

Genetically Engineered Food

An Overview



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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 altera-

tions 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

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

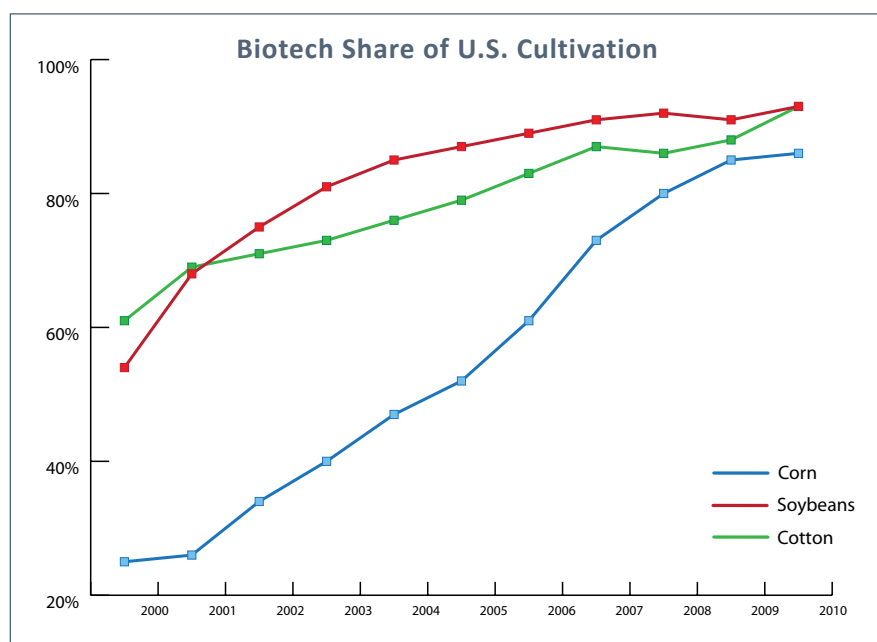
Transgenic animals have been developed to promote faster growth, disease resistance or leaner meat, as well as to minimize the impact of animal waste.²¹ By 2004, the largest biotech firms had filed 12 patents for GE animals.²² As of this writing, no transgenic food animals had been approved in the United 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



Source: USDA



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 awarded 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

