Genetically Engineered Food

An Overview

food&waterwatch

About Food & Water Watch

Food & Water Watch works to ensure the food, water and fish we consume is safe, accessible and sustainable. So we can all enjoy and trust in what we eat and drink, we help people take charge of where their food comes from, keep clean, affordable, public tap water flowing freely to our homes, protect the environmental quality of oceans, force government to do its job protecting citizens, and educate about the importance of keeping shared resources under public control.

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EXECUTIVE SUMMARY

For centuries, farmers were able to use generations' worth of knowledge to breed seeds and livestock for the most desirable traits. However, technological innovation has gradually made this method of breeding nearly obsolete. Today, most soybeans, corn and cotton have been genetically engineered — altered with inserted genetic material — to exhibit traits that repel pests or withstand the application of herbicides.

Mergers and patent restrictions have increased the market power of biotechnology companies. The onslaught of genetic engineering has not only diminished the ability of farmers to practice their own methods of seed selection, but also turned another sector of agriculture into a business monopolized by a few corporations.

Farmers, who now depend on the few firms that sell seeds and affiliated agrochemicals, face higher prices and patent infringement lawsuits if a patent is allegedly violated. Genetic contamination is a serious threat to the livelihoods of non-GE and organic farmers who bear the financial burden for these incidents.

GE crops can take a toll on agriculture and surrounding wildlife as well. The environmental effects of GE crops include intensified agrochemical use and pollution, increased weed and insect resistance to herbicides and pesticides, and gene flow between GE and non-GE crops.

Once GE products are on the market, no labeling is required. This means that U.S. consumers blindly eat and drink GE ingredients every day and are not given the knowledge or choice to do otherwise. Several studies point to the health risks of GE crops and their associated agrochemicals, but proponents of the technology promote it as an environmentally responsible, profitable way for farmers to feed a growing global population. Yet the only ones experiencing any benefits from GE crops are the few, massive corporations that are controlling the food system at every step and seeing large profit margins.

New technologies — like genetic engineering — create uncertainties and risk that should be carefully evaluated rather than being rapidly pushed onto the market. The existing regulatory framework for GE foods simply does not measure up. The U.S. Department of Agriculture, Environmental Protection Agency and Food and Drug Administration have failed to protect the environment, the food system or public health from GE foods.

Food & Water Watch recommends:

- A moratorium on new approvals of genetically engineered plants and animals;
- Mandatory labeling of GE foods;
- Liability for GE contamination that rests with seed patent holders;
- Use of the precautionary principle for the evaluation of GE crops, animals and food;
- A new regulatory framework for GE crops, animals and food; and
- Improved agency coordination and increased post-market regulation of GE foods.

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 and Drug Administration (FDA), the U.S. Department of Agriculture (USDA) and the 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] After nearly 20 years, only one high-yield GE seed had been considered for approval by 2013.[7]

