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SUMMARY

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Gene-Edited Plants: Regulation and Issues for Congress

Throughout history, farmers and plant breeders have employed selective breeding techniques to develop desirable traits in crops. This has involved crossing plants with desired characteristics and selecting offspring with improved traits over successive generations. While effective, conventional breeding techniques are time-consuming and rely on naturally occurring genetic variation. Plant biotechnology, which includes gene editing and genetic engineering, has introduced a way to integrate desired traits directly into a plant's DNA.

The federal government's 1986 Coordinated Framework for Regulation of Biotechnology outlines how agricultural biotechnology products are regulated in the United States. The U.S. regulation and oversight of gene editing in agriculture involve three federal agencies: the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). These agencies base their evaluation of gene-edited products on the product's characteristics and potential impacts on human health and the environment. USDA's Animal and Plant Health Inspection Service (APHIS) administers regulations on gene-edited plants, particularly their importation, interstate movement, and field testing. In 2018, APHIS finalized the Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule, which exempts certain gene-edited plants from review based on their plant-pest risk. FDA oversees gene-edited plants intended for human or animal consumption, evaluating their potential impact on food allergenicity, toxicity, and nutritional composition. The agency generally does not require premarket review for gene-edited plants that closely resemble their conventionally bred counterparts. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulates the pesticidal substance in a gene-edited plant and the genetic material used to produce the pesticidal substance in the plant (i.e., plant-incorporated protectants or PIPs). FIFRA generally requires pesticides subject to the act to be approved through a registration process before they may be commercially marketed. In May 2023, EPA promulgated a final rule to exempt from the registration requirement two categories of PIPs that the agency determined to pose little or no risk to human health and the environment. The EPA rule also established recordkeeping requirements for certain exempted PIPs and a process for determining exemption eligibility.

Public policy issues concerning gene editing in agriculture that could require congressional consideration are multifaceted. Congress may examine whether federal labeling standards such as the National Bioengineered Food Disclosure Standard (NBFDS) adequately address issues raised by gene-edited plants. Over time, the three agencies that oversee agricultural products produced with biotechnology have been directed to update the Federal regulatory system for the products of biotechnology and to establish mechanisms for periodic updates of that system. Congress may review if the agencies are effectively coordinating with each other in their attempts to align the regulations with the state of biotechnology developments and if the updates fulfill their mandates: to accelerate innovation in plant biotechnology and to safeguard human health and the environment. Congress may continue supporting research initiatives in gene editing to further explore agricultural applications. Some of the possible future policy challenges regarding gene editing include managing different types of plants and other gene-edited products as they are released into the environment; legal issues; and the impact of gene-edited plants on ecosystems and biodiversity.

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Introduction

Over the past century, plant breeding in U.S. agriculture has experienced major transformation, progressing from conventional plant propagation techniques to the more accelerated techniques of gene editing. Although capable of producing significant advances, conventional plant breeding is time-consuming and often limited by natural genetic variations.

One milestone in conventional agriculture was reached during the mid-20th century with the advent of the Green Revolution.[1] This agricultural breakthrough, reliant on mutagenesis and selective breeding, increased crop productivity to combat global food shortages.[2] It involved the development and widespread adoption of high-yielding crop varieties, primarily focusing on wheat, rice, and corn.[3]

In the 1980s, a new era in crop improvement emerged with the application of genetic engineering techniques to agriculture, which became known as agricultural biotechnology. Agricultural biotechnology uses both genetic engineering and conventional breeding methods to alter plants, animals, microbes, and other organisms to improve agricultural productivity and address challenges such as pests, diseases, and environmental conditions.[4] Its main goals are to develop agricultural products that are more resilient, productive, or nutritious. Genetic engineering in agriculture involves the use of recombinant DNA[5] technology to introduce specific genes or genetic material into an organism's genome. This process allows scientists to add desired traits to the target organism, which may not be achievable through conventional breeding methods. It typically involves identifying a trait of interest, locating the relevant gene, and then inserting the gene into the host organism's DNA which can be of a different species.[6] This process has led to the development of genetically engineered (GE) crops, also referred to as genetically modified (GM) crops.[7] Such crops can carry desired characteristics, such as pest and herbicide resistance, as well as improved nutritional content. In 1994, the FlavrSavr® tomato became the first genetically engineered food to enter the U.S. market, followed by genetically engineered cotton,

[1] Mohd Fadhli Hamdan et al., "Green Revolution to Gene Revolution: Technological Advances in Agriculture to Feed the World," *Plants*, p. 1297, May 2022.

