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Agricultural Biotechnology: Overview, Regulation, and Selected Policy Issues

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SUMMARY

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Agricultural Biotechnology: Overview, Regulation, and Selected Policy Issues

Agricultural biotechnology refers to a range of tools—including genetic engineering and some conventional breeding techniques—to genetically modify living plants, animals, microbes, and other organisms for agricultural uses (e.g., food, feed, fiber). The term commonly refers to recombinant DNA techniques that introduce desired characteristics into target organisms, predominantly pest and herbicide resistance in crops. It also encompasses a range of new genome editing technologies (e.g., CRISPR-Cas9) that manipulate genetic material at precise locations in the genome. Most genetically engineered (GE) agricultural products are *crops*—in the United States, the only GE *animals* currently approved for human consumption are the AquAdvantage salmon and the GalSafe pig.

When foods containing GE ingredients were first introduced in the 1990s, some members of the public called for banning them based on concerns about their potential to harm human health. In terms of the health and safety of the people consuming them, research repeatedly has found no difference between foods developed with and without genetic engineering. Even so, some consumers remain concerned about genetic engineering, citing health, personal preference, environmental, economic, and other objections. As such, the views of the scientific community, consumers, farmers and ranchers, and the organic industry on the safety, utility, and ethics of agricultural biotechnology do not always overlap. Society continues to debate these issues, and numerous advocacy and trade organizations promote various sides of the debate.

In the United States, three federal agencies share responsibility for regulating the products of agricultural biotechnology within a regulatory system established in 1986, known as the Coordinated Framework. Within this framework, the U.S. Department of Agriculture (USDA), Food and Drug Administration (FDA), and Environmental Protection Agency (EPA) regulate the marketing and environmental release of agricultural biotechnology products under statutes that predate the invention of modern biotechnology.

Within the Coordinated Framework, USDA's Animal and Plant Health Inspection Service (APHIS) and Food Safety Inspection Service (FSIS) each have authorities for aspects of the regulation of agricultural biotechnology products. APHIS authorities derive primarily from the Plant Protection Act (PPA, 7 U.S.C. §7701 et seq.), Animal Health Protection Act (AHPA, 7 U.S.C. §8301 et seq.), and Virus-Serum-Toxin Act (VSTA, 21 U.S.C. §151 et seq.). FSIS authorities derive from the Federal Meat Inspection Act (FMIA, 21 U.S.C. §601 et seq.), Poultry Products Inspection Act (PPIA, 21 U.S.C. §451 et seq.), and Egg Products Inspection Act (EPIA, 21 U.S.C. §1031 et seq.). FDA authorities derive from the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. §301 et seq.) and Public Health Service Act (PHSA, 42 U.S.C. §201 et seq.). EPA authorities derive from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. §136 et seq.).

With the enactment of the National Bioengineered Food Disclosure Standard (P.L. 114-216) in 2016, and the subsequent regulations promulgated by USDA's Agricultural Marketing Service (AMS), the United States joined over 60 nations that require some form of GE labeling. Additional voluntary public and private labeling schemes signal to consumers that labeled food products do not contain GE foods or food ingredients, or they are produced with practices that exclude genetic engineering.

Disparate global views, consumer acceptance, and legal requirements with respect to agricultural biotechnology and its products have raised global trade concerns. The United States is a leading cultivator of GE crops, and market access for agricultural biotechnology products is a major U.S. trade objective. While the policies of some global trading partners support access to biotechnology products, other countries' policies pose a challenge to achieving this objective.

Public debate around agricultural biotechnology includes topics such as its place in the U.S. food system, global food security, global trade, and other matters. Emerging issues that may be of interest to Congress include the ongoing efficacy of the Coordinated Framework; challenges and opportunities of new genetic engineering techniques; the labeling of foods to distinguish between GE and non-GE products; global trade concerns; and potential environmental concerns.

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Introduction

People have been changing plants, animals, and other organisms for more than 10,000 years. After agriculture began, the development of traditional farming practices, followed by conventional breeding, and finally biotechnology techniques has allowed people to shape the characteristics of agricultural species with increasing precision. Recent advances in genetic engineering permit scientists to introduce or suppress—in a single generation—specific traits in organisms raised for food, fiber, pharmaceutical, or industrial uses. This changing landscape has increased interest in the development and regulation of the products of agricultural biotechnology.

The United States is the world's leading cultivator of genetically engineered (GE) crops, accounting for nearly 40% (185 million acres) of total GE crop acres planted worldwide.[1] The vast majority of these crops are commodities destined for processed foods and animal feed. There are also noncommodity GE crops, such as fruits and vegetables, and noncrop agricultural GE products, such as salmon and enzymes used in food processing. The use of biotechnology is predicted to grow in scale and scope, with new agricultural species, trait types, and methodologies employed.[2]

In the United States, three federal agencies share responsibility for regulating the products of agricultural biotechnology, in a regulatory system that has changed little since it was first established in 1986. Scientific reviews of the safety of these products for human health have repeatedly found no difference between GE and non-GE products. Reviews of environmental safety have been less conclusive. Public concerns about the safety and desirability of GE foods and agricultural products persist.

Agricultural biotechnology continues to be a topic of public debate, including its place in the U.S. food system, global food security, global trade, and other matters. Emerging issues include the challenges and opportunities of new genetic engineering techniques and the labeling of foods to distinguish between GE and non-GE products. This report provides an overview of agricultural biotechnology, the U.S. biotechnology regulatory system, scientific and stakeholder views, and issues in international trade. It concludes with an examination of selected issues for Congress and appendices with acronyms (**Appendix A**) and definitions of selected scientific and related terms used in this report (**Appendix B**).

Background

Agricultural biotechnology refers to a range of tools—including genetic engineering and some conventional breeding techniques—to genetically modify living plants, animals, microbes, and other organisms for agricultural uses (e.g., food, feed, fiber). The term commonly refers to recombinant DNA techniques that introduce desired characteristics into target organisms, predominantly pest and herbicide resistance in crops. It also encompasses a range of new *genome*

[1] International Service for the Acquisition of Agri-biotech Applications (ISAAA), *Global Status of Commercialized Biotech/GM Crops in 2018: Biotech Crops Continue to Help Meet the Challenges of Increased Population and Climate Change*, Executive Summary, ISAAA Brief no. 54, 2018, at http://www.isaaa.org/resources/publications/briefs/54/executivesummary/default.asp (hereinafter ISAAA, *Global Status of Commercialized Biotech/GM Crops in 2018*).
[2] See, for example, National Academies of Sciences, Engineering, and Medicine (NASEM), *Preparing for Future Products of Biotechnology*, National Academies Press, 2017 (hereinafter NASEM, *Future Products of Biotechnology*, 2017); and NASEM, *Genetically Engineered Crops: Experiences and Prospects*, National Academies Press, 2016 (hereinafter NASEM, *Genetically Engineered Crops*, 2016).

editing technologies (e.g., CRISPR-Cas9) that manipulate genetic material at precise locations in the genome. Most GE agricultural products are *crops*—in the United States, the only GE *animals* currently approved for human consumption are the AquAdvantage salmon and the GalSafe pig.[3]

The public has come to refer to plants and animals altered through modern biotechnology and genetic engineering as *genetically modified organisms (GMOs)*.[4] Scientific and federal government experts identify the term *genetically modified* as more general than *genetically engineered*; as such, genetically modified may include conventional breeding.[5] In this report, *genetic engineering* refers to the use of genetic modification techniques other than conventional breeding.

Conventional Breeding

Genetic modification predates agriculture, but the pace of such changes accelerated with the onset of agriculture. Agricultural breeding practices referred to as conventional, or traditional, include selective breeding, hybridization, mutation breeding, and marker-assisted selection. These have yielded agricultural varieties with enhanced size, growth rates, and other valuable characteristics. Many conventional breeding practices rely on laboratory techniques and genetic analysis, but they do not employ genetic engineering. Three such examples are mutation breeding, marker-assisted selection, and genomic selection (see text box, below).

Selected Laboratory-Based Conventional Breeding Practices

Mutation Breeding. Mutations arise naturally at low levels in plants and animals. In mutation breeding, in use since the 1920s, plant seeds are intentionally exposed to radiation (e.g., x-rays, gamma rays, neutrons, alpha particles, beta particles) or chemical mutagens (e.g., sodium azide, ethyl methanesulphonate) to rapidly generate many mutations. Breeders can select plants with desirable qualities from among the resulting mutants for further development. In one example, farmers sought grapefruits with deeper red coloration and sweeter flavor than they could find in existing variants. Scientists in Texas irradiated grapefruit seeds to try to induce the desired changes. This research led to the commercial release of the Star Ruby and Rio Red grapefruits in the 1970s and 1980s—the progenitors of most grapefruit now grown in Texas.[6] Although this technique can be successful for plant breeding, it is not suitable for animal breeding.

Marker-Assisted Selection. Since the 1980s, the availability and use of genetic information has strengthened the ability to modify agricultural varieties. Marker-assisted selection is an example of a conventional breeding technique that relies on genetic analysis. With this technique, researchers can reduce the time it takes to develop a new variety with desired qualities by first screening potential breeding candidates for specific molecular markers (DNA sequences known to be associated with certain traits).[7] Only those candidates that have the genetic markers are used in further breeding experiments. Researchers save time because they do not need to wait until the screened individual grows up to express those traits—they can screen many individuals (e.g., seeds, embryos, adolescent animals) without growing or raising all of them to reproductive maturity.

[3] Food and Drug Administration (FDA), "FDA Approves First-of-its-Kind Intentional Genomic Alteration in Line of Domestic Pigs for Both Human Food, Potential Therapeutic Uses," press release, December 14, 2020.

[4] *Modern biotechnology* includes the tools of genetic engineering and other approaches (e.g., fusion of cells from different types of organisms to create new varieties). See Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, CAC/GL 44-2003, World Health Organization and Food and Agriculture Organization (FAO), 2003.

[5] NASEM, *Genetically Engineered Crops*, 2016.

[6] For more information on mutation breeding and Texas grapefruit, see Amanda Kastrinos, "Delicious Mutant Foods: Mutagenesis and the Genetic Modification Controversy," *Genetic Literacy Project (GLP)*, June 13, 2016, at https://geneticliteracyproject.org/2016/06/13/pasta-ruby-grapefruits-why-organic-devotees-love-foods-mutated-by-radiation-and-chemicals.

[7] For more information on marker-assisted selection in plant breeding, see NASEM, *Genetically Engineered Crops*, 2016, pp. 354-355.

Genomic Selection. Genomic selection is a subcategory of marker-assisted selection in which many more markers throughout the genome have been identified and can be used to screen individuals for targeted breeding programs. Genomic selection uses tens of thousands to hundreds of thousands of markers to identify breeding candidates. As such, it requires more prior genetic information and data analytics capability than is needed for marker-assisted selection. This detailed genetic information is not readily available for all species, and this approach may be more resource-intensive than other approaches breeders may use to develop new varieties.

Genetic Engineering

Advances in molecular biology in the 1980s led to the development of techniques to introduce specific traits into organisms where they did not exist before: adding DNA sequences into their genomes. These genetic engineering techniques can change agricultural organisms in ways that would not be possible with conventional breeding, or could take decades to achieve. Recent developments in genetic engineering have allowed for increasingly specific genetic manipulation that does not always require the introduction of foreign DNA.

Genetic engineering includes recombinant DNA technology, genome editing, and other new breeding techniques (NBTs). In each case, genetically engineering agricultural species to express traits of interest is a multistep process that can involve significant time and resources to achieve. Genetic engineering may create changes that are heritable (i.e., changes that can be passed to offspring) or nonheritable (i.e., changes that affect only the GE organism and cannot be passed to offspring).

Recombinant DNA Technology

With recombinant DNA technology, scientists use certain techniques to combine DNA from two or more sources to achieve desired outcomes.[8] Organisms bearing recombinant DNA from an individual of the same species are *cisgenic*, and organisms bearing recombinant DNA from an individual of a different species are *transgenic*. Using this approach, scientists are generally unaware of *where* in the organism's genome the recombinant DNA has been placed; only that it has been integrated into the genome.

In the most general sense, to genetically engineer an organism using recombinant DNA technology, scientists must

- identify a trait of interest (e.g., herbicide tolerance, rapid growth, pink coloration),
- locate or identify the gene underlying that trait,
- extract the gene from the donor organism or synthesize its DNA sequence,
- construct a recombinant DNA vector with the gene,
- insert the vector into the host cell (i.e., transform it), and
- grow the transformed cell into the new GE organism.

[8] See University of Leicester, Virtual Genetics Education Centre, "Recombinant DNA and genetic techniques," at https://www2.le.ac.uk/projects/vgec/schoolsandcolleges/topics/recombinanttechniques.

Researchers have used this approach to develop many of the GE organisms currently in the U.S. food supply, such as nonbrowning apples,[9] herbicide-tolerant corn and soybeans (see "Plants"), and fast-growing salmon (see "Agricultural Animals").

Genome Editing

Genome editing is a more precise form of genetic engineering than recombinant DNA technology. With genome editing, researchers can make specific changes to an organism's DNA by inserting, deleting, or modifying genes or gene sequences. Early genome editing tools include ZFNs (zinc-finger nucleases) and TALENs (transcription activator-like effector nucleases). Use of these tools largely has been eclipsed by the rapid adoption of CRISPR (clustered regularly-interspaced short palindromic repeats) combined with Cas9 (CRISPR-associated protein 9).[10]

The CRISPR-Cas9 system was first used for genome editing in 2013, and researchers and developers have adopted it rapidly since that time.[11] Although ZFNs, TALENs, and CRISPR-Cas9 can all be used to perform genome editing, CRISPR-Cas9 is faster, more effective, and less expensive in many cases (**Figure 1**). Researchers continue to experiment with different CRISPR-associated proteins (e.g., Cas12a, Cas13a) as they work to fine-tune genome editing performance in a variety of circumstances.[12] Researchers have used genome editing to develop crops that are grown commercially in the United States, including genome-edited varieties of canola and soybean.[13]

[9] For more information, see Allison Baker, "Arctic Apples: A Fresh New Take on Genetic Engineering," *Harvard University*, January 15, 2018, at http://sitn.hms.harvard.edu/flash/2018/arctic-apples-fresh-new-take-genetic-engineering/. Researchers created Arctic apples using recombinant DNA technology in combination with a process known as RNA interference.

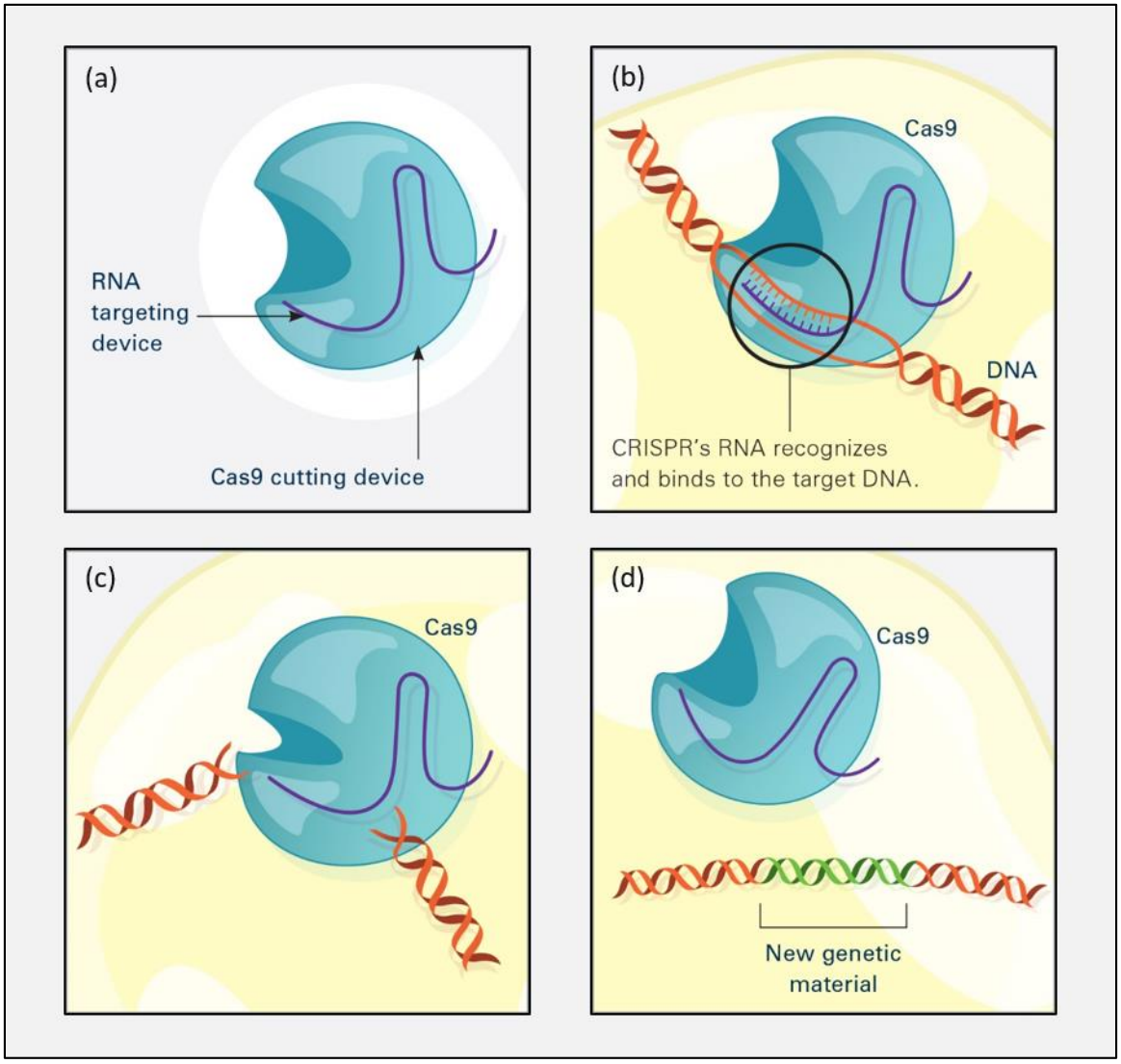
[10] For more information on genome editing and CRISPR-Cas9, see CRS Report R44824, *Advanced Gene Editing: CRISPR-Cas9*, by Marcy E. Gallo et al.