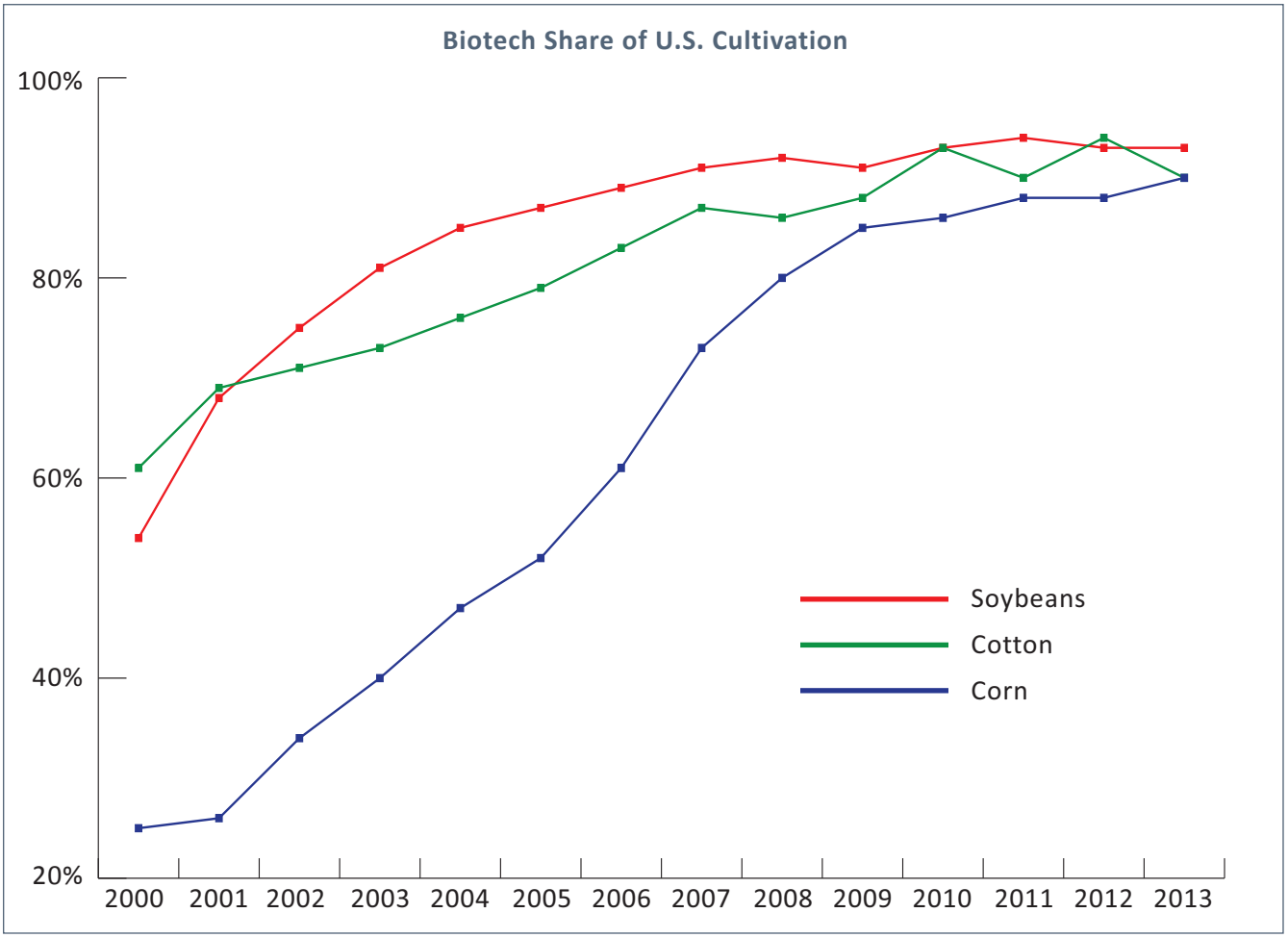
Farmers have bred their best livestock and saved seeds from their most productive crops for thousands of years. Selective crop breeding was accelerated by the development of crop hybridization, which cross-bred

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 2012, more than 420 million acres of GE crops were cultivated in 28 countries—representing more than 10 percent of global cropland.[14] The United States is the world leader in GE crop production, with 172 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 93 percent of soybean and 90 percent of corn acres in 2013.[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 it 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]



Source: USDA

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 from being 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, melon, potato, apple, petunia, millet, switchgrass and tobacco.[27] GE 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] By 2012, Monsanto's Roundup Ready trait was present in 98 percent of the U.S. GE corn market and 86 percent of the U.S. GE cotton market.[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]

Notable GE Crops

ALFALFA: The USDA approved Monsanto's Roundup Ready alfalfa, an important forage crop for livestock, in 2005.[41] In 2007, organic alfalfa producers challenged the USDA's approval on grounds that GE alfalfa could contaminate and wipe out non-GE alfalfa.[42] The USDA's 2010 Environmental Impact Statement 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.[43] Nonetheless, the USDA approved GE alfalfa without any planting restrictions in January 2011.[44]

APPLE: The USDA is currently considering approving Okanagan Specialty Fruits' reduced-bruising Arctic Apple, which would be aimed at the packaged pre-sliced apple market.[45]

CORN: In 2011, the USDA approved Syngenta's amylase corn, which produces an enzyme that facilitates ethanol production.[46] 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 destined for the human and animal food supply.[47] Contamination of corn destined for the food supply is possible, especially without a buffer zone to minimize wind pollination.[48] Even the USDA admits that contamination of high-value organic, blue, and white corns may produce "undesirable effects" during cooking, like darkened color or softened texture.[49]

PAPAYA: In 1999, the EPA approved two papaya varieties that are resistant to the papaya ringspot virus.[50] GE papayas constituted 30 percent of Hawaii's papaya cultivation in 1999, rising to 77 percent by 2009.[51] The USDA approved a third ringspot-resistant papaya in 2009.[52]

