

GENETICALLY ENGINEERED FOOD

An Overview



2016 Edition

About Food & Water Watch

Food & Water Watch champions healthy food and clean water for all. We stand up to corporations that put profits before people, and advocate for a democracy that improves people's lives and protects our environment. We envision a healthy future for our families and for generations to come, a world where all people have the wholesome food, clean water and sustainable energy they need to thrive. We believe this will happen when people become involved in making democracy work and when people, not corporations, control the decisions that affect their lives and communities.

Food & Water Watch has state and regional offices across the country to help engage concerned citizens on the issues they care about. For the most up-to-date contact information for our field offices, visit foodandwaterwatch.org.

National Office

**1616 P Street, NW
Suite 300
Washington, DC 20036
(202) 683-2500**

Oakland, California

1814 Franklin Street
Suite 1100
Oakland, CA 94612
(510) 922-0720

Los Angeles, California

3000 S. Robertson Boulevard
Suite 255
Los Angeles, CA 90034
(323) 843-8450

Florida

1044 NE 15th Avenue
Fort Lauderdale, FL 33304
(954) 372-1881

Colorado

1740 High Street
Denver, CO 80218
(720) 449-7505

Iowa

505 Fifth Avenue
Suite 818
Des Moines, IA 50309
(515) 344-4834

Maine

142 High Street
Suite 501-C
Portland, ME 04101
(207) 619-5845

Maryland

3121 St. Paul Street
Baltimore, MD 21218
(410) 394-7650

Michigan

2727 Second Avenue
Suite 136
Detroit, MI 48201
(313) 486-1356

New Jersey

100 Bayard Street
Suite 202
New Brunswick, NJ 08901
(732) 839-0860

New Mexico

7804 Pan American
East Freeway NE #2
Albuquerque, NM 87109
(505) 633-7366

New York

68 Jay Street
Suite 713
Brooklyn, NY 11201
(718) 943-9085

North Carolina

801 Gilbert Street
Suite 204
Durham, NC 27701
(919) 794-6380

Illinois

670 W Hubbard Street
Suite 300
Chicago, IL 60654
(773) 796-6086

Oregon

917 SW Oak Street
Suite 404
Portland, OR 97205
(971) 266-4528

Pennsylvania

1501 Cherry Street
Second Floor
Philadelphia, PA 19102
(267) 428-1903



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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. Genetically engineered crops are also commonly referred to as genetically modified organisms, or GMOs.

Mergers and patent restrictions have increased the market power of biotechnology companies. The onslaught of genetic engineering has not only diminished the ability for 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-GMO and organic farmers who bear the financial burden for these incidents.

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

Once GMO products are on the market, no labeling is required. This means that U.S. consumers blindly eat and

drink GMO ingredients every day and are not given the knowledge necessary to choose to do otherwise. Several studies point to the health risks of GMO 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 GMO crops are the few, massive corporations that are controlling the food system at every step and seeing large profit margins.

New technologies — such as genetic engineering — create uncertainties and risk that should be carefully evaluated rather than being rapidly pushed onto the market. The existing regulatory framework for GMO 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 GMO foods.

Food & Water Watch recommends:

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



Introduction

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 policy makers 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 to 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 and organization from three U.S. federal agencies — the Food and Drug Administration (FDA), the Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) — has put human and environmental health at risk through inadequate review of genetically engineered foods, commonly known as genetically modified organisms (GMOs). This lack of post-market oversight has led to cases of unintentional food contamination and to a failure

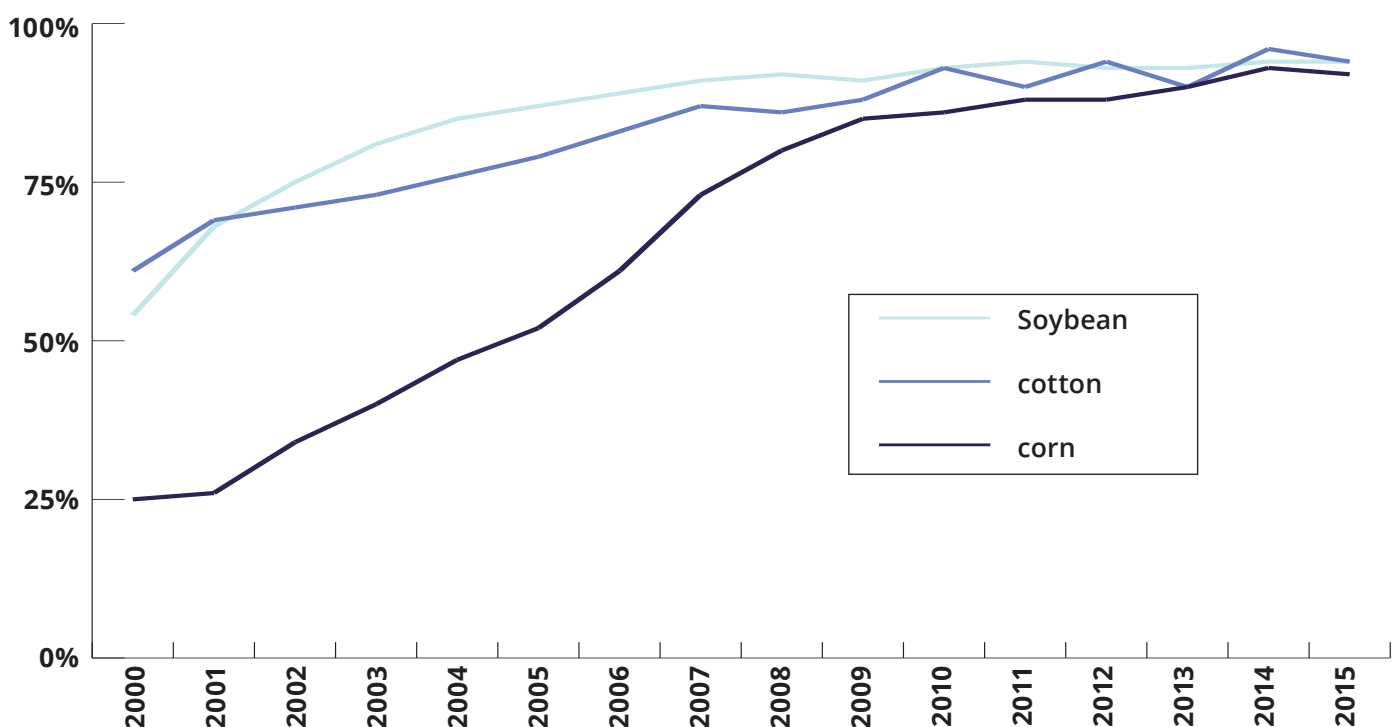
to require labeling of these foods. Organic farming, which does not allow the use of GMOs, has been shown to be safer and more effective than using modified seed. Moreover, public opinion surveys indicate that people prefer food that has not been manipulated, or that they at least want to know whether food has been engineered.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 GMO 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

Figure 1: Biotech Share of U.S. Cultivation



Source: USDA

herbicides to kill weeds without harming GMO crops, or insect-resistant, which protects plants from destructive pests.⁶ After nearly 20 years, only one high-yield GMO seed had been considered for approval as of 2015.⁷

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 GMO tomato even used a fish gene to make the tomato frost-resistant.¹² However, splicing different organisms together could pose risks to consumers who 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 2014, more than 447 million acres of GMO crops and trees were cultivated in 28 countries, according to an industry source.¹⁴ The United States is the world leader in GMO crop production, with 181 million acres, or about 40 percent of global production.¹⁵ It might sound as if GMOs are ubiquitous, but global GMO production makes up just 13 percent of the world's agricultural area able to grow crops.¹⁶ U.S. GMO crop cultivation grew rapidly from only 7 percent of soybean acres and 1 percent of corn acres in 1996, to 94 percent of soybean and 93 percent of corn acres in 2014.¹⁷ (See Figure 1 on page 3.)

Inserting desirable genetic traits from one organism into the embryo of another produces so-called transgenic animals.¹⁸ 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.¹⁹ 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.²⁰ Although no meat or milk in the United States has been disclosed as coming from clones, cloned animals undoubtedly already have entered the food supply²¹ because no binding regulation forbids it.

Another technique used by genetic engineers to create plants with desirable traits is RNA interference (RNAi). This method uses inserted RNA to silence a target gene in an organism.²² So far, RNAi has been used to engineer a reduced-bruising and low acrylamide GMO potato, a non-browning GMO apple and a soybean with altered oil content.²³ Other emerging gene-editing techniques, like CRISPR (clustered regularly interspaced short palindromic repeats) have raised questions from scientists who worry that the technique could edit the wrong genes or could interfere with whole ecosystems.²⁴ One major concern about how to regulate these gene-editing technologies is that there will essentially be no way to track their presence in engineered products.²⁵ And some crops engineered using similar gene-editing techniques have already fallen through the cracks of the USDA's regulatory system.²⁶

Transgenic animals have been developed to promote faster growth, disease resistance or leaner meat, as well as to minimize the impact of animal waste.²⁷ By 2004, the largest biotech firms had filed 12 patents for GMO animals.²⁸ Some animal-derived products, such as pharmaceuticals extracted from goat milk, have been approved.²⁹ The USDA National Organic Program prohibits GMO crops from being utilized in certified organic crops for food and animal feed.³⁰

What Are the GMO Crops?