[11] For a chronology of CRISPR development for genome editing, see Broad Institute, "CRISPR Timeline," at https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/crispr-timeline.

[12] For more information, see Su Bin Moon et al., "Recent Advances in the CRISPR Genome Editing Tool Set," *Experimental & Molecular Medicine*, vol. 51 (November 5, 2019), pp. 1-11.

[13] Jochen Menz et al., "Genome Edited Crops Touch the Market: A View on the Global Development and Regulatory Environment," *Frontiers in Plant Science*, vol. 11, no. 586027 (October 9, 2020).

Figure 1. CRISPR-Cas9



Source: Figure and figure notes adapted by CRS from National Institutes of Health, "Gene Editing—Digital Media Kit," at https://www.nih.gov/news-events/gene-editing-digital-press-kit.

Notes: (a) The CRISPR system has two components joined together: a finely tuned targeting device (a small strand of RNA programmed to look for a specific DNA sequence) and a strong cutting device (an enzyme called Cas9 that can cut through a double strand of DNA). (b) Once inside a cell, the CRISPR system locates the DNA it is programmed to find. The CRISPR seeking device recognizes and binds to the target DNA (circled, black). (c) The Cas9 enzyme cuts both strands of the DNA. (d) Researchers can insert into the cell new sections of DNA. The cell automatically incorporates the new DNA into the gap when it repairs the broken DNA.

New Breeding Techniques (Plants)

NBTs is an umbrella term that includes some genetic engineering approaches and other plant breeding techniques developed in recent years. Some advocates—particularly in the European Union (EU)—have used this term to distinguish between breeding technologies and approaches that use recombinant DNA technology, on the one hand, and those that do not, on the other. While there is no universally agreed upon definition of what approaches are included within the scope of NBTs, they include (1) techniques that change an organism's genetic sequence (e.g., genome

editing and site-directed mutagenesis), and (2) *epigenetic* techniques that change when and how an organism expresses certain genes without changing the underlying genetic sequence. Epigenetic techniques use various mechanisms to silence gene expression, such as RNA interference (RNAi)[14] and RNA-directed DNA methylation.[15]

Cloning (Animals)

Animal biotechnology includes cloning. Cloning is an assisted-reproduction technique that is not considered genetic engineering, as it does not involve adding or altering genes in an organism. It is used to make a genetic copy of an existing individual. Scientists remove the nucleus from an egg cell of the recipient animal (this nucleus contains half of that animal's genomic DNA) and replace it with an adult-cell nucleus from the donor animal (this nucleus contains the full complement of the donor's genomic DNA) to form an embryo. That embryo is then implanted into the uterus of a surrogate female where it can develop into an animal, just as any other embryo would. Scientists have successfully cloned livestock, including sheep, cattle, horses, goats, and swine.

Adoption of Genetic Engineering in Agriculture

The United States has been a global leader in developing advanced genetic technologies and applying them to crops and livestock.[16] Federal regulators first approved a GE food, the Flavr Savr tomato, for sale in 1994.[17] As additional GE crops gained federal approval, farmers rapidly adopted them. Today, about 90% of canola, corn, cotton, soybean, and sugarbeet acres in the United States are planted with GE varieties.[18] GE foods predominantly enter commerce as processed foods and food ingredients (e.g., soybean oil, corn syrup, sugar).[19] Although GE crops are prevalent in the United States, some members of the public seek to avoid consuming GE foods.

Plants

Adoption of genetic engineering in agricultural plants has been robust, with an estimated 474 million acres planted worldwide in 2018 (**Table 1**), an increase of about 185 million acres since 2008. These GE crops include plants grown for food, feed, and fiber in 26 countries. Such plantings are highly concentrated among four crops—soybeans, corn, cotton, and canola—and five countries. The United States accounts for approximately 39% of global GE crop acreage (185.3 million acres), followed by Brazil (27%, or 126.8 million acres); Argentina (12%, or 59.1

[14] For more information on RNAi, see ISAAA, "Pocket K No. 34: RNAi for Crop Improvement," at https://www.isaaa.org/resources/publications/pocketk/34/default.asp.

[15] For more information on RNA-directed DNA methylation, see NBT Platform, *Fact Sheet RNA-Directed DNA Methylation*, 2014, at http://www.nbtplatform.org/background-documents/factsheets/factsheet-rna-directed-dna-methylation.pdf.

[16] For a history of the development of genetic engineering in agriculture and related regulatory policies, see NASEM, *Genetically Engineered Crops*, 2016, pp. 65-96.

[17] In 1994, FDA approved for sale the Flavr Savr tomato, genetically engineered to stay firm after harvest.

[18] Daniel Hellerstein, Dennis Vilorio, and March Ribaudo, eds., *Agricultural Resources and Environmental Indicators, 2019*, U.S. Department of Agriculture (USDA), Economic Research Service (ERS), Economic Information Bulletin (EIB) 208, May 2019, pp. 30-34.

[19] Gregory Jaffe, *Straight Talk on Genetically Engineered Foods: Answers to Frequently Asked Questions*, Center for Science in the Public Interest, 2015.

million acres); Canada (7%, or 31.4 million acres); and India (6%, or 28.7 million acres). These five countries account for about 91% of the global GE crop acreage.

Table 1. Global Area of Genetically Engineered (GE) Crops by Country, 2018

Rank	Country	Area (million acres)	GE Crops
1	USA	185.3	Corn, soybeans, cotton, canola, sugar beets, alfalfa, papaya, squash, potatoes, apples
2	Brazil	126.8	Soybeans, corn, cotton, sugarcane
3	Argentina	59.1	Soybeans, corn, cotton
4	Canada	31.4	Canola, corn, soybeans, sugar beets, alfalfa, potatoes
5	India	28.7	Cotton
6	Paraguay	9.4	Soybeans, corn, cotton
7	China	7.2	Cotton, papaya
8	Pakistan	6.9	Cotton
9	South Africa	6.7	Corn, soybeans, cotton
10	Uruguay	3.2	Soybeans, corn
11	Bolivia	3.2	Soybeans
12	Australia	2.0	Cotton, canola
13	Philippines	1.5	Corn
14	Myanmar	0.7	Cotton
15	Sudan	0.5	Cotton
16	Mexico	0.5	Cotton
17	Spain	0.2	Corn
18	Colombia	0.2	Cotton, corn
19	Vietnam	<0.2	Corn
20	Honduras	<0.2	Corn
21	Chile	<0.2	Corn, soybeans, canola
22	Portugal	<0.2	Corn
23	Bangladesh	<0.2	Eggplant
24	Costa Rica	<0.2	Cotton, soybeans
25	Indonesia	<0.2	Sugarcane
26	eSwatini[a]	<0.2	Cotton
	Total	**473.7**	

Source: International Service for the Acquisition of Agri-biotech Applications (ISAAA), *Global Status of Commercialized Biotech/GM Crops in 2018: Biotech Crops Continue to Help Meet the Challenges of Increased Population and Climate Change*, ISAAA Brief no. 54, 2018.

a. eSwatini was formerly known as Swaziland.

U.S. farmers do not commercially grow all GE crops that have approvals or all GE crops available for sale in the United States. As of the writing of this report, U.S. farmers commercially grew 10 GE crop species (see **Table 1**). These do not include GE tomatoes and tobacco, which have approvals but are not grown commercially. Other GE crops that are not grown in the United

States may enter the U.S. food system via importation from other countries (e.g., the GE PinkGlow pineapple). According to the U.S. Department of Agriculture (USDA) Economic Research Service (ERS), "over 90% of all corn, upland cotton, soybeans, canola, and sugarbeets are produced using GE varieties" (see **Figure 2**).

Production-Oriented Traits

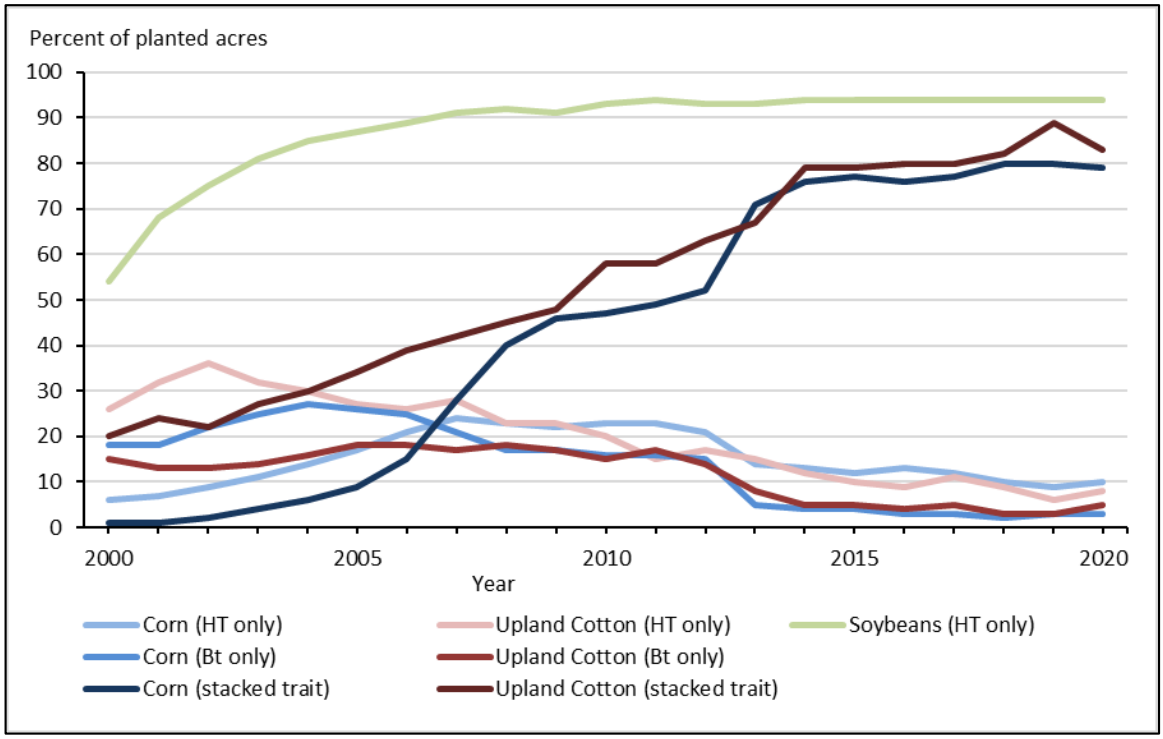
The vast majority of commercial applications of GE crops benefit the production side of agriculture, with herbicide tolerance and pest-resistance by far the most widespread applications of GE crops in the United States and abroad. GE crops may possess a single GE trait (e.g., herbicide tolerance, insect resistance, or pathogen resistance) or multiple GE traits (*stacked traits*).

- **Herbicide Tolerance.** Herbicide-tolerant (HT) GE crops are engineered to tolerate herbicides that would otherwise kill them along with the targeted weeds. HT crops currently on the market include HT soybeans, HT upland cotton, and HT corn. Many HT crops are referred to as "Roundup Ready" because they are engineered to resist Bayer's (formerly Monsanto's) glyphosate herbicide, marketed under the brand name Roundup. Stacked-trait HT varieties that combine traits for glyphosate resistance and resistance to other herbicides (e.g., dicamba; 2,4-D choline) have been developed in recent years. Increasing weed resistance to glyphosate has motivated demand for and development of these newer HT stacked trait varieties.
- **Insect Resistance.** Insect-resistant GE crops are genetically engineered to produce small amounts of pesticides in their cells, with the aim of controlling insect pests without needing to apply chemical pesticides externally. GE traits for insect resistance are referred to as *plant-incorporated protectants (PIPs)*. The most common PIP is Bt, a naturally occurring pesticide derived from the *Bacillus thuringiensis* soil bacterium.[20] Bt crop varieties are most prevalent in upland cotton (to control tobacco budworm, bollworm, and pink bollworm) and corn (to control earworm and several types of corn borers).
- **Stacked Traits for Herbicide Tolerance and Insect Resistance.** Some stacked trait crop varieties in some cases combine HT and insect-resistant traits. As these became available for corn and upland cotton, they soon overtook single-trait GE varieties with HT or insect-resistant GE traits (**Figure 2**).
- **Pathogen Resistance.** Plant pathogens (e.g., viruses, fungi, bacteria) can damage crops and can make growing them untenable in affected geographic regions. Traditional methods of combating some virulent plant pathogens (e.g., pruning, burning, spraying with chemicals) can damage or destroy the infected plants. Researchers have identified pathogen-resistance traits in some living organisms and have used genetic engineering to introduce them into some otherwise susceptible plant varieties. For example, the GE Rainbow papaya, resistant to the papaya ringspot virus, is largely credited with saving the Hawaiian papaya

[20] Because *Bacillus thuringiensis* (Bt) is a natural occurring pesticide, it can be applied onto organically produced plants under certain conditions. Bt's incorporation into genetically engineered (GE) commodities concern some organic producers because of the risk of creating Bt-tolerant pests, thereby decreasing its effectiveness for organic farming operations.

industry.[21] In 2018, 77% of Hawaiian papaya acreage was planted with virus-resistant GE papaya.[22] Citrus greening, also known as Huanglongbing, is a bacterial disease that ruins citrus fruits and has no known treatment. Citrus greening has impacted citrus groves globally, is present in all Florida counties, and has arisen in California and Texas.[23] Researchers are working to develop GE citrus varieties with protection against citrus greening.[24]

Figure 2. Adoption of Selected Genetically Engineered Crops in the United States
(2000-2020)



Source: U.S. Department of Agriculture (USDA), Economic Research Service (ERS), "Adoption of Genetically Engineered Crops in the U.S.," last updated July 17, 2020, at https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.

Notes: Genetically engineered traits include herbicide tolerance (HT), insect resistance via *Bacillus thuringiensis* (Bt), and combined HT and Bt (stacked traits).

Consumer-Oriented Traits

In addition to producer-oriented traits, agricultural plants also can be genetically engineered to address consumer needs and preferences.[25] Such consumer-oriented GE traits in crops may

[21] See, for example, Amy Harmond, "A Lonely Quest for Facts on Genetically Modified Crops," *New York Times*, January 4, 2013, at https://www.nytimes.com/2014/01/05/us/on-hawaii-a-lonely-quest-for-facts-about-gmos.html.

[22] ISAAA, *Global Status of Commercialized Biotech/GM Crops in 2018*.

[23] University of Florida, Emerging Pathogens Institute, "Citrus Greening," at https://epi.ufl.edu/pathogens/plant-pathogens/citrus-greening/.