POTATO: In 1995, the EPA and FDA approved Monsanto's Colorado potato beetle-resistant NewLeaf potato.[53] Monsanto withdrew the potato from the market in 2001 but maintains it may return to potato research in the future.[54] 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.[55] Amflora was the EU's first GE approval since 1998.[56] The USDA is currently considering the approval of a low-acrylamide, reduced-bruising potato produced by McDonald's major supplier, J.R. Simplot.[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]

SOYBEAN: In the past few years, the USDA has approved two soybeans designed to have healthier oil profiles.[66] In December 2011, the USDA approved a soybean lower in saturated fat, and in July 2012 it approved a soybean with higher omega-3 fatty acids.[67]

SUGAR BEET: The USDA approved Monsanto's Roundup Ready sugar beet in 2005 after determining that cultivation poses no risks to other plants, animals or the environment.[68] In 2008, the Center for Food Safety and the Sierra Club challenged the approval in court on grounds that the USDA's Environmental Assessment ignored important environmental and economic impacts.[69] The USDA finally approved GE sugar beets in July 2012.[70]

SWEET CORN: In 2011, Monsanto announced that its Roundup Ready sweet corn would be available for planting.[71] Although sweet corn is Monsanto's first commercialized GE vegetable, the USDA swiftly approved it since the seed's traits — insect resistance and glyphosate tolerance — were previously approved for other crops in 2005 and 2008.[72]

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

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 with rBGH injections can lead to increased milk production and significant animal health problems. Cows injected with rBGH can have serious 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 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 markets for the Enviropig, but this research project is currently stalled.[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

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 provided 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 authorized field trials of GE plants.[117]

1992: The USDA approved 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: The 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: The FDA announced 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]

grows to market size twice as fast as non-GE salmon.[102] In its submission to the FDA, Aquabounty acknowledges that its transgenic fish will not escape from salmon farms.[103]

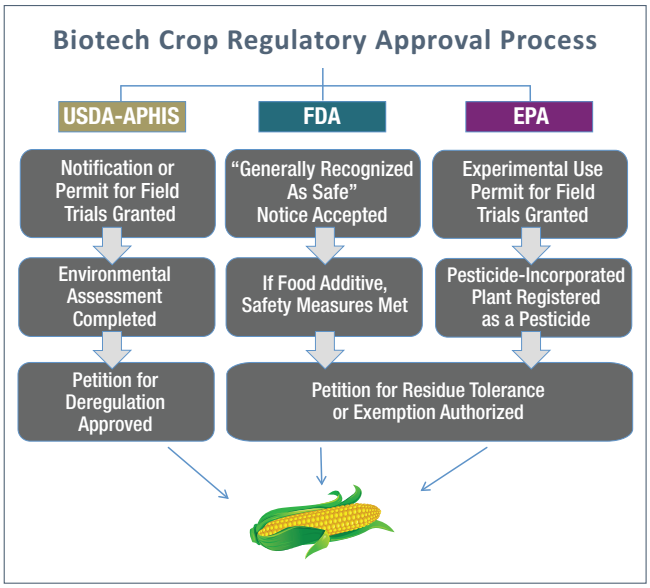
Although the biotech salmon purportedly would be sterile, the large, voracious GE salmon could out-compete wild fish for food, habitat and mates but then fail to successfully reproduce, effectively driving wild salmon to extinction.[104] Moreover, carnivorous farmed fish eat pellets made from wild fish, 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.

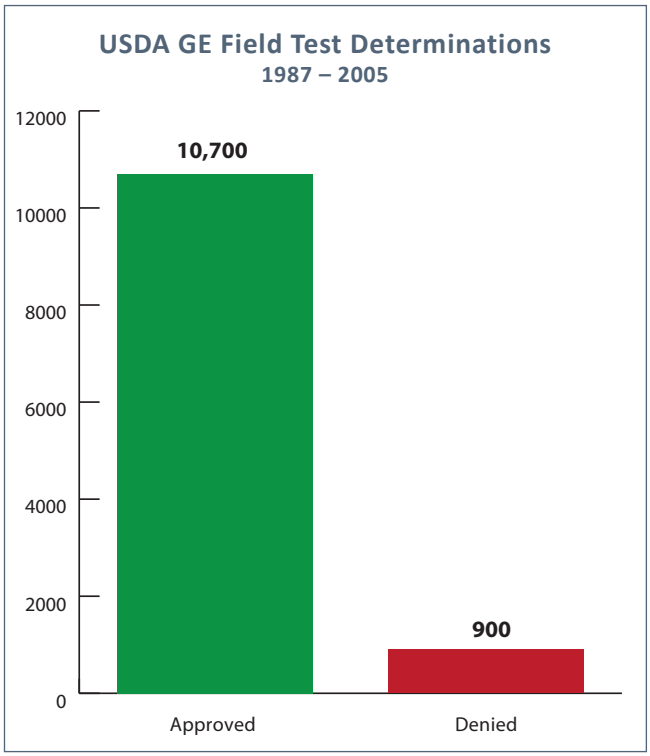
Insufficient Protection

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 EPA and the FDA. Although the missions of