The United States has approved a host of GMO crops, 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.³¹

Herbicide-tolerant or insect-resistant commodities — corn, canola, cotton and soybeans — make up the overwhelming majority of GMO crops.³² Other GMO crops that have been approved for field trials but that are not commercially available include rice, melon, petunia, millet,

Notable GMO Crops

Alfalfa: The USDA approved Monsanto's Roundup Ready alfalfa, an important forage crop for livestock, in 2005.⁴⁷ In 2007, organic alfalfa producers challenged the USDA's approval on grounds that GMO alfalfa could contaminate and wipe out non-GMO alfalfa.⁴⁸ 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.⁴⁹ Nonetheless, the USDA approved GMO alfalfa without any planting restrictions in January 2011.⁵⁰

Apple: In 2015, the USDA approved Okanagan Specialty Fruits' reduced-bruising Arctic Apple, a product aimed at the packaged pre-sliced apple market.⁵¹

Corn (destined for ethanol): In 2011, the USDA approved Syngenta's amylase corn, which produces an enzyme that facilitates ethanol production.⁵² Although the corn is intended specifically for ethanol use, the USDA determined that it also was safe for food and animal feed, allowing it to be planted alongside GMO corn destined for the human and animal food supply.⁵³ Contamination of corn destined for the food supply is possible, especially without a buffer zone to minimize wind pollination.⁵⁴ 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.⁵⁵

Papaya: In 1999, the EPA approved two papaya varieties that are resistant to the papaya ringspot virus.⁵⁶ GMO papayas constituted 30 percent of Hawaii's papaya cultivation in 1999, rising to 77 percent by 2009.⁵⁷ The USDA approved a third ringspot-resistant papaya in 2009.⁵⁸

Potato: In 1995, the EPA and FDA approved Monsanto's Colorado potato beetle-resistant NewLeaf potato.⁵⁹ Monsanto withdrew the potato from the market in 2001 but maintains that it may return to potato research in the future.⁶⁰ In 2010, the European Union approved German chemical company BASF's Amflora potato for cultivation, although the crop was designed for industrial paper and textile use, not for food.⁶¹ Amflora was withdrawn from the European market in 2012 due to public opposition.⁶² The USDA approved two low-acrylamide, reduced-bruising potatoes, including one that is late blight-resistant, produced by J.R. Simplot, a major supplier of McDonald's.⁶³ McDonald's announced that it had no plans of using GMO potatoes in its restaurants.⁶⁴



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.⁶⁵ The first Golden Rice strain failed to deliver enough biofortified beta-carotene to address vitamin A deficiency.⁶⁶ Initial field trials of the second Golden Rice strain revealed yields that were lower than local rice varieties.⁶⁷ Golden Rice must undergo field tests and receive approval by regulators in Bangladesh and the Philippines before being released into target markets in the developing world.⁶⁸

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.⁶⁹ 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.⁷⁰ After more legal proceedings, the USDA finally approved GMO sugar beets in July 2012.⁷¹

(continued on page 6)

Notable GMO Crops (continued from page 5)

Sweet Corn: In 2011, Monsanto announced that its Roundup Ready sweet corn would be available for planting.⁷² Although sweet corn is Monsanto's first commercialized GMO 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 2008.⁷³

Tomato: In 1991, DNA Plant Technology Corporation used a gene from the winter flounder (a type of flatfish) to create a cold-tolerant tomato.⁷⁴ The crop was approved for field trials but was never approved for sale or commercialized.⁷⁵ In 1992, Calgene's Flavr Savr tomato, engineered to stay fresher longer, was the first GMO food on the market.⁷⁶ It later was withdrawn from the market due to harvesting problems and lack of demand.⁷⁷

Wheat: In 2002, Monsanto petitioned the USDA to approve Roundup Ready red spring wheat, the first GMO crop designed primarily for human food consumption rather than for livestock feed or for a processed food ingredient.⁷⁸ Given that Japan and the EU have different restrictions for GMO food crops, the large-scale cultivation of GMO wheat could damage options for U.S. wheat exports. A 2004 Iowa State study forecasted that approving GMO wheat could lower U.S. wheat exports by 30 to 50 percent and depress prices for both GMO and conventional wheat.⁷⁹ Because of export concerns, Monsanto abandoned GMO wheat field trials before obtaining commercial approval, although the company resumed research in 2009.⁸⁰

switchgrass and tobacco.³³ GMO papaya, flax, tomatoes and squash have made it through the field trial approval process, although they are not necessarily currently commercially available.³⁴

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 GMO crops. Most of these crops are resistant to the herbicide glyphosate (sold commercially as Roundup and produced by the agrichemical company Monsanto).³⁵ By 2012, nearly all (98 percent) of the corn and most (86 percent) of the cotton cultivated in the United States was grown from seeds covered by Monsanto patents.³⁶ Other herbicide-tolerant crops include Bayer's Liberty Link corn and Calgene's BXN cotton.³⁷

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.³⁸ 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.³⁹ 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.⁴⁰

Value-added crops

Some GMO 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.⁴¹ GMO canola and soybean oils are manipulated to have lower polyunsaturated fatty acid levels and higher monounsaturated fatty acid (oleic acid) content.⁴² In 2010, the USDA approved a Pioneer-brand soybean that is modified to produce more oleic acid.⁴³ 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.⁴⁴

Industrial and pharmaceutical crops

Other GMO crops contain genes tied to traits 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.⁴⁵ 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 engineered to produce a precursor to human insulin that can be used in the treatment of diabetes.⁴⁶

Regulatory Timeline

1930: The Plant Patent Act of 1930 provides 17-year patent protection for plant varieties, including hybrids.¹⁰²

1952: The Patent Act of 1952 extends broader patent rights to agricultural developments to “any new and useful ... composition of matter” including chemicals and processes.¹⁰³

1961: The International Convention for the Protection of New Varieties of Plants establishes an intergovernmental organization that provides intellectual property rights to the breeders of new plant varieties.¹⁰⁴

1970: The Plant Variety Protection Act of 1970 provides plant variety breeders with exclusive patent rights for 18 years.¹⁰⁵ It includes a “farmer’s exemption” that allows farmers to save seed and to sell saved seeds to other farmers.¹⁰⁶

1980: The U.S. Supreme Court decision *Diamond v. Chakrabarty* extends patent rights to genetically engineered oil-eating bacteria.¹⁰⁷ The Court rules that laboratory-created living things are not “products of nature” under the 1952 Patent Act and are thus patentable. This watershed decision bestows patent protection on GMO plants, animals and bacteria.

1981: The first transgenic mice are produced for tissue manipulation and experimentation.¹⁰⁸

1985-88: A series of rulings by the U.S. Patent and Trademark Office awards patent protection to plants and nonhuman animals.¹⁰⁹

1985: The first transgenic sheep and pigs are modified to display enhanced growth.¹¹⁰

1986: The Reagan White House determines that no new laws are necessary to regulate biotechnology since it does not pose any special or unique risks.¹¹¹

1986: The Technology Transfer Act allows the USDA to share publicly financed research and technology with private businesses.¹¹²

1987: The USDA authorizes field trials of GMO plants.¹¹³

1992: The USDA approves the first GMO commercial cultivation, Calgene’s Flavr Savr tomato.¹¹⁴

1994: The United States ratifies the International Convention for the Protection of New Varieties of Plants, which extends plant patents to 20 years for most crops and prohibits farmers from selling saved patented seed without the patent owner’s permission.¹¹⁵

1995: The EPA registers the first pest-protected plant, Monsanto’s NewLeaf potato.¹¹⁶

1996: The U.S government approves commercial cultivation of GMO soybeans and Bt corn.¹¹⁷

2000: GMO StarLink corn, approved for animal feed, unintentionally contaminates the human food system before being approved for human consumption.¹¹⁸

2001: The FDA releases guidance allowing food companies to voluntarily label GMO or non-GMO foods, provided that the labels are not false or misleading.¹¹⁹

2009: The FDA announces that GMO animals will be regulated as veterinary drugs instead of food (known as Guidance 187) and defines transgenic animals as veterinary drugs under the Federal Food, Drug and Cosmetics Act.¹²⁰

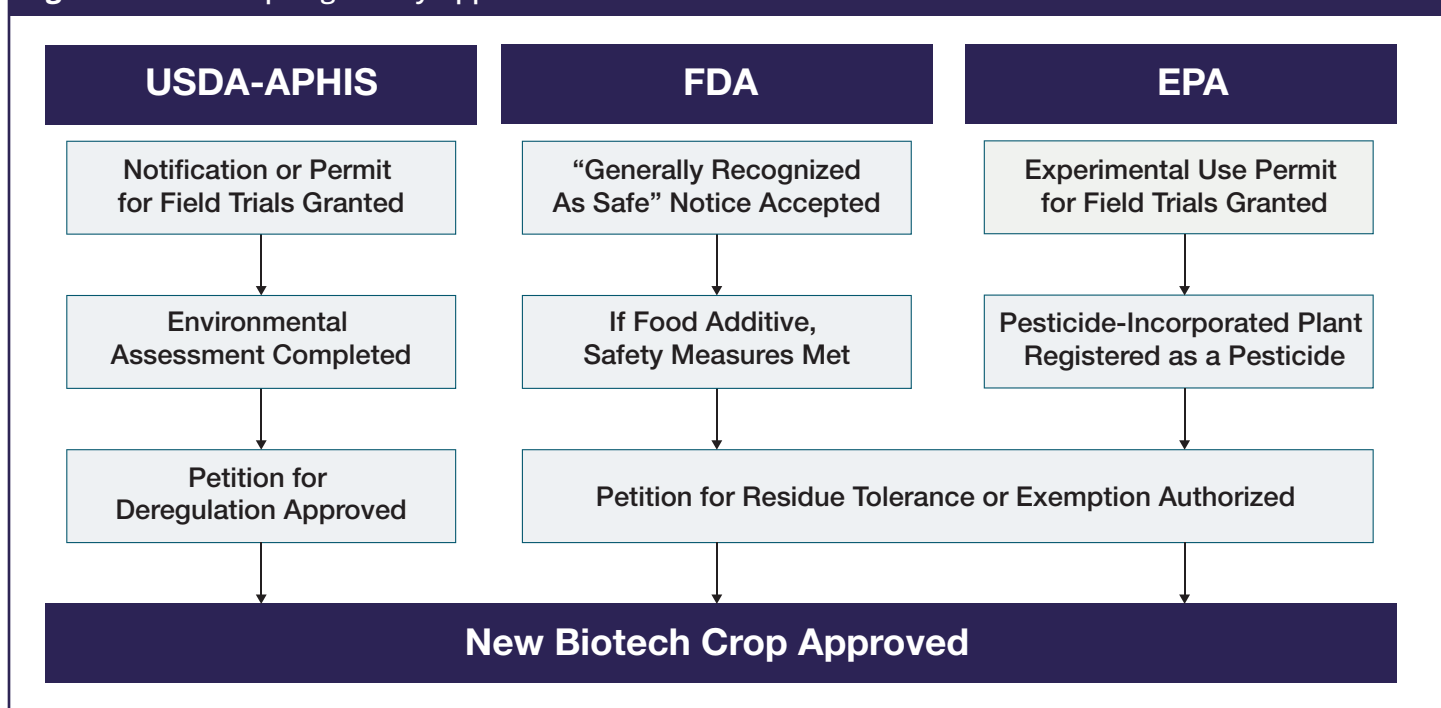
The Next Frontier: GMO Animals

There are fewer transgenic animals than GMO crops, but the number of new GMO 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.⁸¹