[24] See, for example, Juliana M. Soares et al., "Development of genetically modified citrus plants for the control of citrus canker and huanglongbing," *Tropical Plant Pathology*, vol. 45 (May 25, 2020), pp. 237-250.

[25] While consumer-oriented traits address consumer needs and preferences directly, producer-oriented traits may also benefit consumers indirectly (e.g., through lower food prices or higher quality foods).

include aesthetic changes (e.g., nonbrowning and pink color), enhanced nutritional qualities (e.g., added vitamins, altered fatty acid profile), or reduced allergenicity. Some of these GE crops are on the market, and others are under research or pending regulatory approval. GE agricultural products with consumer-oriented traits have not been adopted by producers and consumers to the same extent as those GE products with producer-oriented traits. A few examples are described below.

- **Aesthetic Changes.** In 2015, USDA's Animal and Plant Health Inspection Service (APHIS) granted nonregulated status to the first GE apple varieties—Arctic apples were genetically engineered to *silence*, or turn off, the gene responsible for an enzyme that causes browning when a sliced apple is exposed to air.[26] These apples became commercially available in the United States in 2017, and they have been marketed as a way to reduce food waste.[27] In 2016, the U.S. Food and Drug Administration (FDA) approved for sale in the United States a GE pink-fleshed pineapple—PinkGlow pineapples were genetically engineered to suppress the enzyme that turns a naturally occurring pink pigment in pineapples yellow.[28] This pineapple first became available for purchase in the United States in October 2020, following research and development since 2005.
- **Enhanced Nutritional Qualities.** In 2018, FDA approved a GE rice variety with enhanced nutritional properties—Golden Rice was genetically engineered to serve as a source of Vitamin A, key to preventing a form of blindness.[29] This rice was developed to address nutrient deficiency concerns in Asia and is not intended for consumption in the United States. Following decades of research and development, it has not been sold commercially as of the date of this report. In 2018, USDA first granted nonregulated status to a GE variety of canola with an altered oil profile.[30] Genetic engineering altered this canola variety to increase levels of an omega-3 fatty acid (docosahexaenoic acid) in its seeds. It has been marketed as an alternative to sourcing omega-3 dietary supplements from fish.[31]
- **Reduced Allergenicity.** Researchers have long investigated ways to reduce or eliminate proteins in plants that trigger severe allergic responses in some individuals. Genetic engineering is one path under investigation in crops such as

[26] Under the Animal and Plant Health Inspection Service's (APHIS's) biotechnology regulations prior to revisions effective in 2021, the granting of nonregulated status to a GE product was a final step toward full commercialization, following a lengthy regulatory review and testing process. For more information on this process and revisions effective in 2021, see "Animal and Plant Health Inspection Service." For information on USDA's granting of nonregulated status to Arctic apples, see APHIS, "Questions and Answers: Arctic Apple Deregulation," February 2015, at https://www.aphis.usda.gov/publications/biotechnology/2015/faq_arctic_apples.pdf.

[27] Arctic Apples, "About Us," at https://arcticapples.com/about-us.

[28] For information on FDA approval of this GE pineapple, see FDA, "FDA Concludes Consultation on Pink Flesh Pineapple," December 14, 2016, at https://www.fda.gov/food/cfsan-constituent-updates/fda-concludes-consultation-pink-flesh-pineapple.

[29] For information on FDA approval of Golden Rice, see Letter from Dennis M. Keefe, Ph.D., director of FDA's Office of Food Additive Safety to Donald J. MacKenzie, Ph.D., International Rice Research Institute Regulatory Affairs & Stewardship leader, May 24, 2018, at https://www.fda.gov/media/113719/download.

[30] APHIS, "Nuseed Americas Inc.; Determination of Nonregulated Status of Canola Genetically Engineered for Altered Oil Profile," 83 *Federal Register* 43634, August 27, 2018.

[31] Nuseed, "First Land-Based Omega-3," at https://nuseed.com/us/omega-3_beyondyield.

peanuts and wheat.[32] These applications of genetic engineering have not advanced to commercialization as of the date of this report.

Agricultural Animals and Animal Products (Pharmaceuticals)

Commercialization of genetic engineering in agricultural animals, including those used for food, feed, and fiber, has been limited.[33] Researchers reported production of the first GE agricultural animals in 1985;[34] as of the date of this report, the federal government has approved two such animals for food use: the AquAdvantage salmon and the GalSafe pig. Many in the scientific community assert that the regulation of GE animals is overly burdensome and impedes innovation.[35] FDA has argued that rigorous review of GE animals is necessary to protect animals and public health.[36] Some research has shown that consumer views of GE animals may depend on the intended purpose of the GE changes.[37] This research suggests stronger public support for GE animals intended to benefit human health than for other purposes.

Animals

Researchers have used genetic engineering to introduce a variety of traits into agricultural animals. These include producer- and consumer-oriented traits, some of which also may address worker safety and animal welfare. Among producer-oriented traits are those that increase growth rates, reduce susceptibility to pests and diseases, and reduce physical dangers of animal rearing. Consumer-oriented traits include those that eliminate allergens and those that alter the nutritional profile of animal products. A few examples are discussed below.

- **AquAdvantage Salmon.** In November 2015, FDA announced its first approval of a GE animal intended for food use: a GE salmon developed by the Massachusetts biotechnology firm AquaBounty.[38] The AquAdvantage Atlantic salmon grows at approximately twice the rate of non-GE Atlantic salmon. AquaBounty used genetic engineering to introduce DNA—sourced from Chinook salmon and an ocean pout—into Atlantic salmon, so that the GE Atlantic salmon expresses the Chinook salmon growth hormone. AquAdvantage salmon may become commercially available in the United States in 2021.

[32] For selected examples, see ISAAA, "Anti-Allergy Biotech Crops," Pocket K no. 53, October 2017.

[33] This report does not provide in-depth discussion of nonagricultural GE animals, which may include animals genetically engineered to produce pharmaceuticals or to limit the spread of insect-borne disease.

[34] R.E. Hammer et al., "Production of Transgenic Rabbits, Sheep, and Pigs by Microinjection," *Nature*, vol. 315, no. 6021 (June 20-26, 1985), pp. 680-683.

[35] See, for example, The Editors, "Course Correction," *Nature Biotechnology*, vol. 38, no. 2 (February 7, 2020), pp. 142-143; and Alison L. Van Eenennaam et al., "Genetic Engineering of Livestock: The Opportunity Cost of Regulatory Delay," *Annual Reviews of Biosciences*, vol. 9 (February 2021), pp. 453-478.

[36] Steven M. Solomon, "Genome Editing in Animals: Why FDA Regulation Matters," *Nature Biotechnology*, vol. 38, no. 2 (February 7, 2020), p. 113.

[37] Cary Funk and Meg Hefferon, *Most Americans Accept Genetic Engineering of Animals That Benefits Human Health, but Many Oppose Other Uses*, Pew Research Center, August 16, 2016, at https://www.pewresearch.org/science/2018/08/16/most-americans-accept-genetic-engineering-of-animals-that-benefits-human-health-but-many-oppose-other-uses.

[38] FDA, "AquAdvantage Salmon Approval Letter and Appendix," NADA 141-454, November 19, 2015, at https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/aquadvantage-salmon-approval-letter-and-appendix.

- **GalSafe Pigs.** In December 2020, FDA announced its second approval of a GE animal intended for food use and, coincidentally, its first approval of a GE animal for both food use and human therapeutics: a GE pig free of a sugar that causes allergic reactions in some people.[39] GalSafe pigs have been genetically engineered to inhibit production of alpha-gal sugar, which can cause allergic reactions in people with alpha-gal syndrome. These pigs may be used to produce pork products or biomedical materials, such as blood thinners or transplant tissues, safe for people with alpha-gal syndrome. These GE pigs are not yet on the market as of the date of this report.
- **Polled Cattle.** Dairy cows naturally develop horns, which most farmers and ranchers remove—in a bid to protect animals and people from goring—via mechanical processes that have raised some concerns with animal welfare advocates. Recombinetics, a Minnesota-based gene editing company, has been researching and developing hornless, or *polled*, GE dairy cows. In these cattle, DNA for the polled trait—sourced from a naturally hornless Angus breed—was introduced into a Holstein dairy breed through genetic engineering. A voluntary review by FDA identified the unintended inclusion of nontarget DNA in one of these cattle in 2019, and they remain under development.[40]

Animal Products (Pharmaceuticals)

In addition to genetically engineering animals to express producer- and consumer-oriented traits, researchers have used genetic engineering to induce animals to produce biological products, such as pharmaceuticals. A few examples are discussed below.

- **Goats: Blood Anti-clotting Protein.** In February 2009, FDA approved the first human drug produced by a transgenic animal, as well as the GE animal used to produce it.[41] Researchers used genetic engineering to induce goats to produce antithrombin III, a human anti-clotting protein, in their milk. Since FDA approval, antithrombin III extracted from GE goats' milk remains in use.
- **Rabbits: Blood-Clotting Protein.** Researchers genetically engineered rabbits to produce recombinant human blood-clotting proteins for use in patients with hemophilia. These rabbits express the proteins in their milk, which can be purified for use as a human drug. In December 2018, FDA approved production of the GE rabbits; in April 2020, it approved the drug derived from these rabbits for therapeutic use in people.[42]

[39] FDA, "FDA Approves First-of-its-Kind Intentional Genomic Alteration in Line of Domestic Pigs for Both Human Food, Potential Therapeutic Uses," press release, December 14, 2020, at https://www.fda.gov/news-events/press-announcements/fda-approves-first-its-kind-intentional-genomic-alteration-line-domestic-pigs-both-human-food.

[40] For information on the development and regulatory setbacks associated with these GE polled cattle, see Antonio Regalado, "Gene-Edited Cattle Have a Major Screwup in Their DNA," *MIT Technology Review*, August 29, 2019.

[41] Andrew Pollack, "F.D.A. Approves Drug From Gene-Altered Goats," *New York Times*, February 6, 2009.

[42] FDA, *Freedom of Information Summary: Original New Animal Drug Application: NADA 141-511, Bc2371 rDNA Construct in R69 New Zealand White Rabbits*, December 27, 2018; and FDA, "FDA Approves Additional Treatment for Adults and Adolescents with Hemophilia A or B and Inhibitors," press release, April 1, 2020.

Other Organisms

Beyond plants and animals, biotechnology has been used to alter various types of microorganisms (e.g., bacteria, algae, yeast) and fungi for food, feed, pharmaceutical, energy, and other purposes. A 2017 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) includes such applications of genetic engineering among the future products of biotechnology that may diverge from those applications currently in use.[43] Some of these applications use microorganisms to produce enzymes or hormones originally derived from animals. Some, including fungi intended for food use (i.e., mushrooms), are GE food organisms other than plants and animals. A few current applications are discussed below, and many others are under research and development.

- **Bacteria: Food-Production Enzymes.** Chymosin is an enzyme that naturally occurs in newborn ruminant animals (e.g., cattle, sheep, goats), and it has the effect of curdling milk. It has been used in cheese production for thousands of years. In 1990, chymosin produced in a GE strain of the bacterium *Escherichia coli* (*E. coli*) became the first GE food ingredient approved by FDA.[44] Currently, GE chymosin is used in most hard cheeses produced in the United States.[45]
- **Bacteria: Animal Drugs.** Bovine somatotropin (bST, also known as "bovine growth hormone") is a hormone that naturally occurs in cattle, and it can increase milk production in lactating cows. In the 1980s, researchers began developing ways to produce large quantities of bST with genetic engineering. They introduced the gene for bST into a strain of *E. coli*, which could then produce the hormone in quantities that could be isolated for use in dairy cows. FDA first approved Posilac, a GE bST (an *rbST*), in 1993.[46] More than 20 countries have approved rbST, though it remains prohibited by many U.S. trading partners.[47] Its use in the United States has declined from about 15% of all dairy operations in 2007 to about 10% in 2014.[48]
- **Mushrooms: Food.** In 2016, a white button mushroom became the first test case for USDA regulation of a genome-edited agricultural product.[49] A researcher at Pennsylvania State University used CRISPR-Cas9 to create a nonbrowning mushroom by deleting a few DNA base pairs in a gene linked to browning. In a letter to the researcher, USDA confirmed that the mushroom is not subject to USDA regulation because it does not contain DNA from a plant pest or pathogen

[43] NASEM, *Future Products of Biotechnology*, 2017.

[44] See Eric L. Flamm, "How FDA Approved Chymosin: A Case History," *Nature Biotechnology*, vol. 9 (April 1, 1991), pp. 349-351.

[45] Jon Entine and XiaoZhi Lim, "Cheese: The GMO Food Die-Hard GMO Opponents Love, but Don't Want to Label," *GLP*, November 2, 2018, at https://geneticliteracyproject.org/2018/11/02/cheese-gmo-food-die-hard-gmo-opponents-love-and-oppose-a-label-for.

[46] FDA, "Bovine Somatotropin (bST)," at https://www.fda.gov/animal-veterinary/product-safety-information/bovine-somatotropin-bst.

[47] Among other countries, Japan, Australia, Canada, New Zealand, and the European Union (EU) prohibit use of rbST in dairy cows. Milk containing rbST has fallen out of favor in some places in the United States.

[48] APHIS, *Dairy 2007, Part I: Reference of Dairy Cattle Health and Management Practices in the United States, 2007*, October 2007; and APHIS, *Dairy 2014: Dairy Cattle Management Practices in the United States (Report 1)*, February 2016.

[49] Emily Waltz, "Gene-Edited CRISPR Mushroom Escapes US Regulation," *Nature*, vol. 532, no. 7599 (April 14, 2016), p. 293.

or contain any introduced DNA at all.[50] Reports indicate that as of early 2019, these mushrooms were not commercially available.[51]

Views of Agricultural Biotechnology

When foods containing GE ingredients were introduced in the 1990s, some members of the public called for banning them based on concerns about potential harm to human health.[52] Research has repeatedly found no difference between foods developed with and without genetic engineering, in terms of the health and safety of the people consuming them.[53] Even so, some consumers remain concerned about genetic engineering, citing health, personal preference, environmental, economic, and other objections.[54] As such, the views of the scientific community, consumers, and farmers and ranchers on the safety, utility, and ethics of agricultural biotechnology do not always align. Society continues to debate these issues, and numerous advocacy and trade organizations promote various sides of the debate.

Scientific Assessments

NASEM is an independent scientific organization chartered by Congress with a mandate to provide the federal government with analyses of scientific topics upon request.[55] Over the years, NASEM has examined and reported its findings on the effects, if any, of GE crops and foods on human health, economics, the environment, and other matters. NASEM's findings align with those of many other national and international scientific organizations.

The federal regulatory process also provides scientific assessments of individual GE agricultural products (see "U.S. Regulatory System's Coordinated Framework"). Prior to providing any approvals to release, transport, market, or sell GE environmental products, the federal government evaluates their safety for human and animal consumption and potential environmental release.

[50] Letter from Michael J. Firko, Ph.D., deputy administrator, APHIS, to Dr. Yinong Yang of the Pennsylvania State University, April 13, 2016, at https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/15-321-01_air_response_signed.pdf.

[51] Ashley P. Taylor, "Companies Use CRISPR to Improve Crops," *The Scientist*, February 1, 2019.

[52] Bloomberg BNA, "Group Encourages Consumer Support for U.S. Ban on Genetically Altered Food," *Daily Report for Executives (BNA)*, August 31, 1999; and Alan Yonan Jr., "Environmentalists Escalate Fight Against Altered Crops," Dow Jones, August 24, 1999.

[53] See FDA, "Questions & Answers on Food from Genetically Engineered Plants," January 4, 2018; NASEM, *Genetically Engineered Crops*, 2016; and Institute of Medicine (IOM) and National Research Council (NRC), *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*, 2004.

[54] For reviews of some of these concerns, see Emmanuel B. Omobowale, Peter A. Singer, and Abdallah S. Daar, "The Three Main Monotheistic Religions and GM Food Technology: An Overview of Perspectives," *BMC International Health and Human Rights*, vol. 9, no. 18 (August 2009); and Stefaan Blacke, "Why People Oppose GMOs Even Though Science Says They Are Safe," *Scientific American*, August 18, 2015. See also Non-GMO Project, "GMO Facts," at https://www.nongmoproject.org/gmo-facts.