Source: USDA

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 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 late 2013, only GE salmon and Enviropig had been considered for commercial approval, but no transgenic animals had 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 2012 *Food and Chemical Toxicology* study done by toxicologist Gilles-Eric Séralini found that rats that consumed GE corn over two years had deteriorated liver and kidney functioning and a higher rate of tumor development.[159] This study faced criticism for its findings; yet in June 2013, the EU funded a long-term carcinogen rat feeding study using the same variety of corn.[160] Studies have found irregularities in the livers of rats as well as impaired embryonic development in mice following a GE soybean diet.[161] And a 2007 study found significant liver and kidney impairment of rats that were fed insect-resistant *Bt* corn, noting that, "with the present data it cannot be concluded that GE corn MON863 is a safe product."[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]

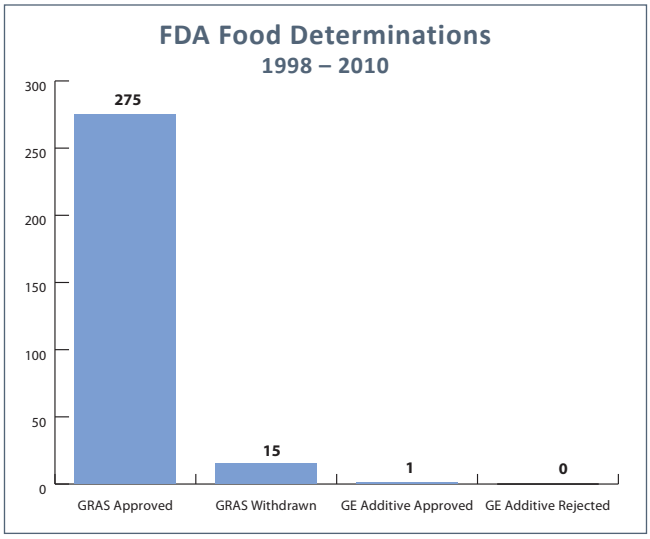
The Roundup Ready trait lowers the nutritional content of crops by inhibiting the absorption of nutrients including calcium, iron, magnesium and zinc, making plants more susceptible to disease.[164] Studies indicate that fusarium — a soil-borne pathogen that infects plant roots — becomes more prevalent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

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, which grows less than one-tenth of a percent of the global genetically engineered 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

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]

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.[168] 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.[169] 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.[170] Yet there are no definitive methods for assessing the potential allergenicity of bioengineered proteins in humans.[171] 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.[172] However, in 2000, StarLink traces were found in taco shells in U.S. supermarkets.[173] The EPA granted Aventis's request to cancel StarLink's registration, helping to remove the GE corn from the food supply.[174] 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.[175] 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.[176]

For consumers to have the opportunity to make informed choices about their food, all GE foods should be labeled. A 2013 *New York Times* poll found that 93 percent of respondents were in favor of a mandatory label for genetically engineered food.[177] A 2010 Consumers Union poll found that 95 percent of U.S. consumers favor mandatory labeling of meat and milk from GE animals.[178] Yet despite this overwhelming support, the FDA will not require labeling of food that comes from genetically modified animals such as the AquAdvantage salmon.[179] In 2013, over 25 states introduced legislation to label GE foods, and these bills passed in Connecticut and Maine.[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 14 weed species in the United States (and 24 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] The industry currently estimates that 61.2 million acres of cropland are now infested with weeds resistant to glyphosate.[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]

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 by an average of 13 percent annually between 2002 and 2012, and soybean seed prices rose by an average of 11 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

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 ruled against portions of Ohio's restrictive limits on affirmative "rBGH-free" labeling, and Ohio finally abandoned its regulation to restrict such labeling in October 2011.[200]

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 2012, nearly all (98 percent) of the corn and most (86 percent) of the cotton 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 January 2013, Monsanto had filed 144 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.