Dairy products were the first bioengineered animal products in the food supply.⁸² 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.⁸³

In 1993, the FDA approved the use of recombinant bovine somatotropin (rBST), also known as recombinant bovine

Figure 2: GMO Crop Regulatory Approval Process



growth hormone (rBGH), to increase milk production in cows.⁸⁴ Although dairy cows naturally produce BST, artificially elevating the hormone levels with rBGH injections can lead to increased milk production as well as to animal health problems. Cows injected with rBGH can have significant health problems, including higher rates of mastitis, an udder infection that requires antibiotic treatment.⁸⁵ In turn, the use of antibiotics in industrial dairies contributes to the growth of antibiotic-resistant bacteria, a growing public health problem.⁸⁶

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-1.⁸⁷ IGF-1 has been linked to breast and prostate cancer.⁸⁸ RBGH has never been approved for commercial use in Canada or the EU due to concerns about the drug's impact on animal health.⁸⁹

By 2007, the use of rBGH was on the wane, especially on small farms.⁹⁰ 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.⁹¹

Researchers are developing transgenic animals that allegedly reduce the spread of disease in animals and humans. The University of Edinburgh has engineered chickens that do not 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.⁹³ And U.K. biotechnology company Oxitec has engineered sterile mosquitoes to combat the spread of dengue fever in the developing world and diamondback moths for insect control in U.S. agriculture.⁹⁴

Yet genetically engineered livestock will merely treat the symptoms of a poorly regulated food safety and agriculture system. They will not adequately prevent disease caused by crowded confinement conditions or pests drawn to monoculture crop production. And current GMO 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 GMO 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 GMO pigs from a study to be slaughtered and sold for human consumption, even though GMO 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 November 2015, the FDA approved the first GMO food animal, 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 is supposed to grow to market size faster than non-engineered salmon.¹⁰⁰ In its submission to the FDA, AquaBounty acknowledged that it cannot guarantee that its transgenic fish will not escape from salmon farms.¹⁰¹

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 GMO products. Lax enforcement, uncoordinated agency oversight and ambivalent post-approval monitoring of biotechnology have allowed risky GMO plants and animals to slip through the regulatory cracks.

Federal regulators approve most applications for GMO field trials, and no crops have been rejected for commercial cultivation.¹²¹ Although some biotechnology companies have withdrawn pending applications, federal regulators approve most GMO crops despite widespread concerns about the risk to consumers and the environment.¹²² 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 GMO regulatory oversight, push for GMO approvals and prevent GMO labeling.¹²³

The current laws and regulations to ensure the health and environmental safety of biotechnology products were established before genetic engineering techniques were even discovered.¹²⁴ The agencies responsible for regulating and approving biotechnology include the USDA, the EPA and the FDA. (See Figure 2 on page 8.) Although the missions of these agencies overlap in some areas, it is the responsibility of the USDA to ensure that GMO crops are safe to grow, the EPA to ensure that GMO products will not harm the environment, and of the FDA to ensure that GMO 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.¹²⁵ The Animal and Plant Health Inspection Service (APHIS) oversees the entire GMO crop approval process, including allowing field testing, placing restrictions on imports and interstate shipping, approving commercial cultivation and monitoring approved GMO crops.¹²⁶

Safe for the Environment?

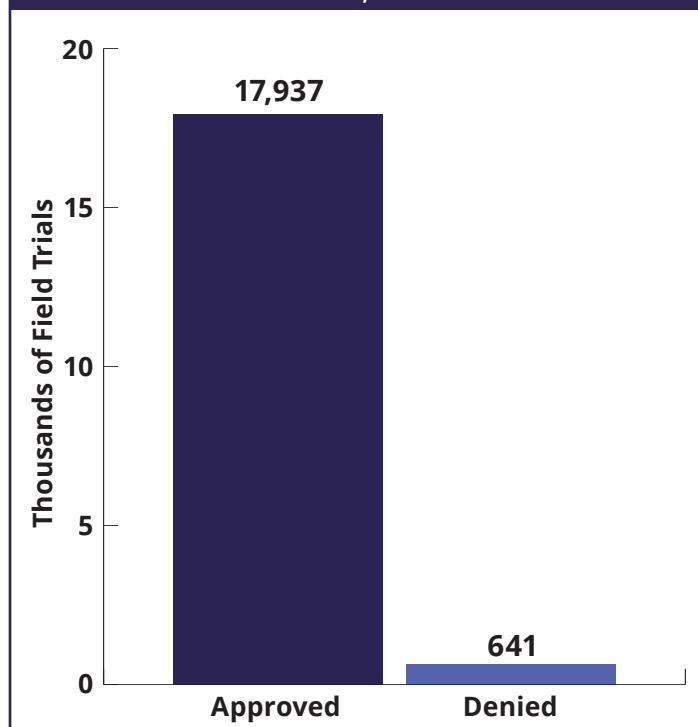
The EPA regulates pesticides and herbicides, including GMO crops that are designed to be insect-resistant.¹²⁷ A pesticide is defined as a substance that “prevents, destroys, repels or mitigates a pest,” and all pesticides that are sold and used in the United States fall under EPA jurisdiction.¹²⁸ The EPA also sets allowable levels of pesticide residues in food, including GMO insect-resistant crops. Between 1995 and 2008, the EPA registered 29 GMO pesticides engineered into corn, cotton and potatoes.¹²⁹

Bioengineered pesticides are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), first enacted in 1947.¹³⁰ New pesticides — including those designed for insect-resistant GMO crops — must demonstrate that they do not cause “unreasonable adverse effects on the environment,” including polluting ecosystems and posing environmental and public health risks.¹³¹ The EPA must approve and register new GMO insect-resistant crop traits, just as the agency does with conventional pesticides.¹³² Biotech companies must apply to field test new insect-resistant GMO crop traits, establish permissible pesticide trait residue levels for food and register the pesticide trait for commercial production.¹³³

Safe to Eat?

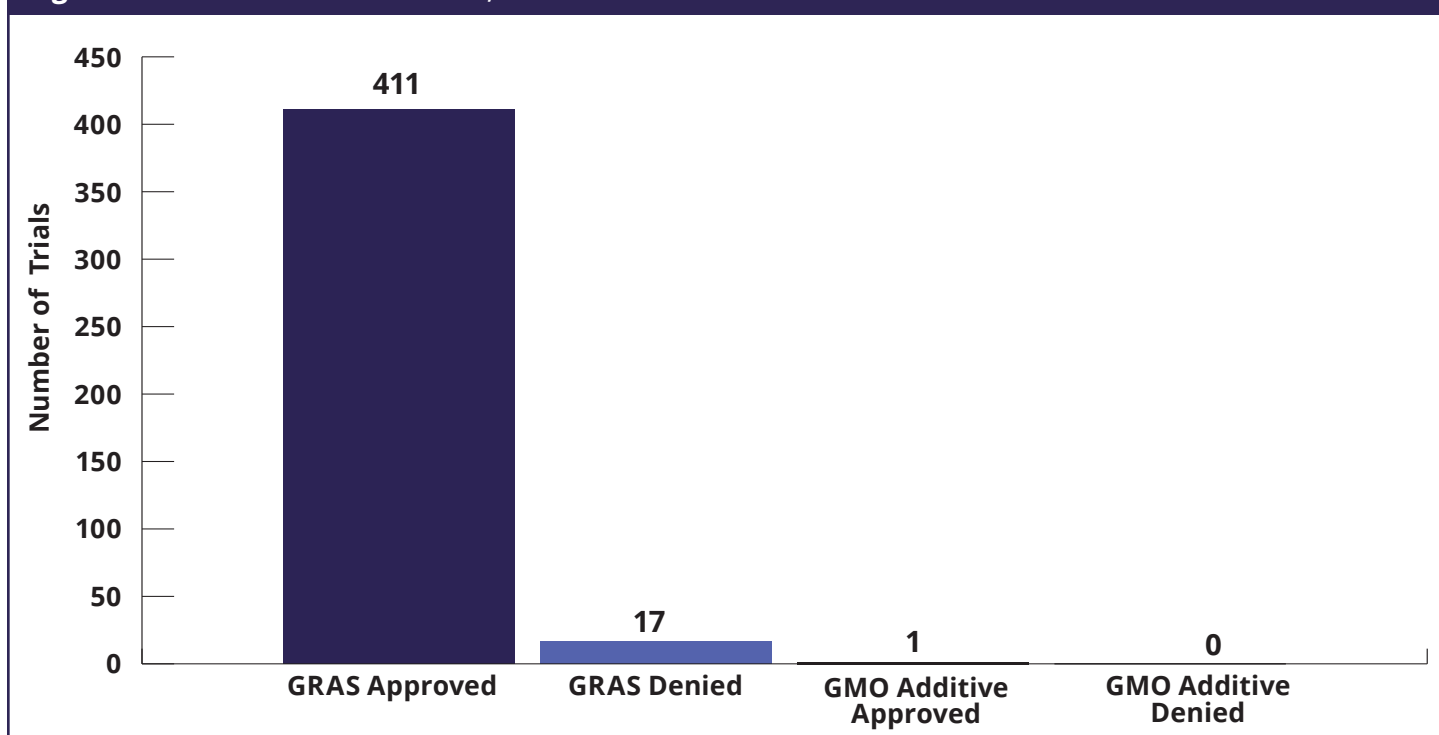
The FDA is responsible for the safety of both conventional and GMO food, animal feed and medicines. The