[55] 36 U.S.C. §150301. In 2015, the National Academy of Sciences (NAS), the National Academy of Engineering (NAE), the IOM, and the NRC were rebranded collectively as NASEM. Reports prior to 2015 may note authorship of individual academies, the NRC, or both, and reports after this date note authorship of NASEM.

Human Health

The potential effects of consuming GE foods on human health has been a major public concern since they were first developed. Before data on health outcomes for people consuming GE foods were available, the potential risks associated with this new technology were unknown. In the decades since the first GE food entered the market, data and evidence have accumulated. Numerous scientific analyses have been conducted, and peer-reviewed scientific studies have been published. The scientific community is now generally in agreement that commercially available GE foods are safe to eat. NASEM has successively reported findings of no difference in the health effects of GE and non-GE foods.[56] Other scientific bodies, including federal agencies and international organizations, also have reached this conclusion (see text box, below).

[56] NASEM, *Genetically Engineered Crops*, 2016; and IOM and NRC, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*, 2004.

Selected Statements of Scientific, Federal, and International Organizations on the Safety of Genetically Engineered (GE) Foods

As reflected in the statements below, the scientific community is generally in agreement that commercially available GE foods are safe to eat.

National Academies of Sciences, Engineering, and Medicine (NASEM)

"On the basis of detailed examination of comparisons of currently commercialized GE and non-GE foods in compositional analysis, acute and chronic animal-toxicity tests, long-term data on health of livestock fed GE foods, and human epidemiological data, the committee found no differences that implicate a higher risk to human health from GE foods than from their non-GE counterparts."

- NASEM, *Genetically Engineered Crops: Experiences and Prospects*, 2016, at https://doi.org/10.17226/23395.

American Association for the Advancement of Science (AAAS)

"Indeed, the science is quite clear: crop improvement by the modern molecular techniques of biotechnology is safe."

- AAAS, *Statement by the AAAS Board of Directors on Labeling of Genetically Modified Foods*, 2012, at https://www.aaas.org/news/statement-aaas-board-directors-labeling-genetically-modified-foods (accessed March 24, 2021).

U.S. Food and Drug Administration (FDA)

"GMO foods are as healthful and safe to eat as their non-GMO counterparts. Some GMO plants have actually been modified to improve their nutritional value."

- FDA, "Agricultural Biotechnology," at https://www.fda.gov/food/consumers/agricultural-biotechnology (accessed March 24, 2021).

World Health Organization (WHO)

"GM foods currently available on the international market have passed safety assessments and are not likely to present risks for human health. In addition, no effects on human health have been shown as a result of the consumption of such foods by the general population in the countries where they have been approved."

- WHO, "Q&A Detail: Food, Genetically Modified," May 1, 2014, at https://www.who.int/news-room/q-a-detail/food-genetically-modified (accessed March 24, 2021).

European Commission (EC)

"The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies."

- EC, *A Decade of EU-funded GMO Research (2001–2010)*, 2010, at https://doi.org/10.2777/97784.

The Royal Society (United Kingdom)

"All reliable evidence produced to date shows that currently available GM food is at least as safe to eat as non-GM food."

- The Royal Society, "Is it Safe to Eat GM Crops?," at https://royalsociety.org/topics-policy/projects/gm-plants/is-it-safe-to-eat-gm-crops (accessed March 24, 2021).

Environmental Effects

Some have expressed concerns that GE crops and agricultural products may harm the environment now or in the future. Specifically, these concerns include that

- HT crops may increase herbicide resistance in agricultural weeds;
- Bt crops may increase pest resistance to agricultural pesticides;
- Bt crops may harm nontarget species, such as butterflies and bees; and
- GE traits may escape into native species through interbreeding or other means.

NASEM has examined these issues in various reports.[57] A 2010 NASEM report found that GE crops generally had fewer negative environmental effects than non-GE crops, but it also warned that this could change over time due to some of the ways that farmers use GE crops as pest management tools.[58] A 2016 NASEM report presented more uncertainty:

> Overall, the committee found no conclusive evidence of cause-and-effect relationships between GE crops and environmental problems. However, the complex nature of assessing long-term environmental changes often made it difficult to reach definitive conclusions.[59]

Other scientific bodies provide similar assessments. A 2019 report by the World Resources Institute, a global nonprofit research organization, researched and proposed solutions intended to address global food security in an environmentally sustainable manner.[60] This report's environmental analysis of GE crops focused on HT and Bt traits and concluded the following:

> Although claims both for and against GM technology have often been overstated, the best evidence is that GM technology has already provided some yield gains from Bt crops and has probably reduced toxicity both to humans and the environment, relative to the use of alternative crop varieties that require more pesticide use.[61]

HT and pest-resistant GE crops have been associated with lower use of chemical herbicides and pesticides than are in use in non-GE crop fields. However, over time, herbicide use on HT crops can lead to herbicide-resistance in agricultural weeds, and agricultural pests can develop resistance to pest-resistant GE crops. If these changes lead farmers to apply more or different types of herbicides and pesticides, then doing so could reverse this trend and increase potential environmental harms associated with these GE crops. **Figure 3** shows that whereas adopters of HT corn varieties used fewer herbicides (pounds per planted acre) than nonadopters in 2001 and 2005, by 2010, there was almost no difference in herbicide use. **Figure 4** shows a similar trend in the use of pesticides by adopters and nonadopters of Bt corn varieties over the same time period.

[57] See, for example, NASEM, *Genetically Engineered Crops*, 2016; NRC, *The Impact of Genetically Engineered Crops on Farm Sustainability in the United States*, National Academies Press, 2010; NAS and NRC, *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*, National Academies Press, 2002; NAS and NRC, *Genetically Modified Pest-Protected Plants: Science and Regulation*, National Academies Press, 2000.

[58] NRC, *The Impact of Genetically Engineered Crops on Farm Sustainability in the United States*, National Academies Press, 2010.

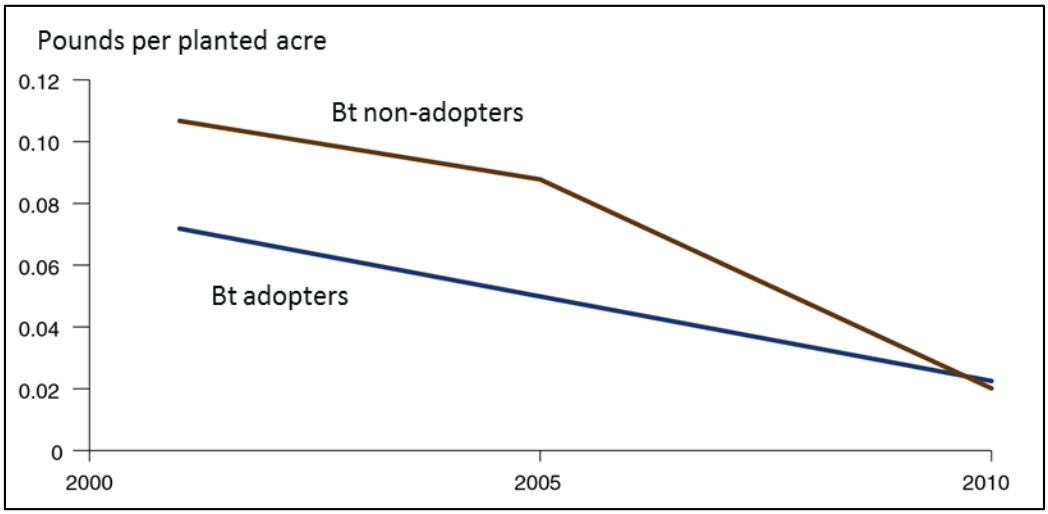
[59] NASEM, *Genetically Engineered Crops*, 2016.

[60] Tim Searchinger et al., *Creating a Sustainable Food Future*, World Resources Report, World Resources Institute, July 2019. For the report's discussion of genetic engineering, see section on "Genetic Modification," pp. 185-192.

[61] Ibid., p. 190.

Figure 3. Insecticide Use, GE and Non-GE Corn Fields

(2001-2010)

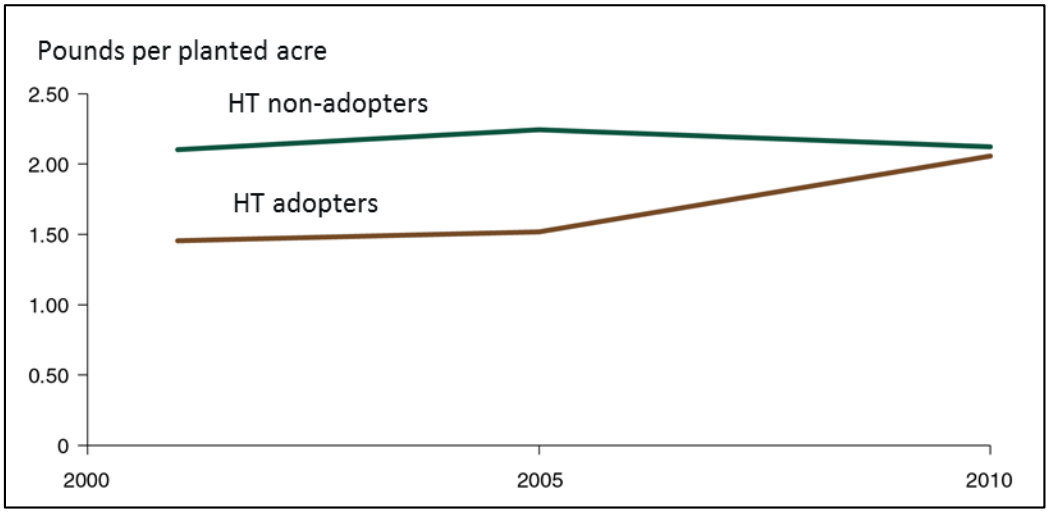


Source: Adapted by CRS from Jorge Fernandez-Cornejo et al., *Genetically Engineered Crops in the United States*, ERS, ERR-162, Figure 13, February 2014.

Notes: Bt corn is genetically engineered to have insect-resistant traits.

Figure 4. Herbicide Use, GE and Non-GE Corn Fields

(2001-2010)



Source: Adapted by CRS from Jorge Fernandez-Cornejo et al., *Genetically Engineered Crops in the United States*, ERS, ERR-162, Figure 14b, February 2014.

Notes: HT corn is genetically engineered to have herbicide-tolerant traits.

Economic Effects

The use of GE crops has been associated with various economic outcomes for farmers, under different conditions and at different points in time. Some have raised concerns about the profitability of GE crops for the farmers that use them, as well as potential economic impacts of GE crops on farmers who use only organic practices.

Some have asserted that GE crops commit some farmers to purchasing agricultural products that they cannot afford, asserting that GE seeds may be more expensive than non-GE seeds and that farmers cannot save harvested GE seeds for future use and so must purchase new seeds each season. A 2016 NASEM report found generally favorable economic outcomes for farmers that use GE commodity crops. It also highlighted that these outcomes vary depending on a number of factors, including pest prevalence, farming practices in use, and agricultural infrastructure.[62] A 2014 study by USDA's ERS found that a majority of U.S. farmers had adopted GE varieties of major commodity crops, and it stated that farmers would continue to use GE crops as long as GE crops are benefiting them.[63] The report advised that increased pest resistance to Bt crops and weed resistance to the herbicide glyphosate, incorporated into many HT crops, may change this calculus in the future. Beyond U.S. farmers, a widely publicized theory attributed farmer suicides in India to economic hardships experienced due to their reliance on GE cotton.[64] Numerous scientific studies have concluded that there is no causal relationship between use of GE cotton and farmer suicides in India.[65]

Others have raised concerns that some farmers' use of GE crops may negatively affect economic outcomes for neighboring farmers who grow and market organic crops. A 2016 ERS report stated, "only 87 organic producers suffered economic losses from the unintended presence of GE material during 2011-14."[66] It concluded that problems of coexistence between GE and non-GE farms might grow in the future as more GE crops are commercialized. Further, the report identified several gaps in available data about GE and non-GE crop production that prevent detailed analysis.

Public Opinion

Agricultural biotechnology has provoked strong public sentiment, both in favor of and against its use. Some have argued that genetic engineering and other biotechnologies are essential tools to address global food insecurity, environmental degradation, global warming, food safety, and animal welfare. Others have argued that agricultural biotechnology is unsafe, poorly tested, a danger to the environment, and a potential source of food safety concerns.

A 2016 survey by the Pew Research Center showed that about half of Americans surveyed believed there is no difference in the health effects of GE versus non-GE foods (**Figure 5**).[67] This survey also showed that 16% of all respondents care a great deal about the issue of GE foods, and among these respondents, most believe that GE foods pose risks to human health and to the environment. Some scholarship suggests that for many individuals, anti-biotechnology arguments

[62] NASEM, *Genetically Engineered Crops*, 2016.

[63] Jorge Fernandez-Cornejo et al., *Genetically Engineered Crops in the United States*, ERR 162, ERS, February 2014 (hereinafter Fernandez-Cornejo et al., *GE Crops in the United States*, 2014), p. 41.

[64] See, for example, Natasha Gilbert, "Case studies: A hard look at GM crops," *Nature*, vol. 497 (May 2, 2013), pp. 24-26; and GM Watch, "Vandana Shiva on seed monopolies, GMOs, and farmer suicides in India," November 16, 2013, at https://www.gmwatch.org/en/news/archive/2013/15165-vandana-shiva-on-seed-monopolies-gmos-and-farmer-suicides-in-india.

[65] See, for example, Keith Kloor, "The GMO-Suicide Myth," *Issues in Science and Technology*, vol. 30, no. 2 (Winter 2014), pp. 65-78; and Guillaume Gruère and Debdatta Sengupta, "Bt cotton and farmer suicides in India: An evidence-based assessment," *The Journal of Development Studies*, vol. 47, no. 2 (February 2011), pp. 316–337.

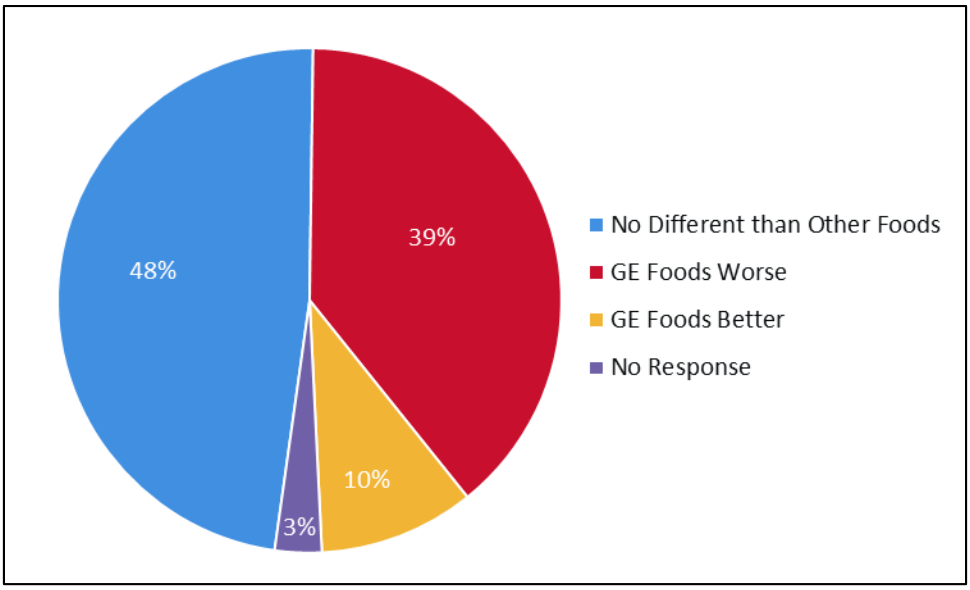
[66] Catherine Greene et al., *Economic Issues in the Coexistence of Organic, Genetically Engineered (GE), and Non-GE Crops*, ERS, EIB-149, February 2016, p. 29.

[67] Cary Funk and Brian Kennedy, *The New Food Fights: U.S. Public Divides Over Food Science*, Pew Research Center, December 1, 2016.

that appeal to intuition and emotion may be more influential than scientific evidence about GE safety.[68]

A 2014 report by USDA's ERS reviewed research on consumer acceptance of GE foods, among other issues.[69] It reported that U.S. consumers are willing to pay a premium for non-GE foods. It also concluded that information about biotechnology can influence consumer willingness to pay for GE foods. Positive information can increase willingness to pay, and negative information can decrease it.

