences*. Vol. 52. 1999 at 68; EPA. "2,4-D: Chemical Summary." 2007 at 1 and 5.

276 Monsanto. "Monsanto Outlines New Weed Management Platform Under the Roundup Ready PLUS Brand." [Press Release]. October 19, 2010.

277 USDA. "Petitions for Nonregulated Status Granted or Pending by APHIS as of July 18, 2011."; Kaskey, Jack. "Dow Plans New Trait to Combat Roundup-Resistant Weeds." *Bloomberg Businessweek*. May 5, 2010.

278 Laurent, François et al. "Metabolism of [14C]-2,4-dichlorophenol in edible plants." *Pest Management Science*. Vol. 62, 2006 at 558.

279 USDA. "Petitions for Nonregulated Status Granted or Pending by APHIS as of July 18, 2011."

280 Monsanto. "How can we squeeze more food from a raindrop?" 2008. On file.

281 International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD). "Executive Summary of Synthesis Report." April 2008 at 8-9.

282 Steiner, Gerald. Statement of the Executive Vice President, Sustainability and Corporate Affairs, Monsanto Company, before the House Foreign Affairs Committee. July 20, 2010 at 1.

283 Gentleman, Amelia. "Despair takes toll on Indian farmers-Asia-Pacific- International Herald Tribune." *New York Times*. May 31, 2006; Sengupta, Somini. "On India's farms, a plague of suicide." *New York Times*. September 19, 2006.

284 Sengupta (2006).

285 Kuruganti, Kavitha. "Effects of pesticide exposure on developmental task performance in Indian children." *Children, Youth and Environments*. Vol. 15, Issu 1. 2005 at 86; Thakur, J.S. et al. "Epidemiological Study f High Cancer Among Rural Agricultural Community of Punjab in Northern India." *International Journal of Environmental Research and Public Health*. Vol. 5, Iss. 5. 2008 at 405.

286 Sengupta (2006).

287 Sainath, P. "17,368 farm suicides in 2009." *The Hindu*. December 27, 2010.

288 Pretty, J.N. et al. "Resource-Conserving Agriculture Increases Yields in Developing Countries." *Environmental Science and Technology*, Vol.40, No. 4. 2006 at 1114.

289 *See* Badgley, Catherine et al. "Organic agriculture and the global food supply." *Renewable Agriculture and Food Systems*. Vol. 22, Iss. 2. 2007 at 86-108.

290 Monsanto. "Climate Change." Available at http://www.producemoreconservemore.com/climate-change/. Accessed February 26, 2011.

291 IAASTD. "Agriculture at a Crossroads." Global Report. 2009 at 285.

292 To date, the United States has only approved herbicide tolerant and insect tolerant canola, corn, cotton and soybeans as well as virus resistant squash and papayas. Fernandez-Cornejo (2008) at 6; ISAAA "Biotech crops poised for second wave of growth." [Press release]. February 11, 2009.

293 IAASTD (2009) at 161.

294 USDA. "Petitions for Nonregulated Status Granted or Pending by APHIS as of July 18, 2011."

295 IAASTD (2009) at 10.

296 Monsanto. "Natural Resources." Available at http://www.producemoreconservemore.com/natural-resources/. Accessed February 26, 2011.

297 IAASTD (2009) at 9.

298 Hoekstra, A.Y. and A.K. Chapagain, "Water Footprints of Nations: Water Use by People as a Function of Their Consumptive Pattern," *Water Resource Management*, Vol. 21, 2007 at 38; USDA ERS. "Major Uses of Land in the United States, 2002." Economic Information Bulletin 14. May 2005 at Abstract.

299 World Bank. World Development Report 2008: Agriculture for Development. 2007 at 64.

300 *Ibid*.

301 Borlaug, Norman E. "The Green Revolution and the Road Ahead." Special 30th Anniversary Lecture. The Nobel Institute. Oslo. September 8, 2000 at 5, 7.