Figure 3: USDA GMO Field Trial Determinations, 1987-2014



Source: Information Systems for Biotechnology, Virginia Tech

Figure 4: FDA Food Determinations, 1998-2014



Source: FDA

agency regulates GMO 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.¹³⁴ GMO foods, like non-engineered foods, can pose risks to consumers from potential allergens and toxins.¹³⁵ The FDA does not determine the safety of proposed GMO foods; instead, it evaluates whether the GMO product is similar to comparable non-GMO products.¹³⁶

The USDA reviews permit applications and performs environmental assessments to decide whether GMO plants will pose environmental risks before field trials may begin.¹³⁷ 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 2014.¹³⁸ (See Figure 3 on page 9.) Once field trials are complete, the USDA can deregulate a crop, allowing it to be grown and sold without further oversight.¹³⁹ By 2014, the USDA had approved nearly 94 percent of new petitions for GMO crop commercializations.¹⁴⁰

The biotechnology industry self-regulates when it comes to the safety of GMO foods. In seeking approval, a company participates in a voluntary consultation process with the FDA, and the agency classifies the GMO substances either as “generally recognized as safe” (GRAS) or as a food additive. So far, only one GMO product has

ever been through the more rigorous “food additive” process; the FDA has denied GRAS status to only 17 foods and traits (3 percent of submissions) since 1998.¹⁴¹ (See Figure 4.) The FDA also enforces tolerances set by the EPA for pesticide residues in food.¹⁴² However, according to the U.S. Government Accountability Office, the FDA has failed to ensure that foods are not sold with residues higher than the regulated levels for at least 6 of the 25 most commonly used herbicides, including glyphosate and 2,4-D.¹⁴³ 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.¹⁴⁴

For more on the U.S. regulation of GMO food, see Appendix A on page 20.

Impact on Consumers

Uncertain Safety

Despite the FDA’s approval of common GMO crops entering the food supply, questions about the safety of eating these crops persist. GMO 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 GMO foods are limited because biotechnology companies prohibit cultivation for research purposes in their seed-licensing agreements.¹⁵³

Some of the independent, peer-reviewed research that has been done on biotech crops has revealed troubling health implications. A 2009 *International Journal of Biological Sciences* study found that rats that consumed GMO corn for 90 days developed a deterioration of liver and kidney functioning.¹⁵⁴ Another study found irregularities in the livers of rats, suggesting higher metabolic rates resulting from a GMO diet.¹⁵⁵ 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 GMO corn MON863 is a safe product.”¹⁵⁶ Research on mouse embryos showed that mice that were fed GMO soybeans had impaired embryonic development.¹⁵⁷ Even GMO 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 GMO diet, suggesting the ability of transgenes to survive pasteurization.¹⁵⁸

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.¹⁵⁹ Studies indicate that fusarium — a soil-borne pathogen that infects plant roots — becomes more prevalent when crops are treated with Roundup.¹⁶⁰

Moreover, some evidence suggests that the most common GMO-affiliated herbicide, glyphosate, may pose animal and human health risks. Although the EPA currently considers glyphosate a group E non-carcinogen, the World Health Organization’s cancer research arm, the International Agency for Research on Cancer (IARC), put out an evaluation of glyphosate in 2015, which determined that glyphosate should be classified as a 2A carcinogen, meaning that it is “probably carcinogenic to humans.”¹⁶¹ A 2010 study published in *Chemical Research in Toxicology* found that glyphosate-based herbicides caused highly abnormal deformities and neurological problems in vertebrates.¹⁶² Another study found that glyphosate caused DNA damage to human cells even at lower exposure levels than those recommended by the herbicide’s manufacturer.¹⁶³

The potential long-term risks from eating GMO food are unknown. The FDA contends that there is not sufficient scientific evidence demonstrating that ingesting these

European 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.¹⁴⁵ The EU has approved more than 40 GMO products for sale in the region, most of which are GMO soy and corn (maize) used in animal feed.¹⁴⁶

Only one GMO crop is currently approved for cultivation in the EU: Monsanto’s insect-resistant corn.¹⁴⁷ Moreover, domestic GMO production is very limited in Europe. In 2014, only five European countries grew GMO insect-resistant corn, making up less than 1 percent of global genetically modified cropland.¹⁴⁸ The EU allows member countries opposed to GMOs to opt out of growing these crops even if they have been approved at the EU level, and many (over half) have requested to do just that.¹⁴⁹

Despite having separate regulation for novel food, EU biotechnology regulation still allows some GMO products to fall through the cracks. EU law requires that all foods and feeds with any GMO content bear labels, including those with more than 0.9 percent accidental biotech content. GMO products considered “processing aids,” such as GMO enzymes used to make cheese, are exempt from the labeling process.¹⁵⁰ In this way, the majority of GMO use, including soy and corn imports, is hidden from consumers in unlabeled meat and milk from GMO-fed livestock. European consumers, who have widely opposed GMO foods, have been duped into believing that these products have been withdrawn from the food chain, when consumers are in fact unwittingly supporting the GMO industry via imported animal feed.¹⁵¹

European consumers are skeptical of the safety of GMO foods. A 2010 biotechnology survey performed by the European Commission reported that 59 percent of Europeans think that GMO food is unsafe for their health and that of their family, and 61 percent do not think that the development of GMO food should be encouraged.¹⁵²

foods leads to chronic harm.¹⁶⁴ But GMO varieties became the majority of the U.S. corn crop only in 2005 and the majority of the U.S. soybean crop only in 2000.¹⁶⁵ 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.

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.¹⁷⁶ Given the amount of controversy surrounding rBGH, 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.¹⁷⁷ 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.”¹⁷⁸

Just days after the FDA released the document, Monsanto filed suit against two dairy farms that had labeled their milk “rBGH-free.”¹⁷⁹ 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.¹⁸⁰ 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.¹⁸¹

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 1994.¹⁸² It aggressively defended that decision by continually modifying the label in order to withstand challenges,¹⁸³ as well as by suing the state of Illinois to protect its right to label its products.¹⁸⁴ Illinois was one of the first states to ban any labeling of an absence of rBGH.¹⁸⁵

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.”¹⁸⁶

In 2007 and 2008, several additional states, at the urging of groups backed by Monsanto,¹⁸⁷ made significant moves to restrict the type of rBGH-free labeling that could appear on dairy products. Some states, such as Utah,¹⁸⁸ 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.¹⁸⁹ Missouri and Pennsylvania went even further by attempting to ban any mention of an absence of rBGH.¹⁹⁰ 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.¹⁹¹ A bill introduced in Missouri was met with a similar reaction, and, in response to consumer protest, the original bill had to be modified¹⁹² before eventually dying in committee.¹⁹³

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 2011.¹⁹⁴

GMO 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.¹⁶⁶ Yet there are no definitive methods for assessing the potential allergenicity of bioengineered proteins in humans.¹⁶⁷ This gap in regulation has failed to ensure that potentially allergenic GMO 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.¹⁶⁸ However, in 2000, StarLink traces were found in taco shells in

U.S. supermarkets.¹⁶⁹ The EPA granted Aventis’ request to cancel StarLink’s registration, helping to remove the GMO corn from the food supply.¹⁷⁰ The StarLink episode is a cautionary tale of the failure of the entire regulatory system to keep unapproved GMO 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 GMO foods as indistinct from conventional foods, the FDA does not require the labeling of GMO food products as such. The FDA does permit voluntary GMO labeling as long as the information

is not false or misleading.¹⁷¹ Food manufacturers can either affirmatively label GMO food or indicate that the food item does not contain GMO ingredients (known as “absence labeling”). Virtually no companies disclose that they are using GMO ingredients under this voluntary scheme. Moreover, consumers in the United States blindly consume foods that contain GMO ingredients.¹⁷²

For consumers to have the opportunity to make informed choices about their food, all GMO 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.¹⁷³ A 2014 Consumers Union poll found that 92 percent of U.S. consumers favor labeling of genetically engineered food.¹⁷⁴ Since 2014, more than 25 states have introduced legislation to label GMO foods, and these bills passed in Connecticut, Maine and Vermont.¹⁷⁵

Impact on the Food System

Superweeds

In the 15 years since herbicide-tolerant crops were first introduced, weeds already have become resistant to GMO-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.¹⁹⁵

At least 14 species in the United States (and 32 worldwide) have been confirmed to be resistant to glyphosate,¹⁹⁶ including aggressive crop weeds such as ragweed, mare’s tail and waterhemp.¹⁹⁷ 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.”¹⁹⁸ The industry estimates that 70 million acres of cropland are now infested with herbicide-resistant weeds.¹⁹⁹ Research shows that higher densities of glyphosate-resistant weeds reduce crop yields.²⁰⁰ Purdue University scientists found that Roundup-resistant ragweed can cause 100 percent corn-crop losses.²⁰¹