[2] *Selective breeding* refers to the process by which humans choose specific plants or animals to reproduce based on desired traits, with the goal of enhancing or strengthening these traits in future generations. For more details, see "Selective breeding and genetics," *Britannica*, last visited September 7, 2023. *Mutagenesis* is the process by which genetic changes, or mutations, are introduced into an organism, either naturally or artificially. For more details, see Justin Durland and Hamid Ahmadian-Moghadam, "Genetics, mutagenesis," *StatPearls Publishing*, 2022.

[3] Govindan Parayil, "Mapping Technological Trajectories of the Green Revolution and the Gene Revolution from Modernization to Globalization," *Research Policy*, pp. 971-990, June 2003.

[4] For more information on Agricultural Biotechnology, see CRS Report R46737, *Agricultural Biotechnology: Overview, Regulation, and Selected Policy Issues*.

[5] DNA (deoxyribonucleic acid) is the molecule carrying genetic information for an organism's development and function. It has a double helix structure with two strands made of sugar and phosphate. These strands are linked by pairs of bases: adenine with thymine and cytosine with guanine. The sequence of these bases encodes biological instructions, like making proteins. For more information, see National Human Genome Research Institute, "Deoxyribonucleic Acid (DNA)," https://www.genome.gov/genetics-glossary/Deoxyribonucleic-Acid.

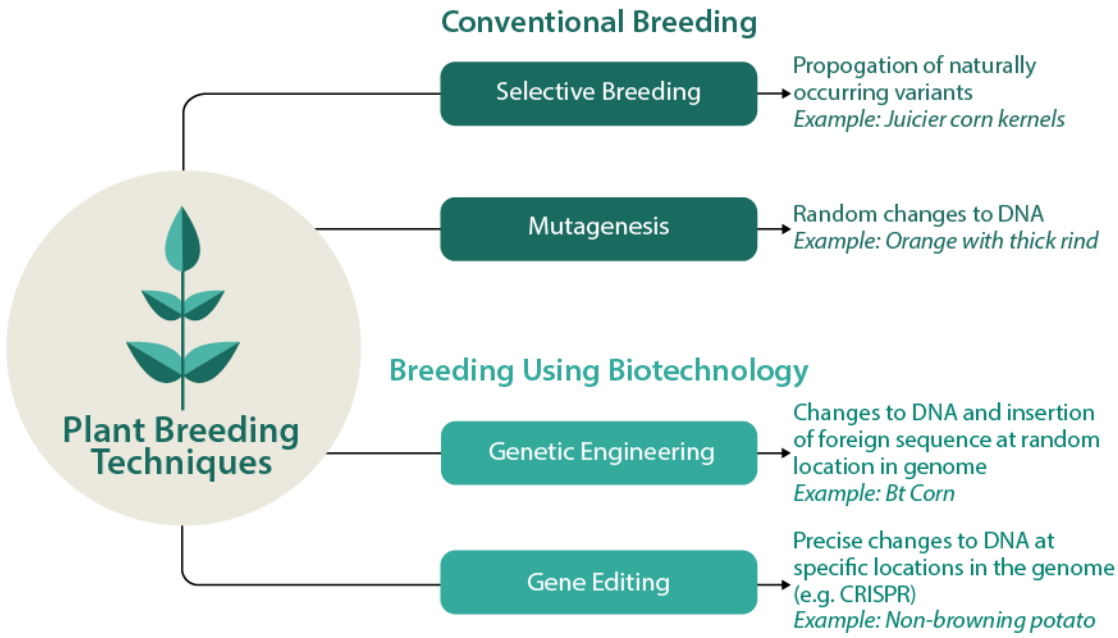
[6] For more information on marker-assisted selection in plant breeding, see National Academies of Sciences, Engineering and Medicine (NASEM), *Genetically Engineered Crops: Experiences and Prospects*, National Academies Press, pp. 354-355, 2016.