Figure 5. Public Opinion: Health Effects of Genetically Engineered (GE) Foods (2016)



Source: Figure created by CRS from Cary Funk and Brian Kennedy, *The New Food Fights: U.S. Public Divides Over Food Science*, Pew Research Center, December 1, 2016.

Notes: Data are drawn from a survey conducted as part of the American Trends Panel, a nationally representative panel of randomly selected U.S. adults living in households, created by Pew Research Center.

Views of Agricultural Producers

Many U.S. farmers and ranchers—including a majority of those that grow commodity crops[70]—use GE biotechnology products, including GE seeds and animal feed made with GE grains. Other farmers and ranchers, including organic farmers, avoid GE agricultural products. Economic factors may influence agricultural producers' views and use of GE versus non-GE products. For example, farmers who use GE products may do so because they are cost effective for their circumstances, while organic farmers who do not use GE products may receive a price premium for non-GE certification. Producer associations that advocate on behalf of U.S. farmers and ranchers have expressed different views of biotechnology through their statements on specific issues and policy platforms. Some of these views are discussed below.

[68] See, for example, Stefaan Blancke, "Why People Oppose GMOs Even Though Science Says They Are Safe," *Scientific American*, August 18, 2015, at https://www.scientificamerican.com/article/why-people-oppose-gmos-even-though-science-says-they-are-safe.

[69] Fernandez-Cornejo et al., *GE Crops in the United States*, 2014.

[70] Fernandez-Cornejo et al., *GE Crops in the United States*, 2014.

Crop Producers

The American Soybean Association (ASA) and the National Corn Growers Association (NCGA) maintain biotechnology as a "key issue."[71] Both organizations support efforts to update the federal regulatory system for biotechnology products, including USDA's 2020 regulatory revision that largely exempts genome-edited agricultural products from regulatory review.[72] Since 2007, ASA has maintained a Biotechnology Working Group as a forum for soybean farmers and technology providers. United Fresh Produce Association, which represents stakeholders from across the produce industry (e.g., retailers, distributors, industry associations, researchers), has also expressed support for updating USDA's regulation of GE plants and federal standards for disclosing the GE status of foods.[73]

Livestock and Producers

In 2019, the National Pork Producers Council (NPPC) launched its "Keep America First in Agriculture" campaign in support of genome editing in livestock.[74] This campaign advocates for revisions to the U.S. regulatory system to facilitate the use of genome editing in livestock and "enabl[e] America's farmers to remain competitive in the global market."[75] The National Cattleman's Beef Association (NCBA) opposes the labeling of meat products solely because the livestock consumed GE feed, and it supports moving regulation of GE livestock from FDA to USDA.[76]

Seafood Industry

The GE salmon known as AquAdvantage salmon was first developed in 1989; in 2015, it became the first GE animal approved by FDA for food use (see also "Animals"). AquaBounty, the company that developed the AquAdvantage salmon, describes these salmon as "fresh, healthy and affordable Atlantic salmon that's ready to feed – and change – the world."[77] Some Members of Congress have raised concerns about GE salmon. They have challenged the FDA approval process,[78] proposed legislation requiring the labeling of GE salmon,[79] and added provisions into annual appropriations legislation to require their labeling.[80]

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[71] American Soybean Association (ASA), "Biotechnology," at https://soygrowers.com/key-issues-initiatives/key-issues/biotechnology/; and National Corn Growers Association (NCGA), "Biotechnology," at https://ncga.com/key-issues/other-topics/biotechnology.

[72] ASA, "ASA Pleased with USDA Final Rule on Biotech Crop Approval," press release, May 15, 2020; and NCGA, "NCGA Commends USDA Rule Updating Biotech Regulation Process," press release, May 15, 2020.

[73] United Fresh Produce Association, "Biotechnology," at https://www.unitedfresh.org/advocacy/biotechnology.

[74] National Pork Producers Council (NPPC), "NPPC Launches 'Keep America First in Agriculture Campaign," press release, June 25, 2019; and NPPC, "Keep America First in Agriculture," at https://nppc.org/kafa.

[75] Ibid.

[76] National Cattleman's Beef Association (NCBA), *2021 Policy Book*, January 2021.

[77] AquaBounty, "About Us," at https://aquabounty.com/about-us (accessed March 24, 2021).

[78] See, for example, letter from eight Senators to FDA Commissioner Margaret Hamburg, July 15, 2011; and letter from 15 U.S. Representatives to FDA Commissioner Margaret Hamburg, July 15, 2011, at https://donyoung.house.gov/uploadedfiles/fish_letter_final_final.pdf.

[79] FDA approved AquAdvantage salmon before the enactment of the National Bioengineered Food Disclosure Standard (the Standard), and they are not required to be labeled under the Standard. Proposed legislation that would have required GE labeling of salmon regardless of when it was approved included H.R. 270, H.R. 1103, and S. 282.

[80] For example, §778 of the Consolidated Appropriations Act, 2021 (P.L. 116-260) requires that "the acceptable market name of any engineered animal approved prior to the effective date of the National Bioengineered Food Disclosure

Organic Agriculture

Various groups representing the organic sector advocate on policies related to genetic engineering in agriculture. USDA's National Organic Program (NOP),[81] and other organic certification programs, exclude any practices or inputs involving genetic engineering or GE products. The Organic Trade Association, which represents organic farmers, retailers, and others involved in organic trade, issued a 2011 policy position that calls for a moratorium on GE organisms in agriculture, supports mandatory labeling of GE products, and commits to continued advocacy on other issues related to genetic engineering.[82] CCOF (California Certified Organic Farmers), an organic-certifying entity and trade association, opposes the use and new approvals of GE agricultural products and supports GE labeling.[83] Policy positions of the National Organic Coalition, which consists of member organizations that represent organic stakeholders, support the prohibition of synthetic biology and genome editing in organic production, criticize the National Bioengineered Disclosure Standard as insufficiently transparent to consumers (see "GE Labeling"), and express concern over the unintentional introduction of GE traits into organic products through gene flow (e.g., pollen transfer) from GE crop fields.[84]

Advocacy Organizations

Numerous advocacy organizations, including Greenpeace, Friends of the Earth, the Center for Food Safety, and Food and Water Watch, have managed long-running campaigns against agricultural genetic engineering.[85] These campaigns publish information questioning the safety, commercial interests, and ethics of GE products, and they have raised legal challenges to biotechnology applications.

Other organizations, including the Biotechnology Information Organization (BIO, a trade organization founded in 1993) and the International Service for the Acquisition of Agri-biotech Applications (ISAAA, an international nonprofit organization founded in 1992), have promoted the use of biotechnology. These organizations publish data on the global use of agricultural biotechnology and information promoting the safety, economic value, and other perceived advantages of biotechnology applications.

Some have argued that funding for advocacy on the part of pro-biotechnology or anti-biotechnology organizations polarizes the debate.[86] The Genetic Literacy Project (GLP), a

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Standard (February 19, 2019) shall include the words 'genetically engineered' prior to the existing acceptable market name."

[81] 7 C.F.R. §205.105. For more information on USDA's National Organic Program (NOP), see USDA, AMS, "National Organic Program," at https://www.ams.usda.gov/about-ams/programs-offices/national-organic-program.

[82] Organic Trade Association (OTA), "Organic Trade Association's Position on GMOs," July 28, 2011, at https://ota.com/organic-trade-association%E2%80%99s-position-gmos (accessed March 24, 2021).

[83] CCOF (California Certified Organic Farmers), "Genetically Modified Organisms/Genetic Engineering," at https://www.ccof.org/policy-advocacy/genetically-modified-organismsgenetic-engineering (accessed March 24, 2021).

[84] National Organic Coalition, "Genetic Engineering," at https://www.nationalorganiccoalition.org/genetic-engineering (accessed March 24, 2021).

[85] See, for example, Greenpeace, "GMOs and Toxic Pesticides," at https://www.greenpeace.org/usa/sustainable-agriculture/issues/gmos; Friends of the Earth, "Genetic Engineering," at https://foe.org/projects/genetic-engineering/?issue=8; Center for Food Safety, "GE Foods," at https://www.centerforfoodsafety.org/issues/311/ge-foods; and Food and Water Watch, "GMOs," at https://www.foodandwaterwatch.org/problems/gmos.

[86] See, for example, Lisa Cornish, "Understanding the Continued Opposition to GMOs," *Devex*, January 22, 2018, at https://www.devex.com/news/understanding-the-continued-opposition-to-gmos-91888; and Lisa Cornish, "How do corporations perceive their role in the GMO debate?," *Devex*, May 11, 2018, at https://www.devex.com/news/how-do-

nonprofit organization that publishes information and commentary about genetic engineering,[87] compiles and publishes data on the funding of anti-biotechnology organizations and pro-biotechnology industry.[88]

U.S. Regulatory System's Coordinated Framework

With a few exceptions, the U.S. regulatory system for the products of biotechnology has changed little since it was established in 1986. At that time, no GE products were commercially available, and modern biotechnology was viewed as an "infant industry."[89] The regulatory system discussed below adapted existing laws—which provided regulatory authorities to three primary federal agencies—to a new purpose: ensuring the safety of biotechnology products produced with then-known and anticipated future technologies and techniques. As new biotechnology approaches and applications have arisen in the decades since the original system was put in place, the federal government has revisited this system through individual agency actions and interagency initiatives coordinated by the White House Office of Science and Technology Policy (OSTP).

The federal government's 1986 *Coordinated Framework for Regulation of Biotechnology* (Coordinated Framework) governs how USDA, FDA, and the U.S. Environmental Protection Agency (EPA) apply existing statutes to evaluate and ensure the safety of biotechnology products (**Figure 6**).[90] A key principle of the Coordinated Framework is to regulate products according to their characteristics and unique features rather than the processes used to develop them—that is whether or not they were developed with biotechnology. This approach contrasts with the approach of some other countries—notably EU countries—that regulate products differently, depending on whether or not they were developed with biotechnology. These countries apply the *precautionary principle*, according to which a product should not be approved for use so long as there is scientific uncertainty regarding the risks that it may pose (see text box, next page).

OSTP updated the Coordinated Framework in 1992 and 2017.[91] These updates provided further policy guidance to federal agencies and summarized the statutes under which they regulate biotechnology products.

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corporations-perceive-their-role-in-the-gmo-debate-92507.

[87] For additional information on the GLP, see GLP, "Mission, Financial Transparency, Governorship, and Editorial Ethics and Corrections," at https://geneticliteracyproject.org/mission-financials-governorship/. This web page states,

> the GLP's goal, through our website and outreach efforts, including the dissemination of educational materials, organizing public and private conferences and initiating briefings with regulators and government officials, is to prevent legislative overreach grounded in ideology rather than science, help in the creation of reasonable ethical and religious oversight of biotechnological innovation, and encourage cooperation among academic and industry researchers, all in an effort to promote the public interest.

[88] GLP, "Anti-GMO Advocacy Funding Tracker," at https://anti-gmo-advocacy-funding-tracker.geneticliteracyproject.org.

[89] Executive Office of the President (EOP), Office of Science and Technology Policy, "Coordinated Framework for Regulation of Biotechnology," 51 *Federal Register* 23302, June 26, 1986.

[90] Ibid; and FDA, "Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology; Public Meeting," 51 *Federal Register* 23302, June 26, 1986. For a compilation of information and resources about U.S. biotechnology regulation, see USDA, FDA, and EPA, "The Unified Website for Biotechnology Regulation," at https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/resources/faq/unified_biotech_faqs.

[91] EOP, OSTP, "Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment," 57 *Federal Register* 6753, February 27, 1992; and OSTP,

Genetically Engineered Regulatory Principles of the United States vs. the European Union

The United States and the EU apply contrasting approaches to the regulation of biotechnology and tolerance of associated risks. The U.S. approach is *product-based*, while the EU approach is *process-based*, as described below. Fundamental differences in the principles that guide these approaches drive much of the global debate around biotechnology products in commerce. Regulatory systems may differ among countries, but the guiding principles underlying these systems are likely to align more closely with the principles of either the United States or the EU.

United States: Principles of the *Coordinated Framework for Regulation of Biotechnology*

The U.S. regulatory approach is product-based. It endeavors to evaluate the risks of new products with the same laws, and to the same standards of risk, irrespective of whether the product was developed with biotechnology. The Coordinated Framework relies on the following principles, among others, as quoted from the 1992 update to the framework:

- Federal oversight "focuses on the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created."
- "Exercise of oversight [by federal agencies] in the scope of discretion afforded by statute should be based on the risk posed by the introduction and should not turn on the fact that an organism has been modified by a particular process or technique."
- "In order to ensure that limited Federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, oversight will be exercised only where the risk posed by the introduction is unreasonable, that is, when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed."

In practice, federal agencies have promulgated regulations specific to genetically engineered (GE) organisms using authorities provided by preexisting statutes. While some have lauded this approach as evidence-based and supportive of innovation, others have argued that it is insufficiently cautious and ignores risks associated with uncertainty.

EU: The Precautionary Principle

The European regulatory approach is process-based. It evaluates the risks associated with new products differently, depending on whether or not they were produced with biotechnology. The European Commission's 2001 *GMO Directive* (Directive 2001/18/EC), which regulates the deliberate release of GE organisms into the environment, is guided by the *precautionary principle*. The European Commission does not define this principle but described it in a 2000 *Communication from the Commission on the Precautionary Principle*:

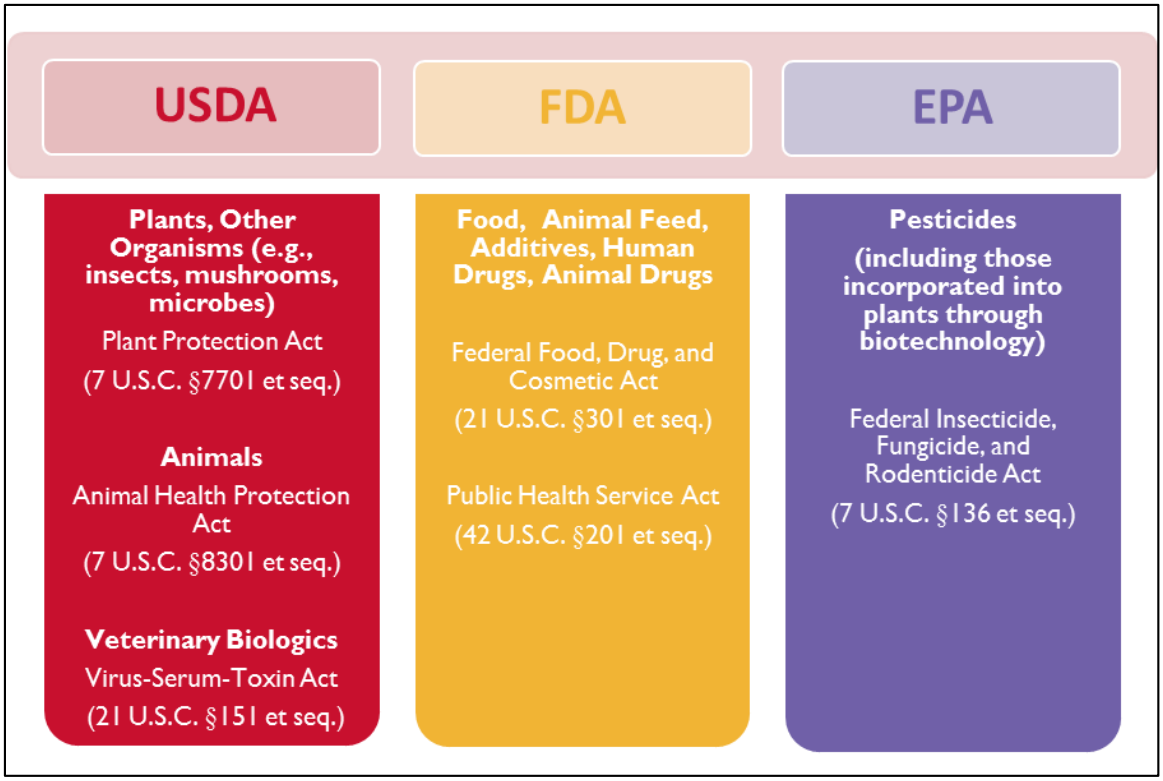
- "Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*: *proportional* to the chosen level of protection, *non-discriminatory* in their application, *consistent* with similar measures already taken, *based on an examination of the potential benefits and costs* of action or lack of action ... , *subject to review*, in the light of new scientific data, and *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment."