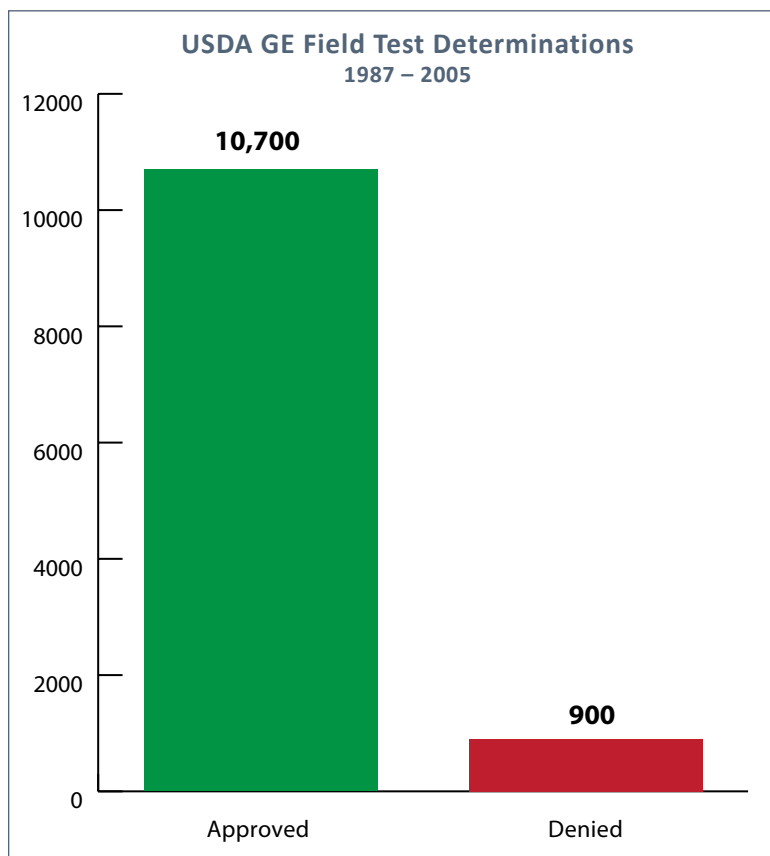
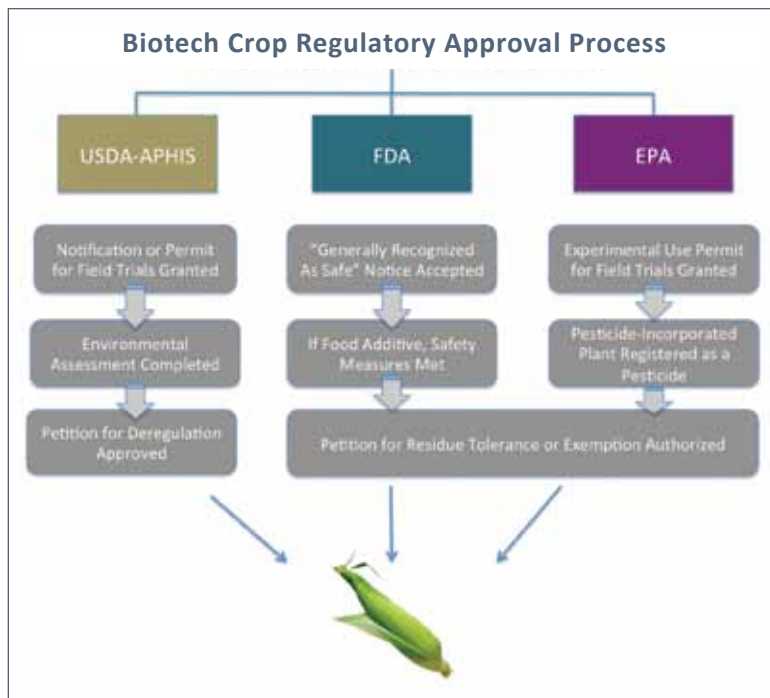
The patchwork of federal agencies that regulates genetically engineered crops and animals in the United States has failed to adequately oversee and monitor GE products. Lax enforcement, uncoordinated agency oversight and ambivalent post-approval monitoring of biotechnology have allowed risky GE plants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

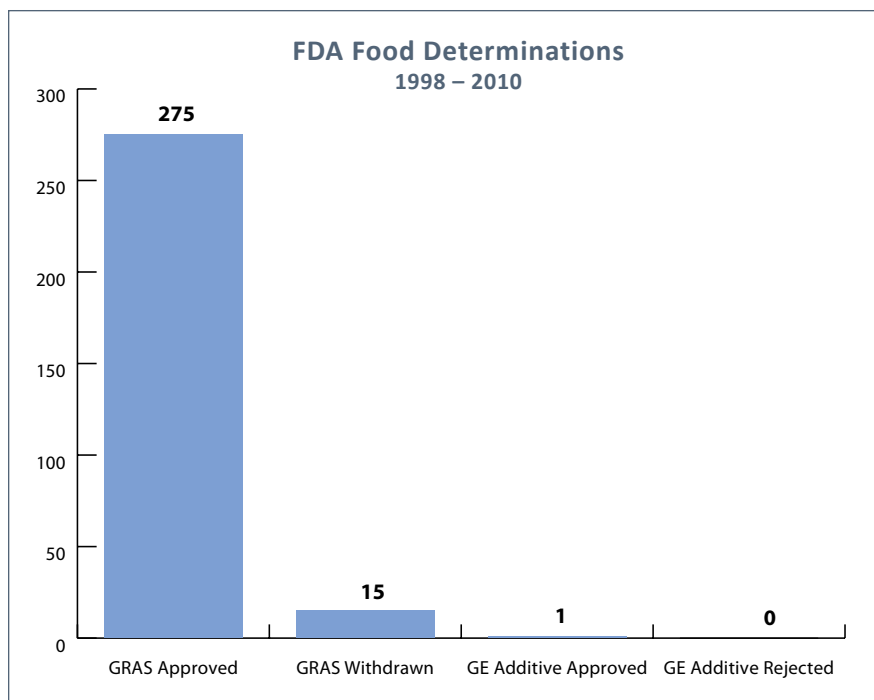
Some of the independent, peer-reviewed research that has been done on biotech crops has revealed some troubling health implications. A 2009 *International Journal of Biological Sciences* study found that rats that consumed GE corn for 90 days developed a deterioration of liver and kidney functioning.¹⁵⁹ 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 modified¹⁹⁸ 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 contaminate 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 glufosinate²⁷⁷ — 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