[7] For the purposes of this report, "Genetically Engineered or GE" products refer to all the products developed through genetic engineering or biotechnology or the targeted or in vitro manipulation of genetic information of organisms, including plants, animals, and microbes except those that have been gene-edited.

soybeans, apples, pineapple, summer squash, and others.[8] In 2014, more than 90% of the corn, cotton, and soybeans grown in the United States were genetically engineered.[9]

In the mid-2010s, gene editing (also called genome editing) tools, such as CRISPR-Cas9 were introduced to agriculture in the United States.[10] Gene editing in agriculture is a more precise and advanced form of genetic engineering than the previous techniques.[11] The use of gene editing techniques on plants offers the potential to modify specific genes in plants, aiming to enhance traits like disease resistance, yield, and nutritional value without introducing foreign genes into the new products (**Figure 1**). Some commercially available food products developed using gene editing are found in the United States, including high-oleic acid soybeans and a leafy green salad mix.[12]

Figure 1. Plant Breeding Techniques



Source: CRS

[8] FlavrSavr tomato, a genetically engineered tomato made to stay firm after harvest, was discontinued a few years later and is not currently available in the U.S. market.

[9] U.S. Department of Agriculture (USDA), Economic Research Service (ERS), "Adoption of Genetically Engineered Crops in the U.S.," September 14, 2022.

[10] For more information on gene editing and CRISPR-Cas9, see CRS Report R44824, *Advanced Gene Editing: CRISPR-Cas9*. Additionally, for a chronology of CRISPR development for gene editing, see Broad Institute, "CRISPR Timeline," at https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/crispr-timeline.

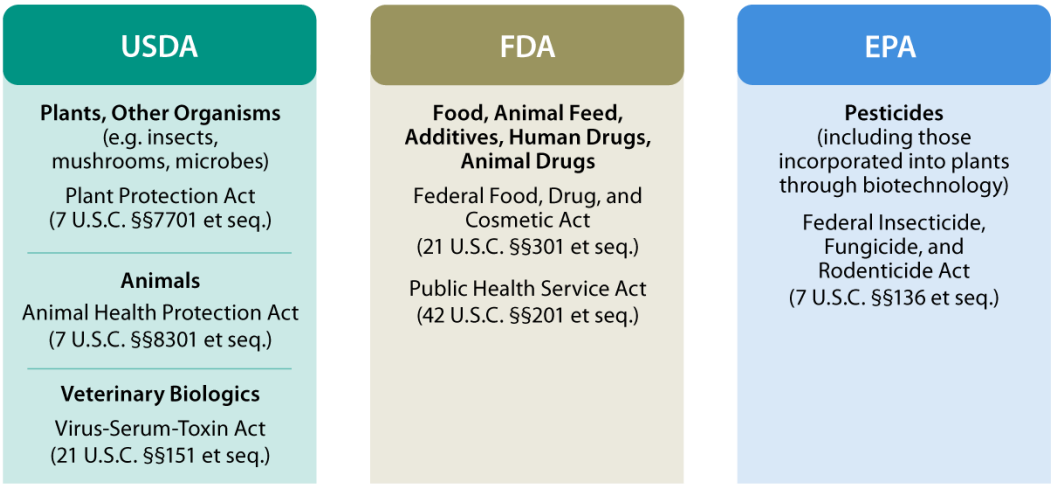
[11] For more information, see Su Bin Moon et al., "Recent Advances in the CRISPR Genome Editing Tool Set," *Experimental & Molecular Medicine*, vol. 51, pp. 1-11, November 5, 2019.