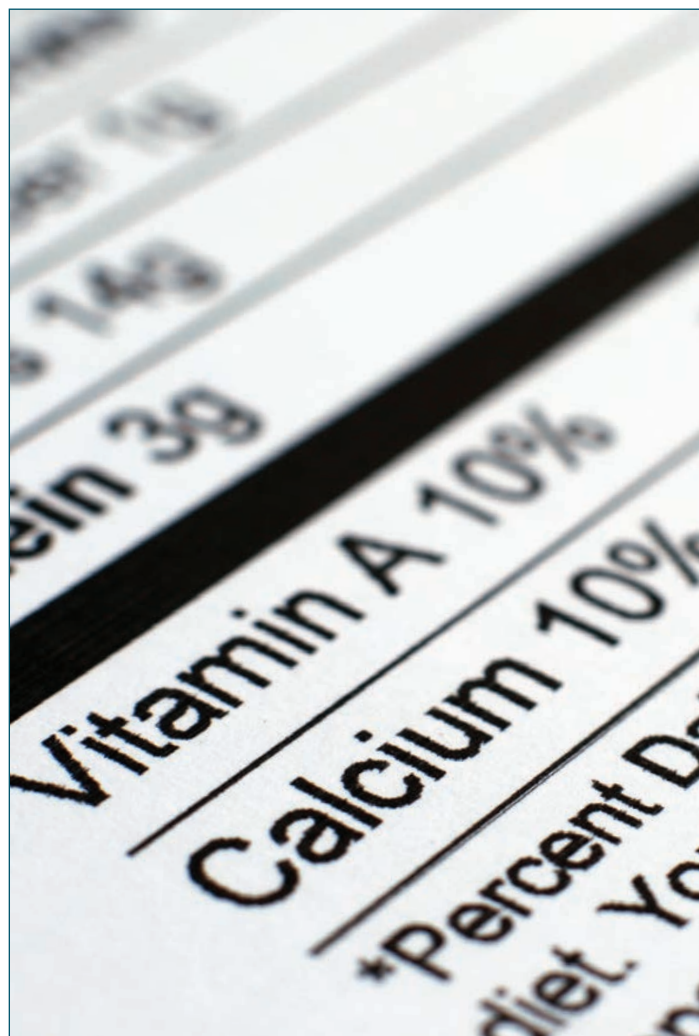
Patent Power and Seed Consolidation

Only a few biotechnology companies dominate the U.S. seed industry, which once relied on universities for most research.²⁰² 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.²⁰³ Biotech corn seed prices increased 14 percent annually between 2004 and

2014, and soybean seed prices rose by an average of 5 percent annually. In 2014, biotech corn and soybean seeds cost about 50 percent more than non-biotech varieties.²⁰⁴ Between 1996 and 2007, Monsanto acquired more than a dozen seed companies.²⁰⁵ The two largest firms sold 58 percent of corn seeds in 2007 and 60 percent of soybean seeds in 2005.²⁰⁶

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.²⁰⁷

Strict patents protect genetically engineered seeds.²⁰⁸ These seeds were not even considered patentable until the 1980s, when several court cases extended patent rights to GMOs.²⁰⁹ Biotech companies further leverage the limited patent monopoly of their seeds through joint ventures and cross-licensing agreements.²¹⁰ The patent owner controls how partnering companies use and combine the traits.²¹¹ Consequently, although there are numerous seed compa-



nies, most of the available corn, soybean and cotton seeds include Monsanto-patented traits that have been cross-licensed to other seed companies.²¹² By 2012, nearly all (98 percent) of the corn and most (86 percent) of the cotton cultivated in the United States was grown from seeds covered by Monsanto patents.²¹³

Farmers pay licensing fees and sign contracts for limited permission to plant GMO seeds.²¹⁴ 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.²¹⁵ Indeed, farmers must buy new seeds every year because they face patent infringement suits if they run afoul of GMO seed-licensing agreements by saving seed.²¹⁶ 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.²¹⁷ By January 2013, Monsanto had filed 144 patent infringement lawsuits, recovering as much as \$160.6 million from farmers.²¹⁸

Impact on Farmers

Contamination

The USDA prohibits the use of GMO material — including enzymes, seeds or veterinary treatments — in any product

that carries the agency's "certified organic" label.²¹⁹

Certified organic farmers can face significant economic hardship if biotech traits contaminate their organic crops or organic livestock feed. Contamination can occur either when GMO seeds are inadvertently mixed with non-GMO seeds during storage or distribution, or when GMO crops cross-pollinate non-GMO crops.²²⁰ A Union of Concerned Scientists study found that 50 percent of non-GMO corn and soybean and 83 percent of non-GMO canola seeds in the United States were contaminated with low levels of GMO residue.²²¹ It is well documented that a farmer's field can be inadvertently contaminated with GMO material through cross-pollination and seed dispersal.²²² Even Monsanto admits that "a certain amount of incidental, trace level pollen movement occurs."²²³

A 2014 survey of organic grain producers, conducted by Food & Water Watch and the Organic Farmers' Agency for Relationship Marketing, collected data on the burden that trying to prevent contamination puts on organic producers.²²⁴ The survey found that one out of three responding farmers have dealt with GMO contamination on their farm. Of those reporting contamination, over half had products rejected by their buyers. Prevention measures taken by organic producers also impose costs. According to survey respondents, the median cost of loss of organic premiums for crops grown in buffer zones was approximately \$2,500 per year, with several farmers reporting annual losses of over \$20,000. And of those who



delay planting as a contamination prevention technique, the median annual cost to farmers was \$5,280 for corn and \$3,312 for soybeans due to loss of yield from missing the optimal timing for planting.

Liability

Farmers who unintentionally grow GMO-patented seeds or who harvest crops that are cross-pollinated with GMO traits could face costly lawsuits by biotechnology firms for “seed piracy.” Farmers who intentionally grow GMO crops are not required to plant non-GMO buffer zones to prevent contamination unless this is stipulated in the farm’s USDA permit.²²⁵ Yet even the use of buffer zones has proven ineffective because these areas usually are not large enough to prevent contamination.²²⁶

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.²²⁷ However, GMO alfalfa can easily cross-pollinate organic alfalfa crops and cause organic farmers to lose their markets if testing reveals contamination.²²⁸ Conventional alfalfa farmers could face seed piracy suits from Monsanto even if their crops are inadvertently pollinated by GMO alfalfa. At least one farmer contends that he was sued when his canola fields were contaminated with GMO crops from neighboring farms.²²⁹

Organic dairy farmers already face difficulty securing organic feed, and this challenge will only worsen if GMO alfalfa begins to contaminate organic alfalfa.²³⁰ Organic dairy farmers receive a price premium for their milk, but they also have higher production costs than conventional dairies.²³¹ GMO 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 require steps to prevent contamination.²³² In addition to alfalfa, GMO wheat — which has not 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 GMO wheat appeared, but a Monsanto representative tried to claim that it was the result of potential sabotage.²³³ In 2014, GMO wheat was discovered growing at Montana



University’s research center, where GMO wheat had not been intentionally grown in over a decade.²³⁴

Global Trade

Although the United States has readily approved GMO 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 GMO foods.²³⁵ Europe has been restrictive in its approval of biotech foods because of uncertainty about the safety of the products for human consumption.²³⁶

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 GMO crop.²³⁷ EU member states currently allow animal feed imports to contain up to 0.1 percent of unapproved GMO material.²³⁸ Additionally, the EU requires all foods, animal feeds and processed products with biotech content to bear GMO labels.²³⁹ Countries that ban GMO foods typically impose strict rules to prevent unauthorized



GMO imports, which blocks or limits U.S. exports of corn and soybeans that are primarily GMO crops. Japan does not grow GMO crops and requires mandatory labeling of all GMO foods.²⁴⁰

Despite the advanced grain-handling system in the United States, GMO grains have contaminated non-GMO shipments and devastated U.S. exports. The Government Accountability Office (GAO) identified six known unauthorized releases of GMO crops between 2000 and 2008.²⁴¹ In 2000, Japan discovered GMO 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.²⁴² After the StarLink discovery, Europe banned all U.S. corn imports, costing U.S. farmers \$300 million.²⁴³ In August 2006, unapproved GMO Liberty Link rice was found to have contaminated conventional rice stocks.²⁴⁴ Japan halted all U.S. rice imports and Europe imposed heavy restrictions, costing the U.S. rice industry \$1.2 billion.²⁴⁵ In 2007, Ireland impounded imported U.S. livestock feed that tested positive for GMOs that are unapproved in the country.²⁴⁶

The United States is aggressively seeking to force its trading partners to overturn their GMO 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 GMO labeling requirements.²⁴⁷ The diplomatic push by U.S. biotech interests extends to developing countries as well: in recent years, the U.S. State Department has pressed governments all over the world to lift GMO restrictions.²⁴⁸

Debunking Monsanto’s Myths

MONSANTO MYTH: *Everything that Monsanto does helps to make agriculture more productive and more profitable for farmers.*²⁴⁹

Biotech companies such as Monsanto claim that their products strengthen farm productivity by improving yields and reducing costs.²⁵⁰ Yet the cost savings are largely illusory, and the yield gains have been limited.