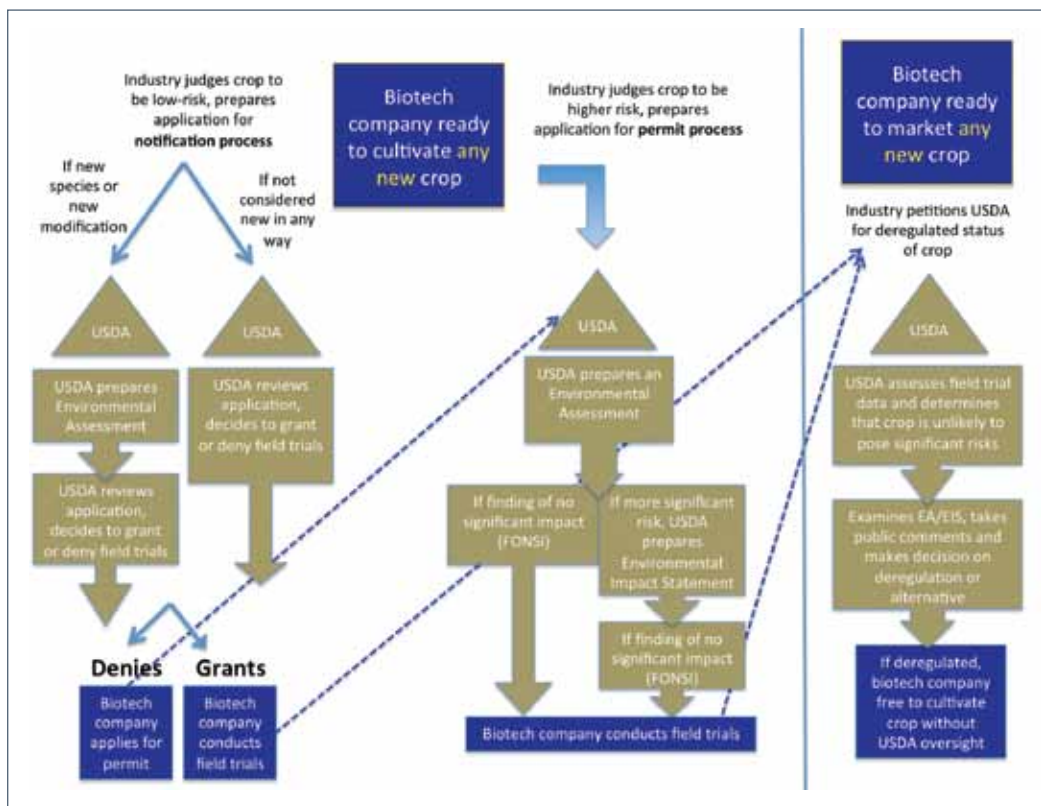
Under the more rigorous permit application process, the USDA determines if the GE field trial poses significant environmental impact before issuing a permit.³¹² The USDA reviews scientific submissions for four months before granting or denying the field test permit request.³¹³ If approved, the permit 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