In practice, the precautionary principle has been interpreted to mean that a biotechnology product should not be approved for use so long as there is scientific uncertainty regarding risks (e.g., societal, environmental) that it may pose. While some have lauded this approach as protective of people and the environment, others have argued that it is not evidence-based and does not account for risks associated with not approving such products.

Within the broader Coordinated Framework, the jurisdiction of the various agencies depends on how the GE products are used. Jurisdiction, authorizing statutes, regulations, and other issues are discussed below for USDA, FDA, and EPA, with respect to GE agricultural products. In practice, all three agencies have more detailed procedures than described below for monitoring and approving the development and commercialization of GE crops and foods, particularly for new uses (e.g., pharmaceuticals). The fundamental guiding policy assumption since 1986 has been that biotechnology processes, such as genetic engineering, pose no unique or special risks; therefore, the general framework demands no new laws beyond those already governing the health, safety, efficacy, and environmental impact of more traditional production methods.

"Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology," January 4, 2017.

Figure 6. Primary Legislative Authorities of Federal Biotechnology Regulation



Source: Figure created by CRS.

Notes: The *Coordinated Framework for Regulation of Biotechnology* incorporates provisions in statutes beyond the primary statutes identified in this figure.

U.S. Department of Agriculture

Two USDA agencies engage in the Coordinated Framework: the Animal and Plant Health Inspection Service and the Food Safety Inspection Service (FSIS). APHIS regulates new plants and other organisms according to their plant-pest and noxious weed risks; biotechnology products that are animal pests or may cause disease in livestock; and veterinary biologics. FSIS regulates food products prepared from domestic livestock and poultry.

Animal and Plant Health Inspection Service

APHIS regulates agricultural biotechnology with respect to both plant and animal health.

Plant Health

USDA's primary engagement with the regulation of biotechnology has been through APHIS's oversight of GE plants under the Plant Protection Act (PPA, 7 U.S.C. §7701 et seq.). Under the PPA, APHIS regulates the importation, interstate movement, and environmental release (including field testing) of GE plants and organisms that do or may pose a plant-pest risk. *Plant-pest risk* refers to the potential for injury, damage, or disease in any plant or plant product resulting from introducing or disseminating a plant pest or the potential to exacerbate a plant pest's impact. APHIS's PPA regulations for GE organisms (7 C.F.R. §340) define *regulated articles* (i.e., the organisms subject to these PPA regulations; most are plants), processes to

determine whether they are regulated, and how APHIS regulates them. In 2020, APHIS finalized a rule updating these regulations.

Prior to 2020, APHIS assessed the plant-pest risk of every new GE variety, regardless of how similar it was to a GE variety that APHIS had evaluated in the past.[92] Product developers could seek an APHIS determination of whether a new organism met the definition of *regulated article* through the APHIS "Am I Regulated?" process. Regulated articles required either permits for their importation, interstate transportation, or environmental release or use of a notification process in lieu of permits when the plant was not considered a noxious weed and met other standards. Regardless of the process used, after testing was completed, a developer could seek nonregulated status from APHIS, the typical route to full commercialization and no further formal oversight. In seeking nonregulated status, the developer was required to provide APHIS with extensive information on plant biology and genetics and potential environmental and plant-pest impacts that could result from the modification. APHIS would conduct a formal environmental assessment under the National Environmental Protection Act (42 U.S.C. §4321 et seq.) and hold a public comment period before deciding whether to grant nonregulated status. A determination of nonregulated status ended further federal regulatory oversight of the GE plant or other organism.

In 2019, APHIS issued a proposed rule to exempt several categories of GE plants from regulatory review under the PPA, citing 30 years of evidence indicating that "genetically engineering a plant with a plant pest as a vector, vector agent, or donor does not in and of itself result in a GE plant that presents a plant pest risk."[93] The proposed rule further stated that new genetic engineering technologies, such as genome editing, do not engage with plant pests in any way.[94] APHIS finalized this "SECURE Rule," in May 2020.[95]

Unlike the prior regulations, USDA's SECURE rule does not require that APHIS assess the risk of every new GE variety. It applies APHIS's current understanding of plant-pest risk to exempt broad categories of new plants from review:

> APHIS' evaluations to date have provided evidence that genetically engineering a plant with a plant pest as a vector, vector agent, or donor does not result in a GE plant that presents a plant pest risk. Further, genetic engineering techniques have been developed that do not employ plant pests … yet may result in organisms that do pose a plant pest risk.

The new regulations identify certain categories of modified plants that are exempt from the regulations.[96] These include plants that APHIS considers could have been developed through conventional breeding (e.g., certain genome-edited varieties) and those that bear sufficient similarity to GE plants for which APHIS has previously granted nonregulated status or determined not to be regulated. Developers can request a written confirmation from APHIS that a plant is not subject to the regulations. Plants that are not exempt must undergo a regulatory status

[92] For example, under the regulations effective prior to the SECURE Rule, the same gene introduced into two different varieties of corn required separate APHIS assessments.

[93] APHIS, "Movement of Certain Genetically Engineered Organisms," 84 *Federal Register* 26514, June 6, 2019.

[94] Under the proposed rule change, APHIS may evaluate new plant varieties created through gene editing for noxious weed risk.

[95] USDA, "Movement of Certain Genetically Engineered Organisms," 85 *Federal Register* 29790, May 18, 2020. SECURE stands for Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient. For additional information, see CRS In Focus IF11573, *USDA's SECURE Rule to Regulate Agricultural Biotechnology*, by Genevieve K. Croft and Tadlock Cowan.

[96] Only plants, not other organism types, can be exempt.

review, which replaces the prior petition process. This review is followed by a new permitting process, which replaces the prior notification process.

Animal Health

Statutes cited in the Coordinated Framework also give APHIS regulatory oversight over biotechnology products that are animal pests or may cause disease in livestock and veterinary biologics (e.g., viruses, serums, toxins for animal vaccines). Under the Animal Health Protection Act (AHPA, 7 U.S.C. §8301 et seq.), APHIS has the authority to restrict or prohibit the importation, transportation, or environmental release of any live animal—including GE and non-GE animals—to prevent the introduction and spread of pests and diseases of livestock.[97] Under the Virus-Serum-Toxins Act (VSTA, 21 U.S.C. §151 et seq.), APHIS has the authority to ensure that veterinary biologics—including GE and non-GE-derived biologics—are pure, safe, potent, and effective. APHIS licenses and continues oversight of veterinary biologics.

Food Safety Inspection Service

Within the Coordinated Framework, FSIS's authority to regulate GE products derives from three statutes: the Federal Meat Inspection Act (FMIA, 21 U.S.C. §601 et seq.), the Poultry Products Inspection Act (PPIA, 21 U.S.C. §451 et seq.), and the Egg Products Inspection Act (EPIA, 21 U.S.C. §1031 et seq.). Under these statutes, FSIS has the authority to review the safety, wholesomeness, and correct labeling of meat, catfish, poultry, and processed egg products intended for human consumption.

Federal Drug Administration

FDA regulates food, animal feed additives, and human and animal drugs, primarily under the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. §301 et seq.) and the Public Health Service Act (PHSA, 42 U.S.C. §201 et seq.). FDA's regulation is intended primarily to ensure that these foods and drugs pose no risks to human health. FDA regulations include oversight of plants, animals, and other organisms produced with biotechnology.

Plants

Under the FFDCA, all food and feed manufacturers must ensure that the domestic and imported products they market are safe and properly labeled. All domestic and imported foods and feeds must meet the same standards, whether or not they are derived from GE plants. Under the FFDCA, FDA must approve any food additive before it can be marketed, unless the additive is *generally recognized as safe* (GRAS).[98]

A May 1992 FDA policy statement clarified FDA policy with respect to foods derived from GE plants.[99] FDA treats most foods derived from GE plants as GRAS, unless the product or products

[97] Under the Animal Health Protection Act (AHPA), *animal* is defined as "any member of the animal kingdom (except a human)" (7 U.S.C. §8302(1)), and *livestock* is defined as "all farm-raised animals" (7 U.S.C. §8302(10)). In this context, animal may be interpreted to include mammals, birds, insects, and other animals, and livestock may be interpreted to include horses, cattle, bison, cervids, camelids, sheep, goats, swine, and other farm-raised animals.

[98] For more information on GRAS, see FDA, "Generally Recognized as Safe (GRAS)," at https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras.

[99] FDA, "Statement of Policy – Foods Derived from New Plant Varieties," 57 *Federal Register* 22984, May 29, 1992; and FDA, "Guidance for Industry: Consultation Procedures under FDA's 1992 Statement of Policy for Foods Derived

that the plant expresses due to GE changes (e.g., proteins, carbohydrates, fats) "differ significantly in structure, function or composition from substances found currently in food."[100] Such substances may be GRAS, or they may be considered to be food additives. The 1992 policy statement noted that foods and feeds from GE plants must undergo a special review under certain conditions. These include if the GE plant would be used to host an industrial or pharmaceutical substance or if the change introduced through genetic engineering produces unexpected genetic effects, changes nutrients or toxicant levels from levels in the food's traditional variety, or might introduce a new allergen.

FDA encourages sponsors of foods and feeds derived from GE plants to participate in its voluntary Plant Biotechnology Consultation Program to help these sponsors with regulatory compliance.[101] GE plant developers have routinely participated in this program since the first such consultation in 1994. In 2019, FDA concluded its first consultation on a plant genetically engineered via genome editing. With few exceptions, the foods and feeds that FDA has reviewed have not been considered to contain a food additive and thus have not required FDA approval prior to marketing.

In June 2006, FDA published new guidance under which developers of new plant varieties intended for food use—including those that are genetically engineered—can provide FDA with any information about new proteins they are using in the early stages of crop development.[102] This Early Food Safety Evaluation Program (also known as a New Protein Consultation) is designed to take place earlier in the development process than a voluntary plant biotechnology consultation and prior to the stage of development when a new protein might "inadvertently" enter the food supply. FDA designed this early consultation to address the possibility that field testing of GE crops—through cross-pollination with other crops—could inadvertently introduce small amounts of proteins into the food supply that FDA has not evaluated (e.g., potential toxins or allergens).

Animals

FDA has regulated GE animals under the new drug provision of the FFDCA (21 U.S.C. §360b) since issuing final guidance on the topic in 2009.[103] The 2009 policy identifies the regulated article (the new animal drug) as "the rDNA construct in a GE animal that is intended to affect the structure or function of the body of the GE animal, regardless of the intended use of products that may be produced by the GE animal." That is to say, the DNA inserted into the animal's genome through genetic engineering is considered a new animal drug. Developers of GE animals and GE-derived animal products must obtain FDA new animal drug approval before these animals and products can be marketed and sold.

from New Plant Varieties," October 2017.

[100] FDA, "Statement of Policy – Foods Derived from New Plant Varieties," 57 *Federal Register* 22984, May 29, 1992.

[101] For more information on FDA's Plant Biotechnology Consultation Program, see FDA, "Consultation Programs on Food from New Plant Varieties," at https://www.fda.gov/food/food-new-plant-varieties/consultation-programs-food-new-plant-varieties.

[102] FDA, "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use," 71 *Federal Register* 35688, June 21, 2006.

[103] FDA, "Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs," Guidance for Industry #187, 74 *Federal Register* 3057, January 16, 2009.

In 2017, FDA issued draft guidance for industry on the "Regulation of Intentionally Altered Genomic DNA in Animals."[104] This draft guidance updates the prior guidance, in which the regulated article was the recombinant DNA construct, to define the regulated article as the "intentionally altered genomic DNA." FDA describes *intentional genomic alterations* (IGAs)—a term that FDA seemingly coined—as including genetic changes introduced through biotechnology techniques that use recombinant DNA, as well as those techniques that do not. This guidance expands FDA oversight of GE animals to include those derived from genome editing. It also clarifies that FDA intends to exercise enforcement discretion, including its intention not to enforce certain requirements for animals of nonfood producing species that (1) are regulated by other government agencies; (2) are raised and used in contained and controlled conditions; or (3) other cases based on FDA evaluation of risk factors. Such GE animals include GE insects regulated by APHIS, GE laboratory animals, and, in a specific example, GloFish (aquarium fish genetically engineered to fluoresce).[105]

FDA also has addressed the regulation of animal cloning. In 2008, FDA released a final risk assessment and industry guidance on the safety of meat and milk from cloned cattle, pigs, and goats, as well as their offspring.[106] This guidance found that such products are as safe to eat as those of conventionally bred animals. FDA also concluded that cloning poses the same risks to animal health as those found in animals created through other assisted reproductive technologies, although the frequency of such problems is higher in cloned animals. FDA does not require premarket approval of food products from cloned cattle, swine, or goats or their offspring.

Environmental Protection Agency

EPA registers and approves the use of all plant pesticides, including those incorporated through genetic engineering (i.e., *plant-incorporated protectants*, or PIPs), under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA, 7 U.S.C. §136 et seq.). EPA uses this process to determine a PIP's environmental safety. EPA also regulates pesticides with respect to human health. Under the FFDCA, EPA establishes tolerances (i.e., safe levels) for pesticides in foods. Pre-commercial regulation occurs through a system of notifications (for small-scale field-tests) or experimental use permits (for larger field-tests). As with any pesticide, EPA requires the manufacturer of a PIP to obtain a registration through a regulatory process intended to ensure its safe use environmentally.

Pending Proposal: The Regulation of GE Animals

As of the writing of this report, FDA regulates animal biotechnology under the FFDCA. The original 1986 Coordinated Framework anticipated that (1) GE food animals would be regulated by FSIS under the FMIA and PPIA, (2) many GE animals would not differ substantially from non-GE animals, and (3) these animals would be subject to the same inspection procedures and regulations as non-GE animals. In 2009, FDA issued guidance on its regulation of GE animals

[104] FDA, "Regulation of Intentionally Altered Genomic DNA in Animals," Draft Revised Guidance for Industry #187, 82 *Federal Register* 6561, January 19, 2017.

[105] For information on intentional genomic alterations (IGAs) in animals for which FDA has used enforcement discretion, including GloFish, see FDA, "Intentional Genomic Alterations in Animals: Enforcement Discretion," at https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/intentional-genomic-alterations-animals-enforcement-discretion.

[106] FDA, "Use of Animal Clones and Clone Progeny for Human Food and Animal Feed," Guidance for Industry #179, 73 *Federal Register* 2923, January 16, 2008.

and animal products under the new animal drug provision of the FFDCA (see "Federal Drug Administration"), identifying the recombinant DNA construct as the new animal drug. Nonetheless, developers of GE animals and of GE-derived products must gain FDA premarket approval.

In December 2020, USDA issued an advance notice in the *Federal Register*, proposing a framework to move the regulation of certain animals genetically engineered for agricultural purposes from FDA to USDA.[107] In January 2021, USDA and the U.S. Department of Health and Human Services (HHS) signed a memorandum of understanding (MOU). In this MOU, USDA committed to establishing new regulatory programs for premarket and post-market review of GE agricultural animals through federal rulemaking, using its authorities under the APHA, FMIA, and PPIA. FDA committed to continuing its regulatory oversight of genetic engineering in animals for nonagricultural purposes and certain other products, including dairy, table and shell eggs, and certain meat products. USDA and FDA committed to working together to achieve comprehensive regulatory oversight.

These proposals were put forward in the final weeks of the Trump Administration, over the objections of the then-commissioner of FDA.[108] As of the writing of this report, it remains to be seen whether these proposals will be implemented.

Defining Boundaries of GE and Non-GE Products

In some cases, the GE status of an agricultural product may be unclear, due to inadvertent comingling of GE and non-GE material or unresolved questions regarding the regulatory treatment of new and emerging technologies. Treatment of the low-level presence of GE material in otherwise non-GE food, feed, and grains, and the regulation of genome-edited products, are discussed below. These issues are relevant to both domestic commerce and international trade (see also "Biotechnology and Global Trade").