GMO seeds and affiliated herbicides typically are more expensive than conventional products. For example, in 2009, Roundup Ready soybean seeds cost twice as much as non-GMO seeds.²⁵¹ 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,²⁵² but GMO soybean seed can cost \$23 more per acre than conventional seed.²⁵³ In 2014, biotech corn and soybean seeds cost 50 percent more than non-biotech varieties.²⁵⁴

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-GMO crops, and insect-resistant corn had only a slight advantage over conventional corn.²⁵⁵ A 2007 Kansas State University study found that non-GMO soybeans had 10 percent higher yields than biotech soybeans.²⁵⁶

MONSANTO MYTH: *Monsanto will help to create more-nutritious, vitamin-rich foods for consumers.*²⁵⁷

Some scientists and development advocates have promoted biotechnology as a means to combat malnutrition. Scientists at Iowa State University, for example, will



be testing whether engineering beta-carotene into cooking bananas can help with vitamin A deficiency in Africa.²⁵⁸ The well-known biofortification project, Golden Rice, also adds beta-carotene to rice to help fight the vitamin A deficiency that causes blindness in a quarter million children annually.²⁵⁹ Yet engineering crops with beta-carotene may not even reduce vitamin A deficiency because consumption alone does not ensure absorption.²⁶⁰ Diets of malnourished people often lack the fats and oils crucial to absorbing vitamin A.²⁶¹ 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.²⁶²

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.²⁶³ 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.²⁶⁴ 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.*²⁶⁵

Most GMO 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.²⁶⁶ Farmers can spray the herbicide on their fields, killing the weeds without harming their GMO crops. Monsanto's Roundup Ready (herbicide-tolerant) corn, soybeans and cotton were planted on 150 million U.S. acres in 2009.²⁶⁷ 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 2012.²⁶⁸

Ubiquitous Roundup application has spawned glyphosate-resistant weeds, driving farmers to apply even more toxic herbicides, according to a 2010 National Research Council report.²⁶⁹ 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.²⁷⁰

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.²⁷¹ Biotech companies also are developing seeds that are tolerant of multiple herbicides to cope with weed resistance. The USDA approved Dow's

2,4-D tolerant corn and soybeans.²⁷² A metabolite of 2,4-D is known to cause skin sores, liver damage and sometimes death in animals.²⁷³ 2,4-D is classified as possibly carcinogenic, in addition to being an immunosuppressant and an oxidative stressor.²⁷⁴ Monsanto, meanwhile, has developed a dicamba-tolerant soybean approved by the USDA in 2015.²⁷⁵

MONSANTO MYTH: *Monsanto squeezes more food from a raindrop.*²⁷⁶

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 for farmers in the global south. 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 the 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.²⁷⁷

Monsanto uses cotton expansion in India as an example of improving food security.²⁷⁸ Indian farmers, wooed by Monsanto's marketing, have widely adopted GMO cotton.²⁷⁹ Many take out high-interest loans to afford the GMO seeds, which can be twice as expensive as conventional seeds.²⁸⁰ 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.²⁸¹ More than half of Indian farmers lack access to irrigation, leaving them dependent on a punctual rainy season for a good crop.²⁸² And when GMO cotton crops fail, farmers are often unable to repay the substantial debt. The steeper treadmill of debt with GMO crops contributes to a rising number of farmer suicides in India — exceeding 17,000 in 2009.²⁸³

By contrast, a 2006 study published in *Environmental Science and Technology* found that low-input farms in developing countries had significant yield gains.²⁸⁴ 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.²⁸⁵ Despite the huge public relations campaigns, biotechnology is not solving our sustainability problems — it is 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.*²⁸⁶

Global warming, drought and catastrophic weather events will affect agriculture for decades to come.²⁸⁷ Biotech firms have long promised high-yield and drought-resistant GMO seeds, but by 2015 only one variety of drought-tolerant corn was approved.²⁸⁸ Crop research has yet to achieve the complex interactions between genes that are necessary for plants to endure environmental stressors such as drought.²⁸⁹ Monsanto's approved drought-tolerant corn has overestimated yield benefits, and there is insufficient evidence that it will outperform already available conventionally bred alternatives.²⁹⁰

Traditional methods of breeding for stress tolerance produce crops that are more resilient to disruption and climate change than GMO crops because these crops complement and thrive in nutrient-rich and biodiverse soil.²⁹¹ 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.*²⁹²

Expanding thirsty GMO crops to more arid developing countries will exacerbate water scarcity. The developing



world faces the most pronounced environmental degradation.²⁹³ 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.²⁹⁴ In the developing world, 85 percent of water withdrawals go toward agriculture.²⁹⁵

Already, parts of northern India pump 50 percent more water than the aquifers can refill.²⁹⁶ Even Nobel Laureate Norman Borlaug, the father 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.²⁹⁷

In the United States, irrigated corn acreage increased 23 percent, and irrigated soybean acreage increased 32 percent, between 2003 and 2008.²⁹⁸ The rising U.S. cultivation of GMO 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.²⁹⁹ 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.³⁰⁰ The worldwide expansion of industrial-scale cultivation of water-intensive GMO 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 GMO 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 GMO foods:** An affirmative label should be present on all GMO foods, ingredients and animal products.
- **Shift liability of GMO contamination to seed patent holders:** The financial responsibility of contamination should be on the patent holders of the GMO 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 GMO foods:** Currently in the United States, most GMO foods, donor organisms and host organisms are generally considered safe for consumption and the environment until proven otherwise.³⁰¹ The United States should enact policies that would more rigorously evaluate the potentially harmful effects of GMO crops before their commercialization to ensure the safety of the public.
- **Develop a new regulatory framework:** Congress should establish regulations intended specifically for GMO 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.³⁰² Additionally, the agencies should adequately monitor the post-market status of GMO plants, animals and food.

Appendix A: The U.S. Regulatory System for GMO Food

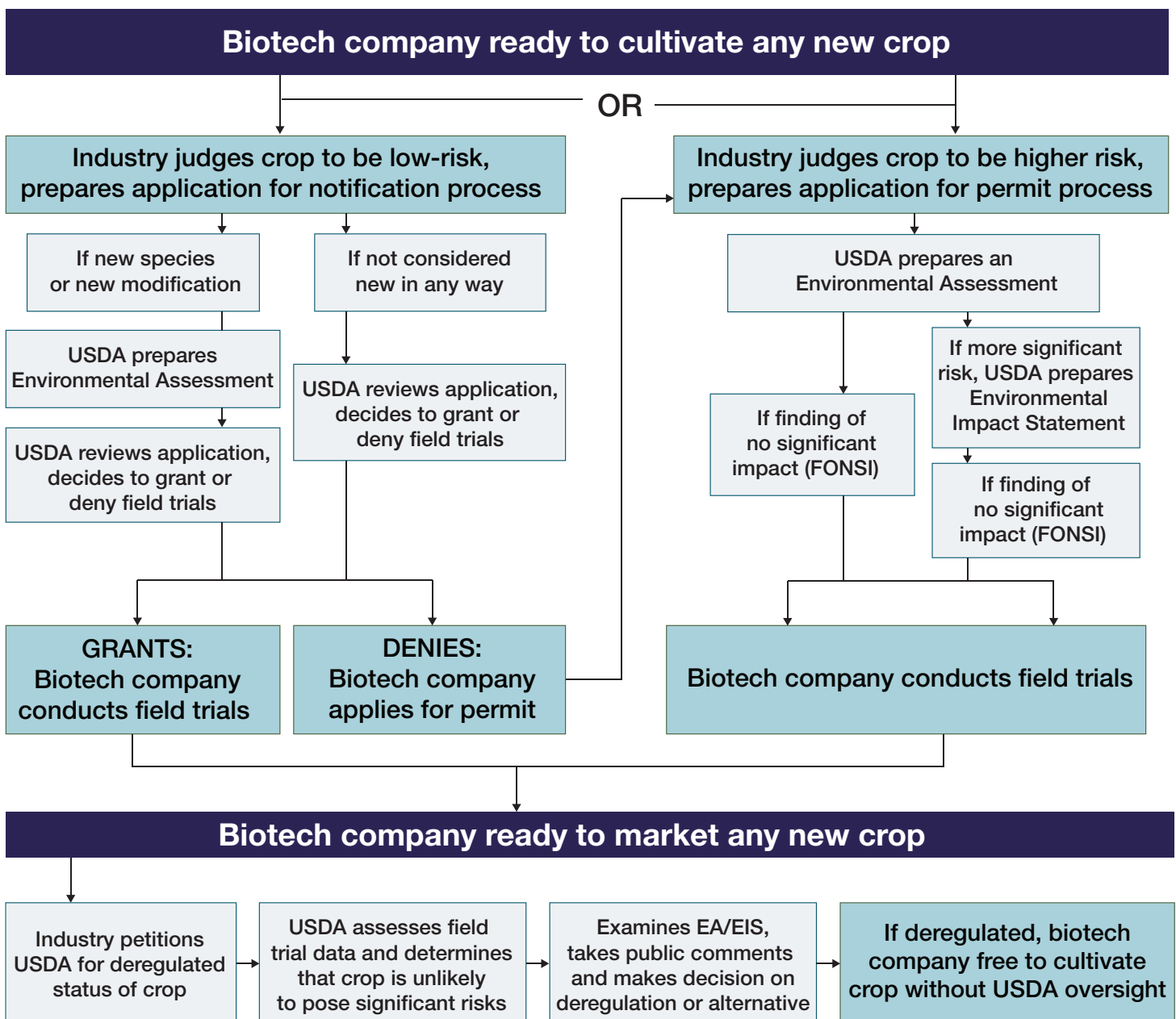
USDA

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 GMO crop approval process, from field tests to commercial cultivation.³⁰³

Biotech companies must either enter a “notification” or “permit” process before GMO field trials begin.³⁰⁴ Under the streamlined notification process, companies submit data showing that the new GMO 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.³⁰⁵ If the USDA denies the notification application, the company can re-apply under the more involved permit process.³⁰⁶ The notification process does not require either an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) for GMO crops that are neither new species nor new modifications.³⁰⁷

Under the more rigorous permit application process, the USDA determines if the GMO field trial poses significant environmental impact before issuing a permit.³⁰⁸ The