[12] For more information, see Calyxt, "First Commercial Sale of Calyxt High Oleic Soybean Oil on the U.S. Market," https://calyxt.com/first-commercial-sale-of-calyxt-high-oleic-soybean-oil-on-the-u-s-market/, February 2019 and United States Food and Drug Administration (FDA), "High Oleic Soybean FAD2KO", Biotechnology Notification File No. 000164, February 2019, https://www.fda.gov/media/120708/download.Pairwise, "Pairwise Introduces Conscious™ Greens, into U.S. Restaurants," May 2023, https://www.pairwise.com/news/pairwise-introduces-conscious-greens-into-u.s.-restaurants.

U.S. Regulation and Oversight of Gene Editing in Plants

The U.S. regulation and oversight of gene editing in plants is facilitated by the Coordinated Framework for Regulation of Biotechnology, which involves the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA) (**Figure 2**).[13] The framework was established in 1986 by the Office of Science and Technology Policy (OSTP) and outlines how the involved U.S. agencies apply their existing statutory authority to evaluate and ensure that gene-edited products in the United States are safe.[14] The premise of this regulatory approach is to focus on the characteristics and unique features of the derived plants, the impacts on the environment in which they are introduced, and on human health, rather than the process by which they are made. Thus, the regulations treat plants equally regardless of whether they were derived through gene editing, genetic engineering, mutagenesis, or selective breeding.[15] This product-based evaluation contrasts with a process-based evaluation, which focuses on the techniques and methods used to produce a plant.[16]

Figure 2. Primary Legislative Authorities of Federal Regulation of Biotechnology



Source: Figure created by CRS. See CRS Report R46737, *Agricultural Biotechnology: Overview, Regulation, and Selected Policy Issues*.

Notes: The Coordinated Framework incorporates provisions in statutes beyond the primary statutes identified in this figure.

[13] White House, OSTP, "Coordinated Framework for Regulation of Biotechnology," 51 *Federal Register* 23302, June 26, 1986.

[14] 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. Also, see CRS Report R47635, *The White House Office of Science and Technology Policy: Issues and Options for the 118th Congress*.

[15] For more information on the distinction of the process vs. product, see Giovanni Tagliabue, "Product, not process! Explaining a basic concept in agricultural biotechnologies and food safety," *Life Sciences, Society and Policy* 13, no. 1, 2017, pp. 1-9.

[16] For more, see Elicia Maine, Sarah Lubik, and Elizabeth Garnsey, "Process-based vs. product-based innovation: Value creation by nanotech ventures," *Technovation*, pp.179-192, 2012.

U.S. Department of Agriculture

The responsibility of regulating gene-edited plants primarily lies with USDA's authority provided by the Plant Protection Act (PPA, 7 U.S.C. §§ 7701 et seq.). USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for protecting U.S. agriculture from pests and diseases and it regulates the importation, interstate movement, and field testing of gene-edited plants and organisms according to their plant-pest and noxious weed risk under the PPA,[17] the Animal Health Protection Act (7 U.S.C. §§ 8301 et seq.), and Virus-Serum-Toxin Act (21 U.S.C. §§ 151 et seq.).

In 2018, APHIS introduced the Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) Rule.[18] The rule revised APHIS's regulations governing certain gene-edited plants[19] (7 C.F.R. §340) and new genetically engineered plants.[20] It exempts broad categories of new plants from regulatory review based on APHIS's current understanding of plant-pest risk, provided they could have been produced through conventional breeding methods and that there was no foreign genetic material incorporated from a plant pest or is intended for use as a plant pest (**Figure 3**).[21] If exempted, developers of gene-edited products can request a written confirmation from APHIS that a plant is not subject to regulations (I). Plants that are not exempt must undergo a regulatory status review (II), followed by a permitting process (III). The SECURE rule was fully implemented in October 2021.[22]

Figure 3. The SECURE Rule Process

Source: CRS.