302 U.S. Department of Agriculture (USDA). "2007 Census of Agriculture: Farm and Ranch Irrigation Survey (2008)." Vol. 3, Pt. 1. July 2010 at Table 27.

303 Dennehy, Kevin F. U.S. Geological Survey (USGS). "High Plains regional groundwater study." USGS Fact Sheet, FS-091–00. August 2000 at 2.

304 Gurdak, Jason J. et al. USGS. "Water Quality in the High Plains Aquifer, Colorado, Kansas, Nebraska, New Mexico, Oklahoma, South Dakota, Texas, and Wyoming, 1999–2004." Circular 1337. 2009 at 10; McGuire, V.L. USGS. "Changes in Water Levels and Storage in the High Plains Aquifer, Predevelopment to 2007." 2009.

305 Pew Initiative on Food and Biotechnology. (2001) at 20-21.

306 GAO (2008) at 4.

307 7 U.S.C. §7701(3) (2000); USDA. Biotechnology Regulatory Services. "APHIS Biotechnology: Permitting Progress Into Tomorrow." 2006 at 1-4.

308 7 CFR §340.3 (a)-(b) (2008)

309 7 CFR §340.3 (b)-(c),(e)(4) (2008); Pew Initiative on Food and Biotechnology (2001) at 11.

310 7 CFR §340.3 (e)(5) (2008); Pew Initiative on Food and Biotechnology (2001) at 11.

311 7 CFR 340.3; 7 CFR §§372.5 (c)-(d) (1995); Pew Initiative on Food and Biotechnology. "Issues in the Regulation of Genetically Engineered Plants and Animals." April 2004 at 33.

312 7 CFR §340.4(b) (2008); Pew Initiative on Food and Biotechnology (2001) at 10.

313 7 CFR §340.4(b) (2008); USDA. Biotechnology Regulatory Services. "APHIS Biotechnology: Permitting Progress Into Tomorrow." (2006) at 3.

314 7 CFR §340.4(f)(2008); USDA. Biotechnology Regulatory Services. "APHIS Biotechnology: Permitting Progress Into Tomorrow." (2006) at 2.

315 Fernandez-Cornejo and Caswell (2006) at 3.

316 7 CFR §340.4(f)(9) (2008).

317 7 CFR §340.4(g) (2008).

318 7 CFR §372.5 (b)(3) (1995).

319 USDA Biotechnology Regulatory Services. "National Environmental Policy Act and Its Role in USDA's Regulation of Biotechnology." Factsheet. February 2006 at 2.

320 7 CFR §372.9 (a); USDA. Biotechnology Regulatory Services. "National Environmental Policy Act and Its Role in USDA's Regulation of Biotechnology." (2006) at 2.

321 7 CFR §372.8(b)(1) (1995).

322 76 Fed. Reg. 19309-19310 (April 7, 2011)

323 7 CFR §340.6(a) (2008); Pew Initiative on Food and Biotechnology (2001) at 11-12.

324 7 CFR §340.6(d)(2) (2008).

325 7 CFR §340.6(d)(3) (2008).

326 GAO (2008) at 11.

327 Taylor, Michael R. and Jody S. Tick. Pew Initiative on Food and Biotechnology. "Post-Market Oversight of Biotech Foods – Is the System Prepared?" April 2003 at 19.

328 USDA. GIPSA. "Grain, Rice & Pulses: Biotechnology." Accessed on February 9, 2011. On file and Available at http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=rd-bi

329 67 Fed. Reg. 50853-50854. (August 6, 2002).

330 21 U.S.C. 346a(c)(2)(A); Pew Initiative on Food and Biotechnology (2001) at 13.

331 21 U.S.C. 346a(b)(2)(ii) (2002).

332 Reuben, Suzanne H. "Reducing Environmental Cancer Risk: What We Can Do Now." The President's Cancer Panel: 2008-2009 Annual Report, Dept of Health and Human Services, National Institutes of Health, National Cancer Institute. April 2010 at 46.