Alfalfa contamination is already occurring in the United States. In August 2013, a Washington state farmer reported that his alfalfa was rejected for export due to the presence of a genetically engineered trait. However, the USDA decided not to take any action to investigate transgenic alfalfa gene flow or to address ways to prevent contamination.237 In addition to alfalfa, GE wheat — which hasn't been field-tested since 2005 — was found in an Oregon farm in May 2013, causing Japan and South Korea to suspend some U.S. wheat imports. It is unclear how the GE wheat appeared, but a Monsanto representative tried to claim it was the result of potential sabotage.[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 pressured governments all over the world 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 2013, biotech corn and soybean seeds cost 45 and 32 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 million U.S. acres in 2009.[272] Glyphosate use on Roundup Ready crops has grown steadily. The total volume of glyphosate applied to corn, cotton and soybeans has increased 10-fold from 15 million pounds in 1996 to 159 million pounds in 2012.[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 is seeking approval for GE corn and soybean varieties that are 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 dicamba-tolerant soybeans and cotton.[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 by 2013 only one variety of drought-tolerant corn was approved.[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] Monsanto's approved drought-tolerant corn has overestimated yield benefits, and there is insufficient evidence that it will outperform already available conventionally bred alternatives.[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] The development of patented drought-tolerant crops allows biotechnology companies to 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.**
- **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.
- **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.