Low-Level Presence of GE Material

Low-level presence (LLP) refers to any incidental appearance of very small amounts of foreign material in a food, feed, or grain, which can occur at any time during production, harvesting, storage, or marketing. Presently in the U.S. grain business, even shipments of the highest grades are permitted to contain some specified low levels of unwanted material, such as weeds, damaged kernels, and leaves. For example, U.S. grain standards permit corn graded No. 1 to contain up to 2% foreign material.[109] In the context of biotechnology, LLP and the similar term *adventitious presence*, refer to the unintended inclusion of GE material in otherwise non-GE commercial food, feed, or grain.[110] This incidental inclusion is known as LLP when the GE source has been authorized for use in food, feed, or grain (in at least one country when the concern involves international trade) and as adventitious presence when the GE source has not been authorized

[107] USDA, "Regulation of the Movement of Animals Modified or Developed by Genetic Engineering," 85 *Federal Register* 84269, December 28, 2020. FDA found that insufficient information was available to make a determination on cloned sheep, and it did not examine other animals.

[108] See Sarah Owermohle and Adam Cancryn, "FDA Fights for Independence in Trump Administration's Final Days," *Politico*, January 12, 2021.

[109] 7 C.F.R. §810.404.

[110] See, for example, APHIS, "APHIS Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Materials," 72 *Federal Register* 14649, March 20, 2007.

(e.g., contamination from a field trial of a GE crop that has not yet received regulatory approval).[111]

As more crops and acreage are devoted to GE varieties, it becomes increasingly difficult to avoid their trace presence in non-GE varieties. Beyond setting thresholds and developing testing protocols, a related issue is assessing liability if such mixing occurs or if GE plants prove harmful to the environment. For example, to what extent, if any, should biotechnology companies share liability with producers and others who use their products? This is an ongoing issue for U.S. exports (see "Biotechnology and Global Trade").

APHIS published a notice in the *Federal Register* in March 2007, describing its policy on responding to the LLP of regulated GE plant materials in commercial seed or grain that might be used for food or feed. Under this policy, an LLP event would not be subject to regulatory action unless APHIS determines that it is likely to result in the introduction or dissemination of a plant pest or noxious weed.[112]

Regulation of Genome-Edited Products

Since the emergence of CRISPR-Cas9 in 2013, and its rapid adoption as an efficient and targeted genome editing technique, questions have arisen regarding its place within regulatory systems that assess the safety of foods developed with biotechnology. Some have proposed that products of genome editing in agriculture should not be regulated as GE products and should be treated in the same manner as the products of conventional breeding.[113] Some of these advocates have argued that because genome editing does not necessarily require the use of recombinant DNA, which defines the products of genetic engineering in some policies and regulations, it does not meet the definition of genetic engineering. Others have stated that the changes induced by genome editing could otherwise be found in nature or produced through conventional breeding, albeit on a much longer timeline, and thus genome-edited products do not pose the same potential risks as GE products. Further arguments state that because genome editing is more precise and targeted than other forms of biotechnology, it is safer.

In contrast, some have proposed that genome-edited organisms should be regulated in the same manner as GE organisms.[114] Some of these advocates have argued that genome-edited organisms may experience unintended genetic changes or demonstrate unexpected interactions with the environment, and close regulatory oversight is necessary to ensure they are safe.

Beyond these questions, concerns have been raised about the technical ability to detect genome editing in agricultural products and how such challenges may affect regulatory enforcement.[115]

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[111] See Food and Agriculture Organization (FAO), *Technical Consultation on Low Levels of Genetically Modified (GM) Crops in International Food and Feed Trade*, Technical Background Paper 2, TC-LLP/2014/3, March 20-21, 2014, p. 5.

[112] APHIS, "APHIS Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Materials," 72 *Federal Register* 14649, March 29, 2007.

[113] See, for example, Biotechnology Innovation Organization (BIO), *Issue Brief: Plant Genome Editing*, at https://archive.bio.org/genome-editing/plant-animal-genome-editing/issue-brief-plant-genome-editing; and BIO, *Issue Brief: Animal Genome Editing*, at https://archive.bio.org/genome-editing/plant-animal-genome-editing/issue-brief-animal-genome-editing.

[114] See, for example, Janet Cotter and Dana Perls, *Gene-Edited Organisms in Agriculture: Risks and Unexpected Consequences*, Friends of the Earth and Logos International, September 2018.

[115] Joachim Schiemann et al., "Editorial: Plant Genome Editing – Policies and Governance," *Frontiers in Plant Science*, vol. 11, no. 284 (March 11, 2020).

Within the federal government, USDA and FDA have taken different approaches to the regulation of genome-edited agricultural products (see "U.S. Regulatory System's Coordinated Framework"). Whereas USDA's 2020 revision of its biotechnology regulations under the Plant Health Act largely exempts genome-edited plants,[116] FDA's 2017 draft guidance on the regulation of animals developed through biotechnology expanded its oversight of GE animals under the FFDCA's new animal drug provision to include genome-edited animals.[117]

GE Labeling

Consumer groups have long advocated for the labeling of GE foods, arguing that consumers should have the opportunity to see the GE status of their food and make food choices based on their own views about its perceived quality or safety. Many in the food and biotechnology industries have opposed mandatory GE labeling. Among other concerns, they contended that consumers might interpret GE labels as "warning labels," implying that the foods are less safe or nutritious than conventional foods, despite scientific evidence indicating otherwise. The 2016 enactment of P.L. 114-216 (the 2016 Act) established the National Bioengineered Food Disclosure Standard (the Standard), marking the first time the United States would require some form of *GE labeling*, or on-package disclosure of GE foods or food ingredients.[118] USDA's Agricultural Marketing Service (AMS) is responsible for the Standard (see "Mandatory Labeling: The National Bioengineered Food Disclosure Standard"). Along with this mandatory standard, various voluntary food labeling programs address consumer demand for information about the GE content of food. These include public and private initiatives that directly or indirectly certify the absence of GE food and food ingredients. Federal responsibilities for food labeling, as well as several existing GE labeling approaches, are discussed below.

Federal Responsibility for Food Labeling

FDA and USDA (through FSIS) are the primary federal authorities responsible for assuring that foods sold in the United States are safe, wholesome, and properly labeled (neither false nor misleading).[119] FDA released a policy statement on GE foods in 1992, indicating that in most cases, these foods are "substantially similar" to non-GE foods and do not require additional regulation or labeling beyond what is required for comparable non-GE foods.[120] A legal decision in 2000 upheld this policy.[121] FDA requires labeling of GE foods that (1) have nutritional characteristics that differ from comparable non-GE foods, (2) contain GE material from known allergenic sources, or (3) have elevated levels of toxic compounds. This labeling is required to identify the different characteristic and is not required to indicate the GE status of the food. Prior

[116] USDA, "Movement of Certain Genetically Engineered Organisms," 85 *Federal Register* 29790, May 18, 2020.

[117] FDA, "Regulation of Intentionally Altered Genomic DNA in Animals," Draft Revised Guidance for Industry #187, 82 *Federal Register* 6561, January 19, 2017.

[118] A *disclosure* may be a discrete statement or symbol; a *label* may provide more comprehensive information about a product. This report may use *labeling* as a proxy for *disclosure*.

[119] For more information, see CRS In Focus IF10650, *Understanding Process Labels and Certification for Foods*.

[120] FDA, "Statement of Policy: Foods Derived from New Plant Varieties," 57 *Federal Register* 22984, May 29, 1992. Through this document, FDA permitted voluntary labeling to indicate that foods have or have not derived from GE plants or animals. For updated draft guidance documents, see FDA, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, Regulations.gov, FDA-2000-D-0075-0017, updated March 3, 2019; and FDA, *Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon: Guidance for Industry*, Regulations.gov, FDA-2015-D-4272, revised March 11, 2019.

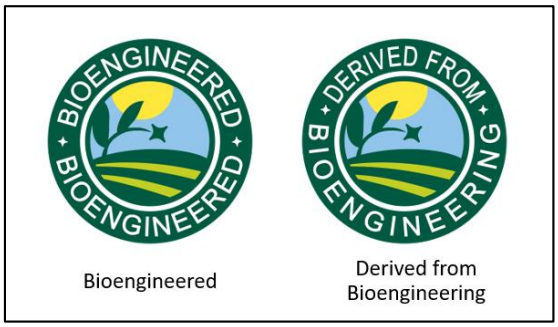
[121] Alliance for Bio-Integrity v. Shalala, 116 F.Supp.2d 166 (D.D.C. 2000).

to enactment of P.L. 114-216, the federal government did not require that GE foods be labeled as such.

Mandatory Labeling: The National Bioengineered Food Disclosure Standard

In July 2016, Congress enacted the 2016 Act (P.L. 114-216),[122] requiring USDA to establish mandatory labeling of bioengineered food products—the Standard—within two years.[123] The 2016 Act followed decades of societal debate about genetic engineering, and it marked the first time that the federal government would mandate the disclosure of the presence of GE foods to consumers (the 2016 Act and the Standard use the term *bioengineered*, which is similar to GE).[124] AMS finalized the regulations for the Standard in December 2018, and mandatory compliance begins in January 2022. The Standard requires on-package disclosure of bioengineered foods or food ingredients via options that include written text, symbol (**Figure 7**), electronic or digital link, and text message. The Standard does not apply to certain meat, poultry, and egg products (7 U.S.C. §1636a)[125] or refined products that do not contain detectable modified DNA (e.g., oils, sugars). The Standard identifies certain exemptions, including food served in restaurants, food produced by *very small food manufacturers*,[126] and food containing bioengineered substances below a threshold amount. Both

Figure 7. National Bioengineered Food Disclosure Standard Symbols



Source: Figure created by CRS from USDA, "BE Symbols," at https://www.ams.usda.gov/rules-regulations/be/symbols.

Notes: Foods that meet criteria in the Standard must display the "bioengineered" symbol. The "derived from bioengineering" symbol may be displayed on foods that do not meet the criteria but derive from bioengineered foods (e.g., refined foods that do not contain detectable modified DNA).

[122] P.L. 114-216 (2016 Act), "An Act to Reauthorize and Amend the National Sea Grant College Program Act, and for Other Purposes," enacted July 29, 2016. Congress used the reauthorization of the National Sea Grant College Program Act as a legislative vehicle to enact GE labeling legislation. The 2016 Act amended the Agricultural Marketing Act of 1946 (7 U.S.C. §1621 et seq.) to add the National Bioengineered Food Disclosure Standard (the Standard) as a new subtitle.

[123] For additional information about the 2016 Act and the subsequent USDA regulations, see CRS Report R46183, *The National Bioengineered Food Disclosure Standard: Overview and Select Considerations*, by Genevieve K. Croft.

[124] The 2016 Act defined *bioengineering* (7 U.S.C. §1639(1)), with respect to food, as a food "(A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature." Many groups interpret the Standard as not applying to foods derived from gene editing and other new technologies that do not use recombinant DNA.

[125] The Standard applies to foods subject to the Federal Meat Inspection Act (21 U.S.C. §601 et seq.), the Poultry Products Inspection Act (21 U.S.C. §451 et seq.), or the Egg Products Inspection Act (21 U.S.C. §1031 et seq.), only if the most predominant ingredient of the food (or the second-most predominant ingredient if the first is water or broth) would independently be subject to labeling requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.).

[126] The Standard defines a *very small food manufacturer* as having annual receipts under $2,500 (7 C.F.R. §66.1).

proponents and opponents of mandatory GE labeling continue to express concerns about the Standard (see "GE and Non-GE Labeling").

Voluntary Labeling Programs

Voluntary labeling programs that identify the absence of GE ingredients predate the Standard. On-package symbols from these private and public-private programs indicate to consumers that foods do not contain GE ingredients. They may either certify the absence of GE foods or food ingredients directly (i.e., the food does not contain GE ingredients) or indirectly (i.e., the food was produced according to a suite of standards that exclude genetic engineering). Food producers and manufacturers may choose to opt into these programs and to bear associated costs. The Non-GMO Project Verified label is an example of a private, voluntary labeling program that directly certifies the absence of GE foods or food ingredients.[127] Examples of voluntary labeling programs that indirectly certify the absence of GE foods or food ingredients or materials include USDA's NOP and the Global Organic Textile Standard.[128]

Biotechnology and Global Trade

Disparate global views, consumer acceptance, and legal requirements with respect to agricultural biotechnology and its products have raised global trade concerns. U.S. trade objectives and selected policy issues relevant to trade are discussed below.[129]

U.S. Trade Objectives and Trade Agreements

The United States is the leading cultivator of GE crops,[130] and market access for agricultural biotechnology products is a major U.S. trade objective.[131] These objectives include establishing a common framework for GE approvals and adoption, as well as creating labeling practices consistent with U.S. guidelines and harmonized regulatory procedures concerning GE presence in agricultural products.[132] In other countries, adoption of GE crops has been mixed.[133]

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[127] This program considers GE presence of less than 0.9% of the inputs and ingredients of "wholesale or retail goods for human or pet use that are either ingested or topically applied including OTC drugs and homeopathic remedies" to be below its "action threshold"—that is, products with GE content below this threshold are compliant with the program. See Non-GMO Project, *Non-GMO Project Standard (Version 16)*, December 30, 2020.

[128] For more information on certified organic production, see USDA, AMS, "National Organic Program," at https://www.ams.usda.gov/about-ams/programs-offices/national-organic-program; and CRS In Focus IF10278, *U.S. Farm Policy: Certified Organic Agricultural Production*, by Renée Johnson. For more information on the Global Organic Textile Standard, see Global Organic Textile Standard, "The Standard," at https://global-standard.org/the-standard.

[129] For more information on biotechnology in agricultural trade, see also CRS Report R46653, *Major Agricultural Trade Issues in the 117th Congress*, coordinated by Anita Regmi.

[130] ISAAA, *Global Status of Commercialized Biotech/GM Crops: 2018*, Executive Summary.

[131] See U.S. Trade Representative (USTR), *2021 Trade Policy Agenda and 2020 Annual Report*, March 2021; and USTR, *2020 National Trade Estimate Report on Foreign Trade Barriers*, March 2020.

[132] The United States seeks harmonization consistent with the Codex Alimentarius Commission guidelines available at FAO, "Annex 3: Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food," in *Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants*, CAC/GL 45-2003.

[133] For a review of restrictions on GE organisms in other countries, see Law Library of Congress, Global Legal Research Center, *Restrictions on Genetically Modified Organisms*, March 2014.

Several international trade agreements include provisions related to agricultural biotechnology. These provisions may focus on improving transparency and coordination in approving and bringing such products to market. The U.S.-Mexico-Canada Agreement (USMCA), for example, was the first free trade agreement to include provisions addressing agricultural products created with genome editing and other genetic engineering techniques.[134] In another example, China made commitments related to agricultural biotechnology in the U.S.-China Phase One trade agreement.[135] Despite increased attention to biotechnology concerns through trade agreements, some have questioned some countries' compliance with the terms of certain of these trade agreements.[136] Many differences remain to be negotiated, resolved, or both.[137]

Standards for Low-Level Presence of GE Material

There are no internationally recognized standards for what amounts, if any, of GE material should be permitted in non-GE commodities. In the absence of international standards—and given the increasing global sourcing of food—individual countries are establishing their own, often varying, thresholds. The biotechnology industry and other trade groups have asserted that the lack of consistent, scientifically sound standards confuses consumers and disrupts trade.[138] See "Low-Level Presence of GE Material," above.

Treatment of Genome Editing

Countries have begun to address the issue of how to regulate agricultural products developed with genome editing, and their approaches have varied.[139] For example, in 2015, Argentina became the first country to determine that it would not regulate genome-edited plants under its biosafety regulations if foreign DNA had not been introduced into the plant.[140] Since 2020, U.S. regulations have largely exempted genome-edited plants from its GE plant regulations.[141] In contrast, the European Court of Justice ruled in July 2018 that in principle, organisms deriving from genome

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[134] USTR, Chapter 3, §B in *Agreement between the United States of America, the United Mexican States, and Canada 7/1/20 Text*, at https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between.

[135] USTR, Chapter 3 in *Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China*, at https://ustr.gov/countries-regions/china-mongolia-taiwan/peoples-republic-china/phase-one-trade-agreement/text.

[136] See, for example, Letter from 192 farm groups to President Trump, June 16, 2020, available at https://www.profarmer.com/system/files/inline-files/ChinaLetterPhase1.pdf; Letter from Sen. Ron Wyden, ranking member of the Senate Committee on Finance, to President Trump, October 30, 2020. See also, Inside U.S. Trade, "Grassley: Lighthizer Prepared to Take Enforcement Action on USMCA," *World Trade Online*, November 3, 2020.

[137] See, for example, Foreign Agricultural Service, *United Kingdom: Agricultural Biotechnology Annual*, GAIN Report UK2019-0013, April 9, 2020. This required annual report is no longer available on the USDA website.