333 21 U.S.C. §346a(c)(2)(A) (2002); Pew Initiative on Food and Biotechnology (2001) at 14.

334 EPA (2007) at 7.

335 7 U.S.C. 136(u)(1); 40 CFR 174.3. *See* "plant-incorporated protectant"

336 Pew Initiative on Food and Biotechnology (2004) at 39.

337 40 CFR 172.2(a); Pew Initiative on Food and Biotechnology (2001) at 12.

338 40 CFR 172.3(a),(c).

339 40 CFR 172.5(b).

340 40 CFR 172.8.

341 GAO (2002) at 7.

342 EPA. "Biopesticides Registration Action Document: *Bacillus thuringiensis* (*Bt*) Plant-Incorporated Protectants." October 15, 2001 at 17-18.

343 U.S. Environmental Protection Agency. "Insect Resistance Management Fact Sheet for *Bacillus thuringiensis* (*Bt*) Corn Products." Updated February 2011. On file and available at http://www.epa.gov/oppbppd1/biopesticides/pips/bt_corn_refuge_2006.htm; U.S. Environmental Protection Agency. "Insect Resistance Management Fact Sheet for Bacillus thuringiensis (Bt) Cotton Products." Updated February 2011. On file and available at http://www.epa.gov/oppbppd1/biopesticides/pips/bt_cotton _refuge_2006.htm

344 EPA (2001) at 17.

345 EPA. "EPA Fines Monsanto for Distributing Genetically Engineered Pesticide." Press Release. July 8, 2010.

346 57 Fed Reg. 22984. (May 29, 1992 at I).

347 66 Fed. Reg. 4706. (January 18, 2001)

348 Pew Initiative on Food and Biotechnology (2001) at 19-20.

349 *Ibid*. at 20.

350 21 CFR 170.30; Pew Initiative on Food and Biotechnology (2001) at 21.

351 21 CFR 170.35(c)(4), (c)(5); Pew Initiative on Food and Biotechnology (2001) at 20.

352 Cowan (September 10, 2010) at 6.

353 FDA. GRAS Notice Inventory. Accessed April 28, 2011.

354 GAO (2002) at 11-12.

355 21 CFR 171.1(c).

356 21 CFR 170.38(c).

357 66 Fed. Reg. 4708. (January 18, 2001); Pew Initiative on Food and Biotechnology (2001) at 21, note 15.

358 21 CFR 7.4(c); H.R. 2751, 111th Cong. §206 (2010).

359 Shames, Lisa. GAO. Testimony on the Federal Oversight of Food Safety: FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan. Subcommittee on Oversight and Investigations. Committee on Energy and Commerce. House of Representatives. June 12, 2008 at 1-3.

360 EPA (2007) 9.

361 FDA (2009) at 4-5.

362 Biotechnology Industry Organization. "Genetically Engineered Animals Frequently Asked Questions." October 22, 2009 at 4.

363 21 U.S.C. §360b(b)(1) (2002).

364 21 CFR 511.1, 21 U.S.C. §360b(1).

365 21 CFR 511.1(b)(5); Pew Initiative on Food and Biotechnology (2001) at 22.

366 21 CFR 25.20 (m).

367 FDA. "FDA Approves Orphan Drug ATryn to Treat Rare Clotting Disorder." [Press Release]. February 6, 2009; Cowan (September 10, 2010) at 2.

368 21 CFR 25.50 (b).

369 FDA (2009) at 11.

370 FDA. "Guidance for Industry 179: Use of Animal Clones and Clone Progeny for Human Food and Animal Feed." January 15, 2008.

371 Knight, Bruce I. "Animal Cloning: Transitioning from the Lab to the Market." Advisory Committee on Biotechology and 21st Century Agriculture (AC21), Washington, DC. March 5, 2008 at 3.

372 *Ibid*.

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