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

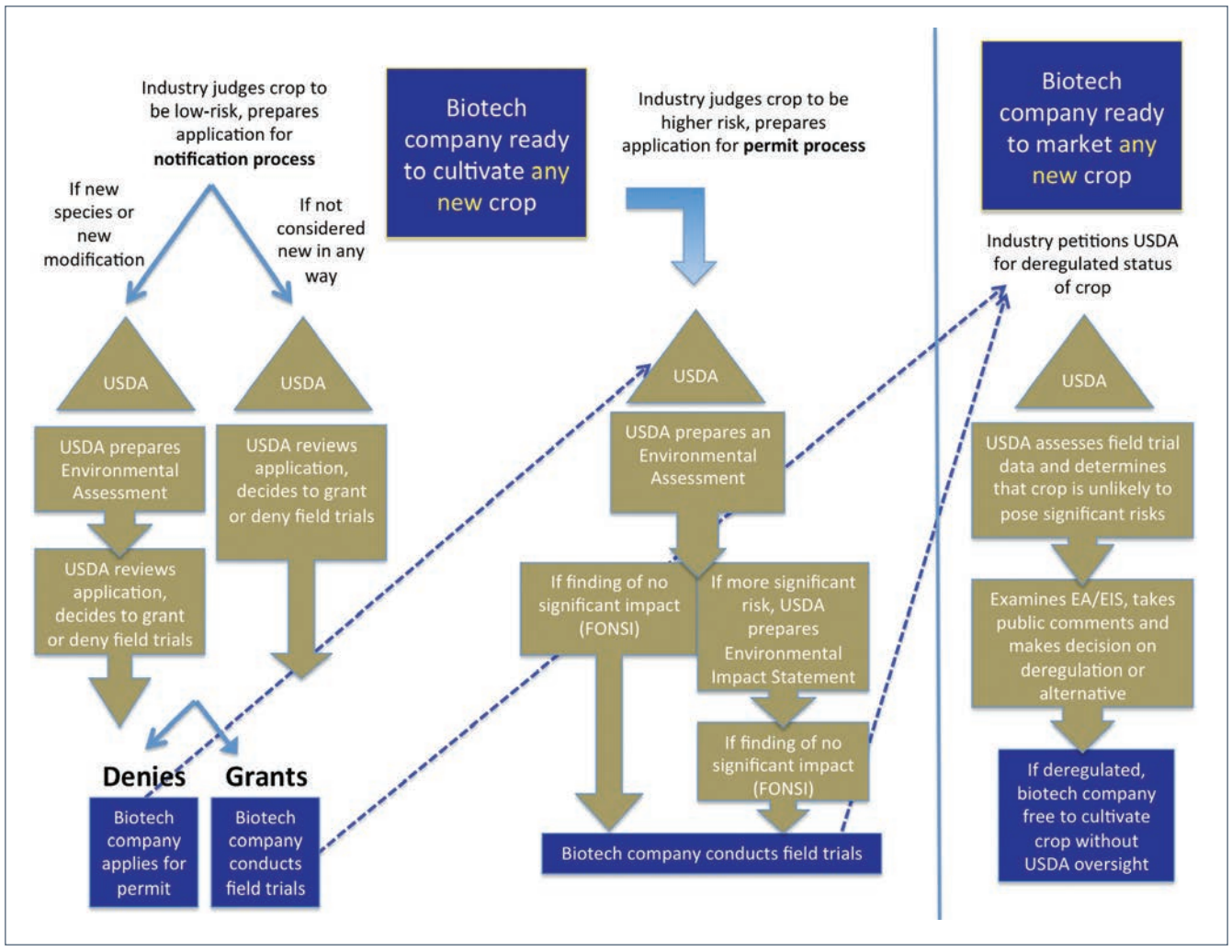
USDA

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 Na-



tional 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 is accelerating its approval process for GE crops even as the seed companies hurry the new, untested varieties to market. In November 2011, the USDA unveiled its new streamlined process for GE crop approvals to shorten approval timelines by 13 to 15 months.[322]

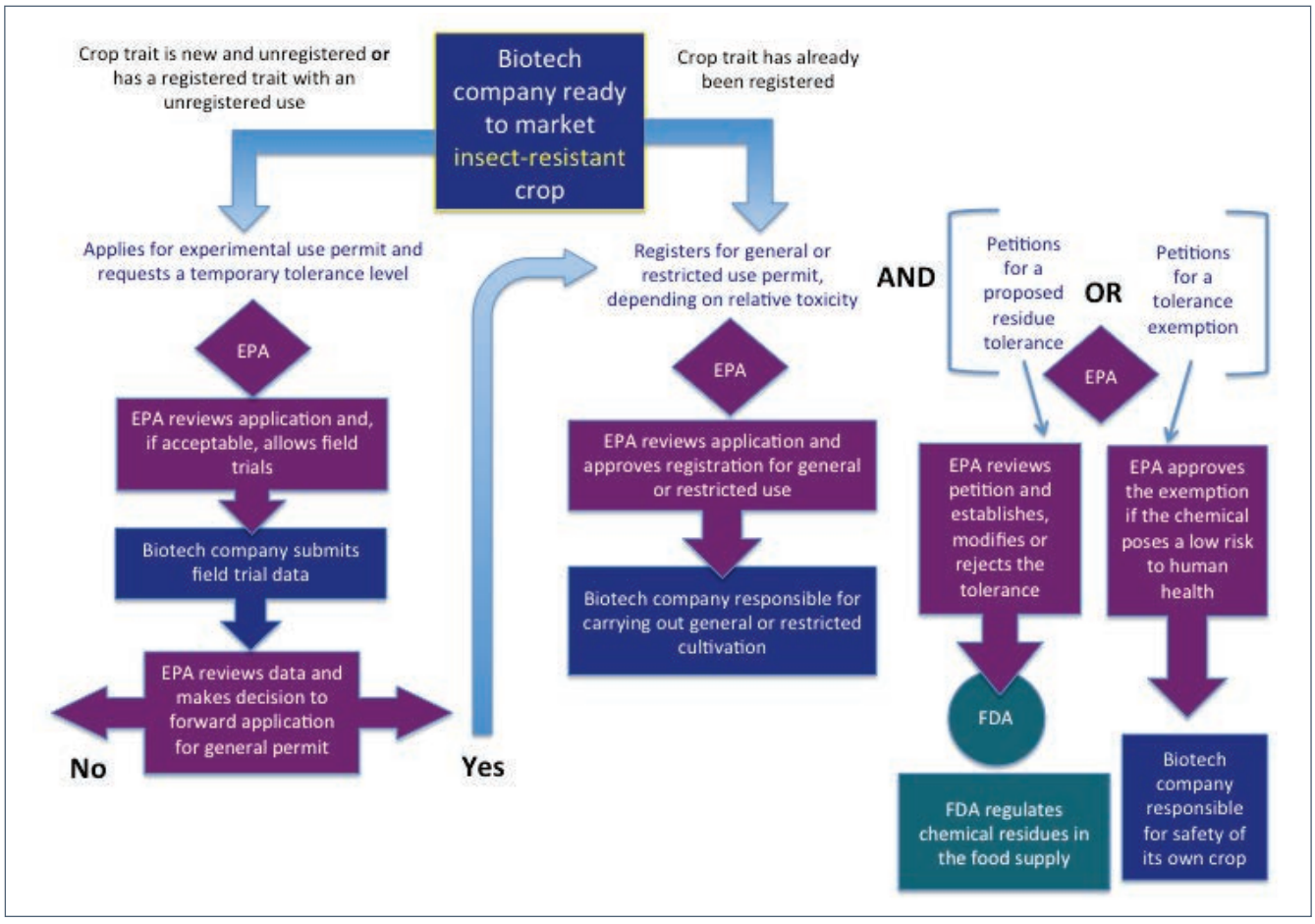
If a field trial does not reveal significant risks, the company can petition for nonregulated status, allowing the crop to be cultivated and sold commercially without further oversight.[323] The USDA solicits public comments on the deregulation for 60 days.[324] After reviewing available data, the USDA 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]