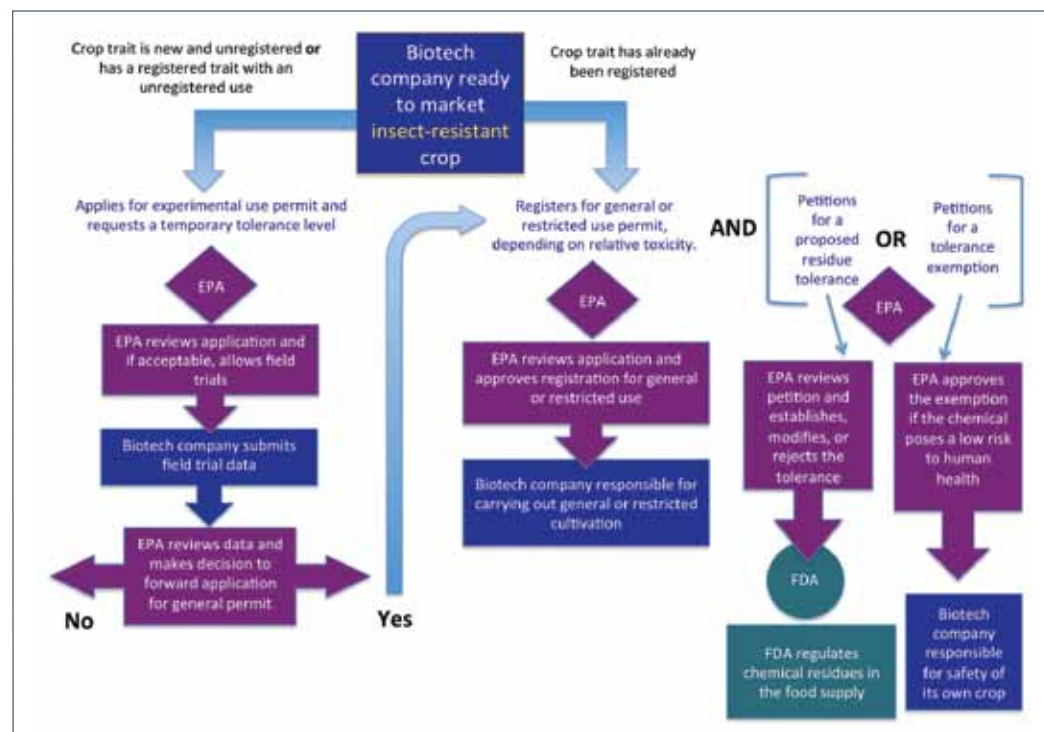
The EPA pesticide tolerances appear generous. A 2010 National Institutes of Health cancer risk study reported criticism by environmental health professionals and