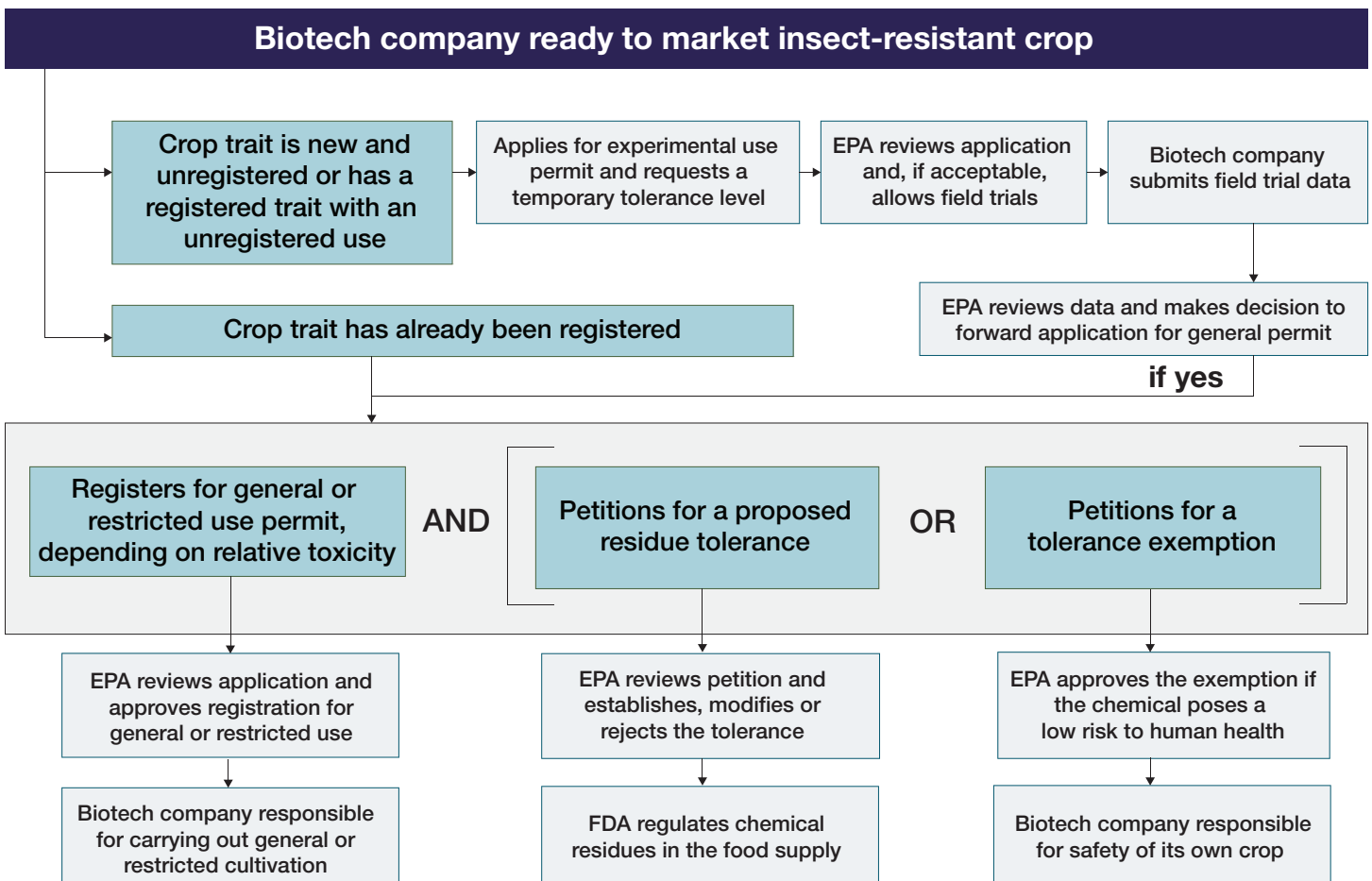
USDA reviews scientific submissions for four months before granting or denying the field test permit request.³⁰⁹ If approved, the permit imposes restrictions on planting or transportation to prevent the GMO plant material from escaping and posing risks to human health or the environment.³¹⁰ The USDA approved the vast majority — 92 percent — of the applications for biotech field releases between 1987 and 2005.³¹¹ 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.³¹² If the applicant violates the permit, the USDA can withdraw it.³¹³

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.³¹⁴ The EA determines whether the GMO crop will pose significant risks to human health or the environment if cultivated.³¹⁵ If there is no significant risk, the USDA issues a “finding of no significant impact” (FONSI).³¹⁶ But if the USDA finds more significant environmental implications, it must also perform a more thorough EIS.³¹⁷

The USDA is accelerating its approval process for GMO crops even as the seed companies hurry the new, untested varieties to market. In November 2011, the USDA unveiled its new streamlined process for GMO crop approvals to shorten approval timelines by 13 to 15 months.³¹⁸

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.³¹⁹ The USDA solicits public comments on the deregulation for 60 days.³²⁰ After reviewing available data, the USDA makes a final decision within six months.³²¹ By 2014, the USDA had approved nearly 94 percent of new petitions for GMO commercializations.³²²

After GMO crops are approved, the USDA performs almost no post-release oversight and has no program for monitoring approved GMO plants.³²³ Instead, the USDA’s primary post-market role with GMO crops is through the Agricultural Marketing Service (AMS), which helps facilitate the export of transgenic crops by verifying their genetic identity.³²⁴ The AMS does not test for GMO presence in grains; it only works with interested shippers who participate in a voluntary verification program.³²⁵



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.³²⁶ 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.³²⁷

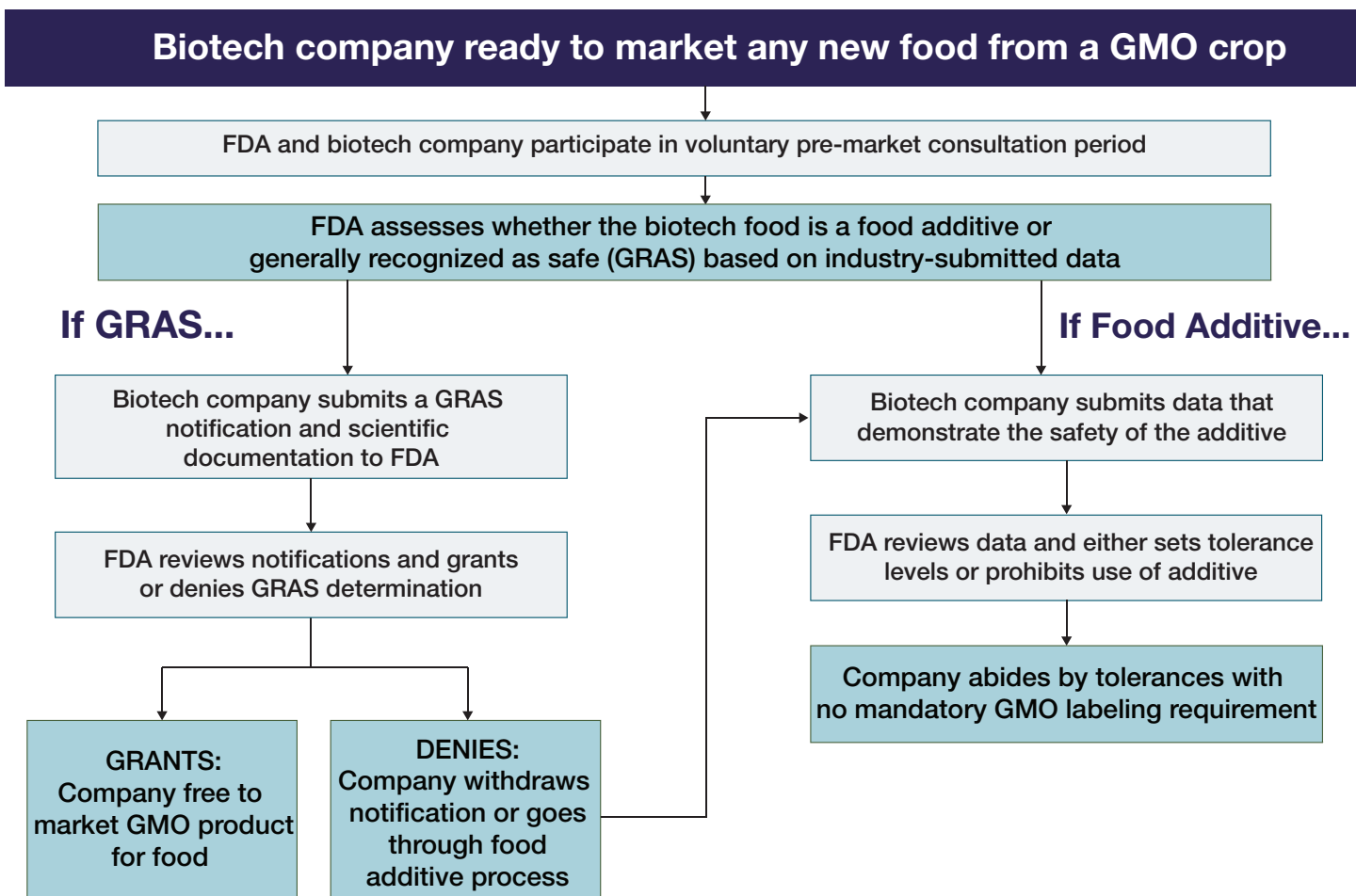
The EPA pesticide tolerances appear generous. A 2010 National Institutes of Health cancer risk study reported criticism by environmental health professionals and advocates that agribusiness influence at the EPA deterred the agency from establishing sufficiently strong pesticide limits.³²⁸ The EPA can even exempt pesticides from establishing tolerances if it finds a low probability of risk to public health.³²⁹ Theoretically, tolerance exemptions allow food to contain any amount of that pesticide residue.³³⁰

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.”³³¹

All new pesticides must be registered with the EPA.³³² Additionally, the EPA reviews and grants experimental use permits for field tests of unregistered pesticides or of registered pesticides tested for an unregistered use.³³³ Biotech companies must apply for an experimental use permit for insect-resistant GMO crops if they are grown on more than 10 acres of land.³³⁴ Experimental use permits typically limit field trials to one year.³³⁵