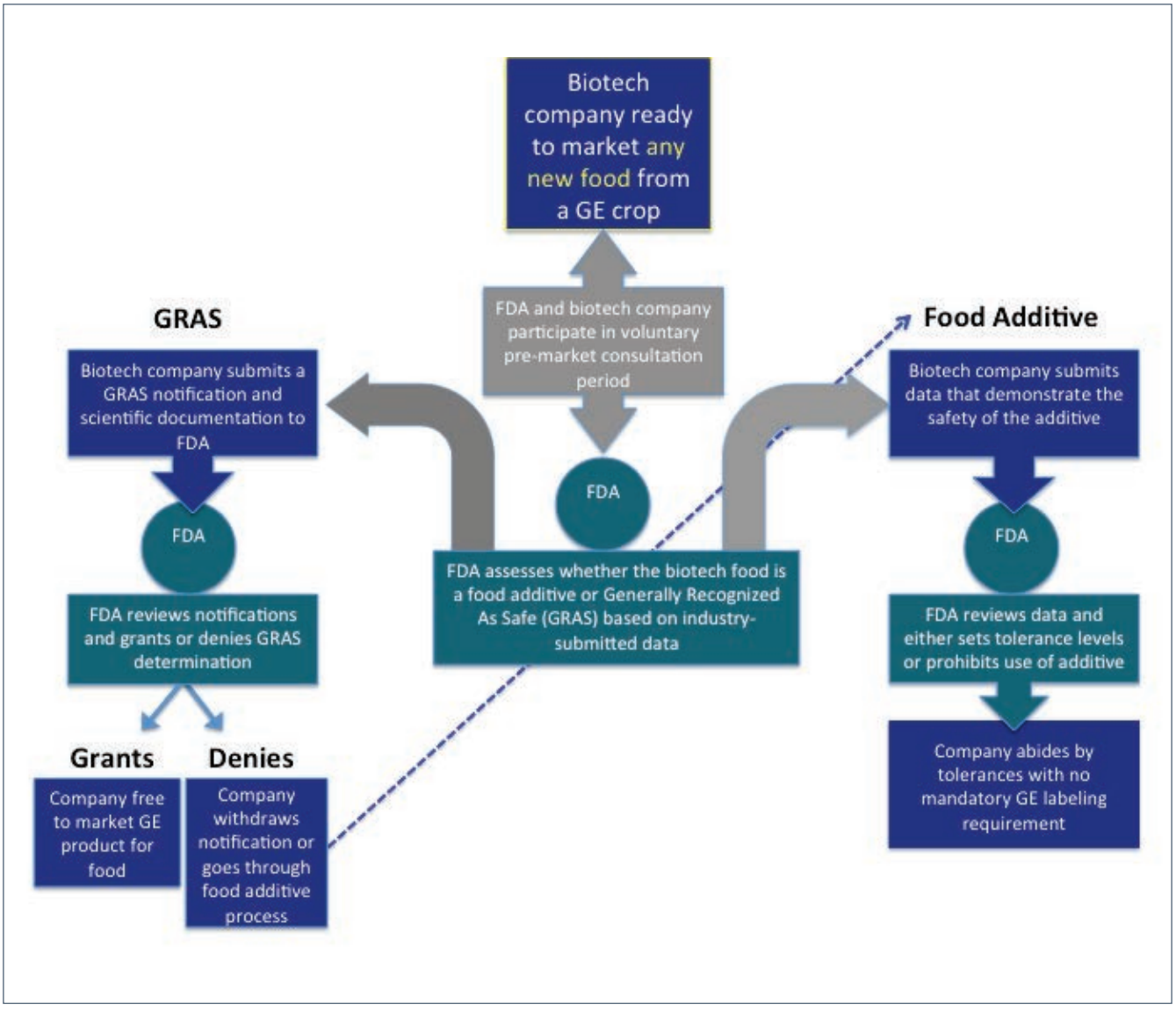
The EPA pesticide tolerances appear generous. A 2010 National Institutes of Health cancer risk study reported criticism by environmental health professionals and advocates that agribusiness influence at EPA deterred the agency from establishing sufficiently strong pesticide limits.[332] The EPA can even 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 2013, 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 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