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 cultivat-

ing 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

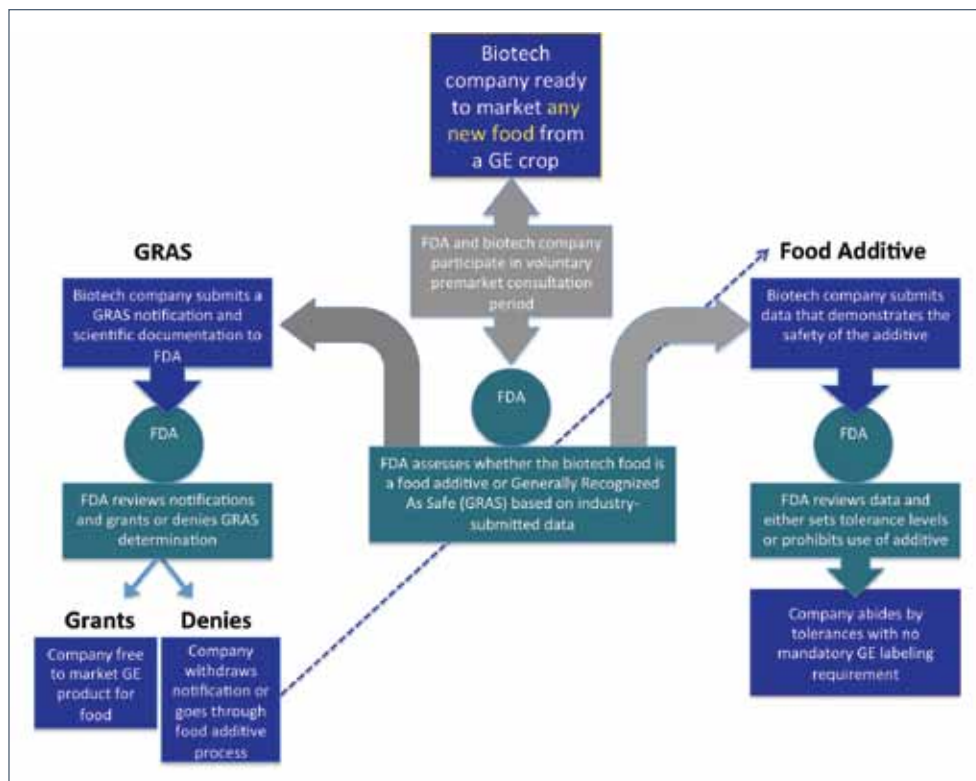
In most cases, the biotechnology industry self-regulates when it comes to the safety of genetically engineered foods. In 1992, the FDA issued guidance that gave the biotech industry responsibility for ensuring that new GE foods are safe and compliant with the federal Food, Drug and Cosmetics Act.³⁴⁶ 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.

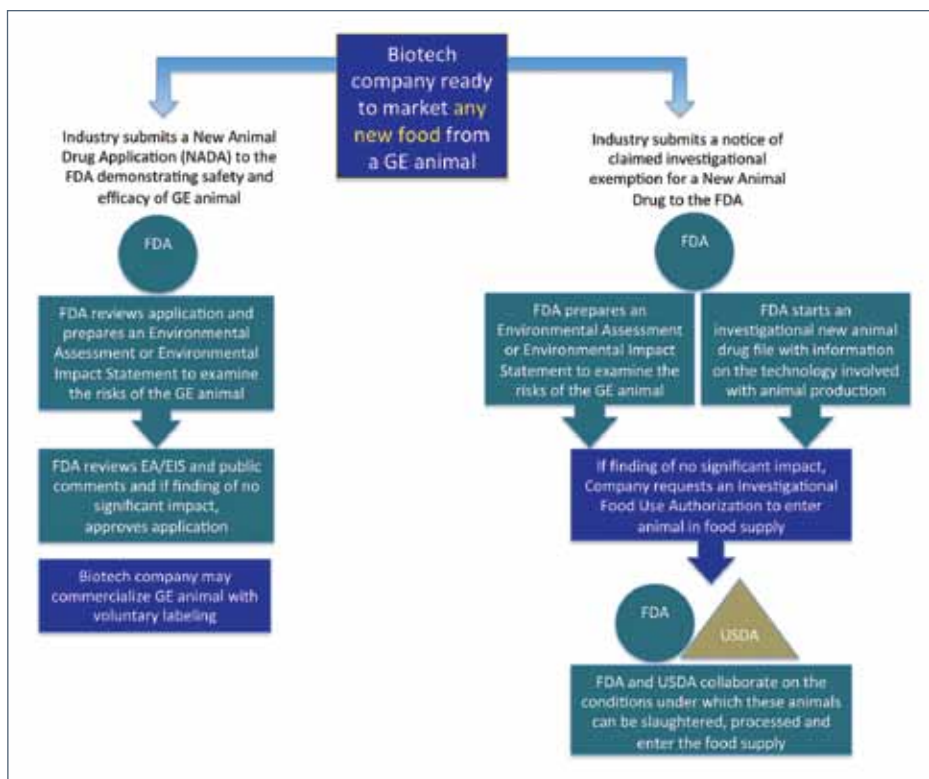
GE Animals

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.

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