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.³³⁶ 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.³³⁷

Applications for permit registration must include management plans that describe any limitation on cultivating the new insect-resistant GMO crops.³³⁸ The management plans often require the designation of a non-insect-resistant seed buffer refuge along the border of the GMO crop.³³⁹ This “refuge” is intended to give pests access to non-pesticidal plants so that a pest does not develop



resistance to the pesticide.³⁴⁰ 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 GMO seed between 2002 and 2007 without informing Texas farmers about EPA-mandated planting restrictions.³⁴¹

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 GMO foods are safe and compliant with the federal Food, Drug and Cosmetics Act.³⁴² In 2001, the FDA proposed a rule requiring companies to submit data and information on new biotech-derived foods 120 days before commercialization.³⁴³ As of early 2015, 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.³⁴⁴ However, for substances added to food, such as biotech traits, the FDA classifies them as “generally recognized as safe” (GRAS) or as food additives.³⁴⁵ The FDA grants GRAS determinations to GMO-derived foods that are considered equivalent to the structure, function or composition of food that currently is considered safe.³⁴⁶ A company may voluntarily submit a GRAS notification and scientific documentation to the FDA, but it is not a requirement.³⁴⁷ If the FDA determines that the GMO 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.³⁴⁸ The FDA has awarded “generally recognized as safe” status to almost all — 97 percent — of the GRAS applications submitted for food since 1998, according to the agency’s GRAS Notice Inventory.³⁴⁹

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 GMO 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 GMO substance to a comparable conventional food.³⁵⁰ The FDA evaluates company-submitted data and does not do safety testing of its own.³⁵¹ The agency can approve the GMO

substance, establish certain regulatory conditions (such as setting tolerance levels) or prohibit or discontinue the use of the additive entirely.³⁵² The FDA evaluates the safety of all additives, but it has evaluated only one GMO crop trait as an additive, the first commercialized GMO crop, Flavr Savr tomatoes.³⁵³

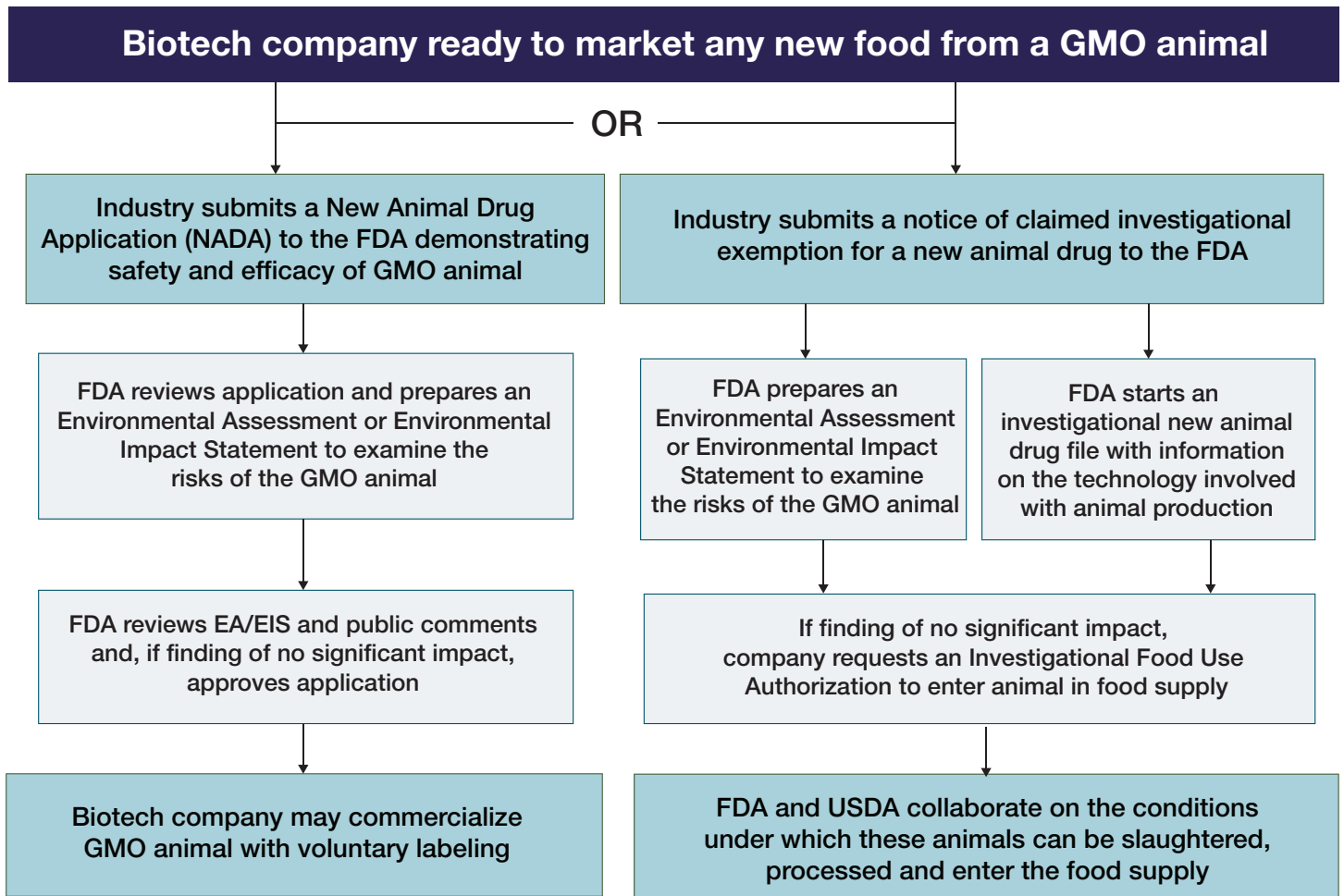
Once a GMO food product has been approved and is on the market (either by GRAS designation or as a food additive), the FDA is responsible for its safety. Until recently, the agency could ask companies to recall dangerous food products only voluntarily; however, the Food Safety Modernization Act of 2011 granted the FDA mandatory recall authority.³⁵⁴ Generally, the FDA has awaited outbreaks of foodborne illness before taking action, rather than vigorously monitoring and inspecting food manufacturers.³⁵⁵ This reactive approach has been ineffective in preventing foodborne illnesses. The FDA did pressure a company to recall one GMO food product — StarLink corn, which was unapproved for human consumption — when it entered the food supply.³⁵⁶ The FDA’s lack of post-market monitoring can expose the public to unapproved GMO traits in the food supply.

GMO 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.³⁵⁷ This allows the FDA’s Center for Veterinary Medicine to approve GMO 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.³⁵⁸

The FDA must approve a New Animal Drug Application before it can be commercialized. The application must demonstrate the GMO 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.³⁵⁹ Veterinary drug manufacturers that are introducing their products for investigational use are exempt from new animal drug approval requirements.³⁶⁰

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.³⁶¹ The biotech company must also prepare an Environmental Assessment for investigational GMO animals.³⁶² In 2009, the FDA used the investigational use process to approve the first commercial biologic from a GMO animal, the anticlotting agent ATryn produced with transgenic goat milk.³⁶³ 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 GMO animals.³⁶⁴

Once the FDA approves the production of experimental GMO animals, the USDA must consider if and under what restrictions these animals can be slaughtered, processed and enter the food supply.³⁶⁵ As of November 2015, the only GMO animal that had been approved to enter the food supply was GMO salmon.

It seems unlikely that the USDA will keep meat products derived from GMO 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.³⁶⁶ 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.³⁶⁷ 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.³⁶⁸ As of early 2016, 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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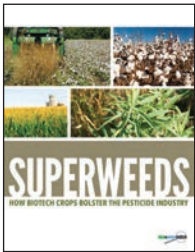
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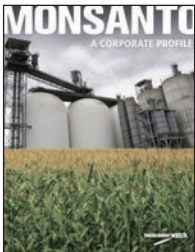
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Superweeds: How Biotech Crops Bolster the Pesticide Industry

Genetically engineered crops were first approved in the United States in the 1990s, and since then the United States has been the biggest global adopter of this technology. GE crops were supposed to improve yields, lower costs for farmers and reduce agriculture's environmental impact. Yet nearly 20 years after their introduction, genetically engineered crops have not provided the benefits promised by the companies that patented them. This analysis looks at the rapid proliferation of GE crops and affiliated pesticides in the United States and points out the interdependent relationship between these two industries that also fuels the crisis of weed resistance.



Monsanto: A Corporate Profile

Most of Monsanto's history is steeped in heavy industrial chemical production — a legacy that is extremely at odds with the environmentally friendly, feed-the-world image that the company spends millions trying to convey. Nearly all of soybeans and most of the corn in the U.S. are grown with seeds containing Monsanto-patented genetics. The company's power and influence affects not only the U.S. agricultural industry, but also regulatory processes and the structure of agriculture systems all over the world.



The So-Called "Scientific" Consensus on GMOs

Biotechnology seed companies, aided by advocates from academia and the blogosphere, are using their substantial resources to broadcast the myth of a "scientific consensus" on the safety of genetically engineered crops, asserting that the data is in and the debate is over. This public relations campaign, helped along by industry front groups, has caught the attention of some of the most visible news outlets in the country, with biotech advocates portraying GMO critics as akin to climate change deniers, out of step with science. However, unlike climate change, a subject on which climate scientists almost universally agree, there is no general agreement on GMO safety.



The Case for GMO Labeling

It took government regulation to make food processors put ingredient lists and nutrition facts on food packaging — labels that consumers are now accustomed to seeing and are using to make food choices. But the government has failed to require that consumers get to know other basic information about our food, like that it is genetically engineered. For consumers to have the opportunity to make informed choices about their food, all GMO foods should be labeled.

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National Office

1616 P Street, NW
Suite 300
Washington, DC 20036
(202) 683-2500

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