[138] See, for example, Global Alliance for Ag Biotech Trade, "Low-Level Presence," at http://www.gaabt.org/agbiotech-and-trade/low-level-presence; and CropLife, "Adventitious Presence (AP) or Low Level Presence (LLP)," fact sheet, at https://croplife.org/wp-content/uploads/pdf_files/Fact-Sheet-Adventitious-Presence-or-Low-Level-Presence.pdf.

[139] For a 2020 summary of global approaches to genome editing in agriculture, see Sarah M. Schmidt, Melinda Belisle, and Wolf B. Fromer, "The Evolving Landscape around Genome Editing in Agriculture," *EMBO Reports*, May 19, 2020. See also Genetic Literacy Project, "Global Gene Editing Regulation Tracker," at https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org.

[140] Ministry of Agriculture, Livestock, and Fisheries of Argentina, *Resolution No. 173/2015*, May 12, 2015.

[141] For additional information, see CRS In Focus IF11573, *USDA's SECURE Rule to Regulate Agricultural Biotechnology*.

editing and similar processes are within the scope the EU's existing GMO regulations.[142] As of the writing of this report, in New Zealand, genome-edited foods are regulated in the same manner as other GE foods; the country is reviewing the regulatory treatment of genome editing and other NBTs.[143]

GE Labeling Policies

Trade negotiations concerning agricultural biotechnology may also involve GE labeling issues. More than 60 countries require some form of GE labeling of food.[144] These countries include the EU countries, Australia, Brazil, China, Russia, Saudi Arabia, and others. Countries that do not require GE food labeling include Canada, Mexico, most in Africa, and most in Central and South America. Differences exist among the labeling requirements of those countries that require it, including in the types of foods that must be labeled, the threshold of GE content above which foods must be labeled, and the manner in which foods must be labeled. Countries also differ in their requirements for standards, testing, certification, and enforcement. Food products exported from the United States must be labeled in compliance with the requirements of their destinations. Similarly, U.S. importers are responsible for the compliance of their goods with the Standard (see "Mandatory Labeling: The National Bioengineered Food Disclosure Standard").[145] USDA notified this rule to the World Trade Organization (WTO), and USDA has stated that it does not expect the Standard to disrupt foreign trade.[146]

Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international agreement relating to the safe handling, transportation, and use of GE organisms. The United States is not a party to the Convention on Biodiversity; thus, it is not a party to the protocol. However, as the protocol affects U.S. exports to ratifying countries, the United States has actively participated as an observer in related negotiations and preparations for implementation.

The protocol, adopted in 2000, took effect in 2003, and more than 170 countries have signed onto it. The protocol permits a country to require formal prior notification from countries exporting biotech seeds and *living modified organisms (LMOs)* intended for introduction into the environment.[147] It requires that shipments of products that may contain LMOs, such as bulk

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[142] For additional information, see European Court of Justice, *Organisms Obtained by Mutagenesis are GMOs and are, in Principle, Subject to the Obligations Laid Down by the GMO Directive*, press release, July 25, 2018.

[143] See Food Standards Australia New Zealand, "Food derived using new breeding techniques – review," April 2020, at https://www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx; and Food Standards Australia New Zealand, *Final Report: Review of Food Derived Using New Breeding Techniques*, December 2019.

[144] For a summary of international laws, see Center for Food Safety, "International Labeling Laws," at https://www.centerforfoodsafety.org/issues/976/ge-food-labeling/international-labeling-laws. This summary may not be comprehensive.

[145] The labeling standard does not require refined products derived from bioengineered crops (e.g., refined soy oil, high-fructose corn syrup) to be labeled if the modified genetic material is not detectable in the food product.

[146] USDA, AMS, "BE Frequently Asked Questions—General," at https://www.ams.usda.gov/rules-regulations/be/faq/general. See also 7 U.S.C. §1639c(a), a provision in the act that states, "This subchapter shall be applied in a manner consistent with United States obligations under international agreements."

[147] The Cartagena Protocol on Biosafety defines a *living modified organism* as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology." It defines *modern*

grains, be appropriately labeled and documented and provides for an international clearinghouse for the exchange of LMO information, among other provisions. The protocol further establishes a process for considering more detailed identification and documentation of LMO commodities in international trade.

Issues for Congress

Biotechnology has yielded opportunities and challenges for agriculture and its stakeholders. Several policy issues have captured the attention of industry, consumer groups, and policymakers. In some respects, the key policy and regulatory issues of the coming decade may not be fundamentally new or different from the biotechnology issues of the past 20 years. Rather, certain issues are increasing in importance as the industry matures, technologies evolve, and long-standing regulatory issues take new forms. A selection of potential issues are discussed below. Congress has passed, or may consider, legislation relating to some of these issues, and it may choose to exercise its oversight responsibilities for these and other issues.

Efficacy of the Coordinated Framework

Led by OSTP, the federal government has revisited and updated the Coordinated Framework over the years since 1986. Each time, the federal government has concluded that the underlying legislation is sufficient to address the regulation of biotechnology, and these updates have clarified the roles and responsibilities of USDA, FDA, and EPA as interpreted through agency policies and regulations. The agencies have updated their policies and regulations over the years as new issues have arisen, largely in consultation with each other. Recent concerns regarding the regulation of the products of new technologies, regulation and oversight of biotechnology in agricultural animals, and labeling foods with respect to their GE status have challenged this coordinated system. Congress may choose to exercise its oversight, appropriations, and legislative authorities with respect to these concerns.

Regulation of New Technologies and New Trait Types

The development and rapid adoption of genome editing has challenged the U.S. biotechnology regulatory system. Some observers have noted that although genome editing is the current new technology of concern, scientific advancements may lead to new technologies that might pose challenges to the U.S. regulatory system.[148] New types of traits introduced into agricultural plants and animals might present regulatory questions. For example, the introduction of stacked trait varieties (i.e., plant varieties with multiple GE traits) is likely to increase and may result in GE varieties that intersect with the regulatory authorities and responsibilities of multiple federal agencies. GE traits that confer improved nutritional qualities and resistance to environmental stress (e.g., drought) might also challenge existing regulatory processes.

biotechnology as "the application of (a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection." UN Convention on Biodiversity, "Article 3. Use of Terms," in *Cartagena Protocol on Biodiversity*, January 19, 2000.

[148] See, for example, NASEM, *Future Products of Biotechnology*, 2017.

GE and Non-GE Labeling

Implementation of the Standard, which requires the on-package disclosure of most bioengineered foods, is expected to affect consumers, food producers, processors and importers, and USDA's AMS as the federal agency overseeing implementation. As implementation proceeds, questions remain regarding stakeholder reactions to the scope and manner of disclosure, impacts, if any, on market demand for bioengineered versus nonbioengineered products, and any interactions with international trade. Some have raised questions regarding FDA's oversight of non-GMO labeling, as well as consumer demand for these labels in light of the Standard.[149] Congress may choose to monitor the Standard's implementation, as well as related issues, in accordance with its oversight responsibilities.

Global Trade Concerns

Globally, countries have different policies, regulations, and attitudes toward agricultural biotechnology. Differences in the definition and terms used to describe GE organisms, LLP tolerance levels for commodity shipments, GE labeling requirements, and other issues can raise global trade concerns. U.S. trade policy supports market access for biotechnology products. Various bilateral and multilateral trade agreements between the United States and other nations include biotechnology provisions and commitments. Some have questioned the compliance of some countries with the terms of these agreements. Congress could consider whether to grant Trade Promotion Authority to the executive branch to direct it to address U.S. trade concerns over GE products in trade negotiations.[150]

Environmental Concerns

As noted above, the evolution of herbicide-resistant weeds, especially those resistant to glyphosate, is a growing concern. As herbicide resistance increases among weed varieties, there could be increased reliance on herbicides that are arguably less benign than glyphosate (e.g., dicamba; 2,4 D). Biotechnology companies have engineered new plant varieties that are tolerant to these herbicides and varieties for which several herbicide-tolerant traits are "stacked" into a single variety. The environmental effects of the increasing herbicide resistance and the resort to other herbicides may raise environmental questions for policymakers as companies commercialize new plant varieties.

[149] See, for example, C. Dean McGrath, Jr., "Is the 'Non-GMO' Butterfly an Endangered Species?," *The Hill*, June 5, 2019, at https://thehill.com/opinion/energy-environment/447026-is-the-non-gmo-butterfly-an-endangered-species.

[150] For information on Trade Promotion Authority, see CRS In Focus IF10038, *Trade Promotion Authority (TPA)*, by Ian F. Fergusson.

Appendix A. Acronyms

AHPA	Animal Health Protection Act
AMS	Agricultural Marketing Service of USDA
APHIS	Animal and Plant Health Inspection Service of USDA
ARS	Agricultural Research Service of USDA
BRS	Biotechnology Regulatory Service of APHIS
Bt	*Bacillus thuringiensis*, a bacterium with pesticidal properties
bST	Bovine somatotropin, also known as *bovine growth hormone*
CRISPR	Clustered regularly interspaced short palindromic repeats, a genome editing technique
EPA	U.S. Environmental Protection Agency
EPIA	Egg Products Inspection Act
ERS	Economic Research Service of USDA
FAO	Food and Agriculture Organization of the United Nations
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FMIA	Federal Meat Inspection Act
GE	Genetically engineered
GMO	Genetically modified organism
GRAS	Generally recognized as safe
HT	Herbicide tolerant
ISAAA	International Service for the Acquisition of Agri-biotech Applications
LLP	Low-level presence
LMO	Living modified organism
NASEM	National Academies of Sciences, Engineering, and Medicine
NBT	New breeding technique
OSTP	Office of Science and Technology Policy of the Executive Office of the President
PHSA	Public Health Safety Act
PPA	Plant Protection Act
PPIA	Poultry Products Inspection Act
PIP	Plant-incorporated protectant, a GE pesticide
rbST	Recombinant bovine somatotropin
RNA	Ribonucleic acid
RNAi	RNA interference
TALEN	Transcription activator-like effector nuclease, a genome editing tool
TSCA	Toxic Substances Control Act
USDA	U.S. Department of Agriculture
VSTA	Virus-Serum-Toxin Act
WHO	World Health Organization of the United Nations
WTO	World Trade Organization
ZFN	Zinc finger nuclease, a genome editing tool

Appendix B. Glossary of Selected Scientific Terms

Many terms are used to describe human alterations of plants and animals. Unless otherwise noted, these definitions derive from the U.S. Department of Agriculture's online *Agricultural Biotechnology Glossary*.[151]

Adventitious presence	Detection of the unintentional presence of GM crops that have not been approved in any countries on the basis of a food safety assessment according to the relevant Codex guidelines.[152]
Agricultural biotechnology	A range of tools, including traditional breeding techniques, that alter living organisms, or parts of organisms, to make or modify products; improve plants or animals; or develop microorganisms for specific agricultural uses. Modern biotechnology includes the tools of genetic engineering.
Conventional breeding	Undefined in USDA's *Agricultural Biotechnology Glossary*, which defines the similar term, *traditional breeding*, as "modification of plants and animals through selective breeding. Practices used in traditional plant breeding may include aspects of biotechnology such as tissue culture and mutational breeding."
DNA (deoxyribonucleic acid)	The chemical substance from which genes are made. A long, double-stranded helical molecule made up of nucleotides composed of sugars, phosphates, and derivatives of four bases: adenine (A), guanine (G), cytosine (C), and thymine (T). The sequence of base pairs in DNA strands determines its genetic information.
Epigenome	The physical factors affecting the expression of genes without affecting the actual DNA sequence of the genome.[153]
GE labeling	On-package disclosure of genetically engineered (GE) foods or food ingredients.[154]
Genetic engineering	Manipulation of an organism's genes by introducing, eliminating, substituting, or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques.
Genetic modification	The introduction of heritable improvements in plants or animals for specific uses via genetic engineering or more traditional methods. Some countries other than the United States use this term to refer specifically to genetic engineering.
Genetically engineered (GE)	Produced through genetic engineering.[155]
Genetically modified organism (GMO)	An organism produced through genetic modification.
Genome	All the genetic material in all the chromosomes of a particular organism.
Genome editing	Specific modification of the DNA of an organism to create mutations or introduce new alleles or new genes.[156]

[151] Available at USDA, *Agricultural Biotechnology Glossary*, at https://www.usda.gov/topics/biotechnology/biotechnology-glossary.

[152] FAO, *Technical Consultation on Low Levels of Genetically Modified (GM) Crops in International Food and Feed Trade*, Technical Background Paper 2, TC-LLP/2014/3, March 20-21, 2014, p. 5 (hereinafter FAO, *Technical Consultation on Low Levels of GM Crops*, 2014).

[153] NASEM, "Appendix G: Glossary," in *Genetically Engineered Crops: Experiences and Prospects*, National Academies Press, 2016 (hereinafter NASEM, "Appendix G: Glossary," in *Genetically Engineered Crops*, 2016).

[154] CRS.

[155] CRS.

[156] NASEM, "Appendix G: Glossary," in *Genetically Engineered Crops*, 2016.

Living modified organism (LMO)	A term specific to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, defined as any living organism that possesses a novel combination of genetic material obtained via modern biotechnology.[157]
Low-level presence	The detection of low levels of GM crops that have been approved in at least one country on the basis of a food safety assessment according to the relevant Codex guidelines.[158]
Marker-assisted selection	The use of DNA sequences to determine which selection plants or organisms have a particular version (allele) of existing genes. Markers do not become part of the plant's genome.[159]
Mutation	Any heritable change in DNA structure or sequence. The identification and incorporation of useful mutations has been essential for traditional crop breeding.
Mutation breeding	A plant breeding technique in which radiation or chemical mutagens are used to produce new genetic variation.[160]
New breeding techniques (NBTs)	Also known as *new breeding technologies* (also NBTs) and *new plant breeding techniques (NPBTs)*. While there is no universally agreed upon set of components, NBTs are generally considered to include (1) techniques that change an organism's genetic sequence (e.g., genome editing and site-directed mutagenesis), and (2) epigenetic techniques that change when and how an organism expresses certain genes, without changing the underlying genetic sequence.[161]
Plant pest	An organism that may directly or indirectly cause disease, spoilage, or damage to plants, plant parts, or processed plant materials. Common examples include certain insects, mites, nematodes, fungi, molds, viruses, and bacteria.
Recombinant DNA (rDNA)	A molecule of DNA formed by joining different DNA segments using recombinant DNA technology.
Recombinant DNA technology	Tools, techniques, and procedures used to join DNA segments in a cell-free system (e.g., in a test tube outside living cells or organisms). Under appropriate conditions, a recombinant DNA molecule can be introduced into a cell and copy itself (replicate), either as an independent entity (autonomously) or as an integral part of a cellular chromosome.
RNA (ribonucleic acid)	A chemical substance made up of nucleotide compounds of sugars, phosphates, and derivatives of four bases: adenine (A), guanine (G), cytosine (C), and uracil (U). RNAs function in cells as messengers of information from DNA that are translated into protein or as molecules that have certain structural or catalytic functions in the synthesis of proteins. RNA is also the carrier of genetic information for certain viruses. RNAs may be single or double stranded.
Selective breeding	Making deliberate crosses or matings of organisms so the offspring will have particular desired characteristics derived from one or both parents.
Traditional breeding	Modification of plants and animals through selective breeding. Practices used in traditional plant breeding may include aspects of biotechnology, such as tissue culture and mutational breeding.
Transgene	Any gene transferred into an organism by genetic engineering.[162]

[157] UN Convention on Biodiversity, "Article 3. Use of Terms," in *Cartagena Protocol on Biodiversity*, January 19, 2000.

[158] FAO, *Technical Consultation on Low Levels of GM Crops*, 2014, p. 5.

[159] NASEM, "Appendix G: Glossary," in *Genetically Engineered Crops*, 2016.

[160] CRS.

[161] CRS.

[162] NASEM, "Appendix G: Glossary," in *Genetically Engineered Crops*, 2016.

Transgenic event	A unique insertion of a transgene into a genome.[163]
Transgenic organism	An organism resulting from the insertion of genetic material from another organism using recombinant DNA techniques.
Variety	A subdivision of a species for taxonomic classification also referred to as a "cultivar." A variety is a group of individual plants that is uniform, stable, and distinct genetically from other groups of individuals in the same species.

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[163] CRS.