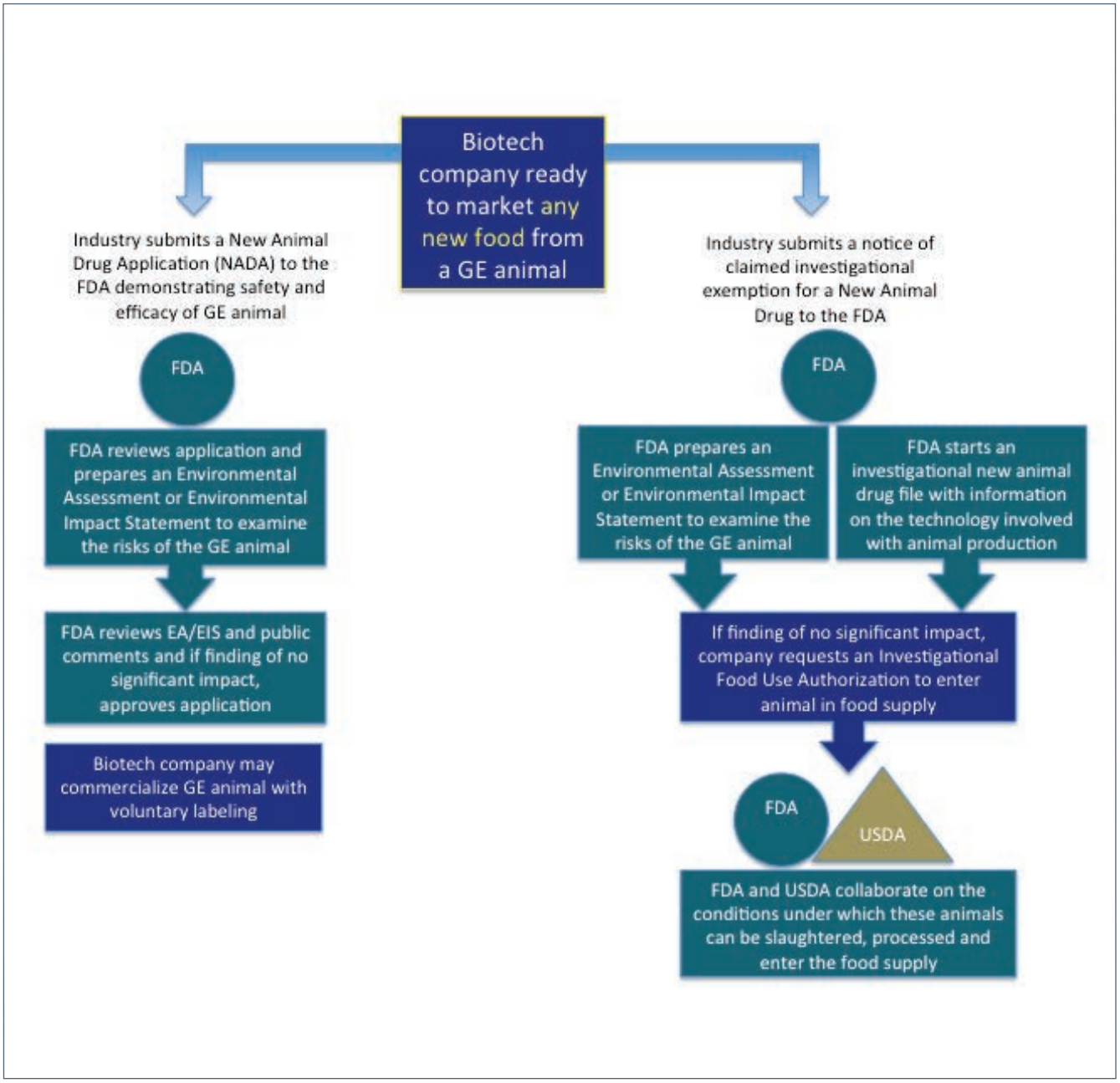
The federal government regulates genetically engineered animals the same as veterinary medicines. In 2009, the FDA decided that the Food, Drug and Cosmetics Act definition of veterinary drugs as substances "intended to affect the structure of any function of the body of man or other animals" includes 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 2013, 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 2013, 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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