[17] 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. According to APHIS, "The potential for direct or indirect injury to, damage to, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential for exacerbating the impact of a plant pest."

[18] In the context of the Coordinated Framework, if a gene-edited plant contains genetic material from a plant pest or if it is intended for use as a plant pest, it falls under the purview of APHIS regulation as a genetically engineered organism. This means that such plants would be subject to a more stringent regulatory process to assess their safety, potential environmental impacts, and potential risks to agricultural systems.

[19] APHIS, "Movement of Certain Genetically Engineered Organisms," 85 *Federal Register* 29790-29838, August 17, 2020.

[20] For additional background on the SECURE Rule, see CRS In Focus IF11573, *USDA's SECURE Rule to Regulate Agricultural Biotechnology*.

[21] USDA APHIS, *Final Rule*, 85 *Federal Register* 29790, May 18, 2020.

[22] For more information on the steps of the process under the SECURE rule, see 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.

Food and Drug Administration

FDA oversees gene-edited plants 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 regulates gene-edited plants that are intended for human or animal consumption, based on food safety considerations. FDA also provides guidance on *voluntary* consultation for developers to evaluate the safety of new plant varieties. New gene-edited plant varieties may be evaluated by FDA for their potential impact on food allergenicity, toxicity, and nutritional composition.[23] Since its first consultation of a gene-edited product in 2019, none have been found to contain a food additive and thus have not required FDA approval prior to marketing.[24]

Environmental Protection Agency

EPA regulates any pesticidal substance found in a gene-edited plant and the genetic material used to produce the pesticidal substance in the plant (i.e., plant-incorporated protectants or PIPs). As part of this regulation, EPA requires any PIP to be registered before the gene-edited plant that contains the PIP can be commercially marketed. EPA's authorities for regulating pesticidal substances, including PIPs, are derived from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. §§ 136 et seq.) and Section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 346a). Under FIFRA, EPA may only register a pesticidal substance if the agency determines that the pesticidal substance will perform its intended function and not generally cause "unreasonable adverse effects on the environment" when used in accordance with the label.[25] For pesticidal substances that may be present in or on food, Section 408 of FFDCA requires EPA to establish, through rulemaking, tolerances (i.e., maximum residue limits) or tolerance exemptions for pesticidal substances. EPA initially proposed regulations for PIPs in the mid-1990s and promulgated the final rule regulating PIPs in July 2001.[26] EPA has also promulgated tolerance and tolerance exemptions for PIPs, which are codified in 40 C.F.R. Part 174, Subpart W.

In July 2023, EPA promulgated a final rule to exempt two categories of PIPs from registration requirements under FIFRA.[27] The two categories of PIPs exempt from registration are (1) "PIPs created through genetic engineering from a sexually compatible plant" and (2) "loss-of-function" PIPs. The first category refers to PIPs created using genetic engineering (including gene editing) in which a gene from a sexually compatible plant is either inserted into or used to modify the genome of the recipient plant. The term "sexually compatible" is defined in regulation and means that the plant from which genetic material was sourced and the recipient plant must be capable of naturally interbreeding and producing viable offspring.[28] In considering this exemption, EPA found that "PIPs exempted through this rulemaking are equivalent to those that are created

[23] 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.

[24] Under sections 201(s) and 409 of the Food, Drug, and Cosmetic Act, any substance that is intentionally added to food is a food additive, and is therefore subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe.

[25] 7 U.S.C. § 136a(c)(5).

[26] EPA, "Regulations under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides)," final rule, 66 *Federal Register* 37771-37817, July 11, 2001. The final rule amended 40 C.F.R. Part 152 (Pesticide Registration and Classification Procedures) and added 40 C.F.R. Part 174 (Procedures and Requirements for Plant-Incorporated Protectants).

[27] EPA, "Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies," 88 *Federal Register* 34756-34779, May 31, 2023.

[28] 40 C.F.R. § 174.3.

through conventional breeding," which were already exempt from registration.[29] Although PIPs in this category are exempted from registration, the EPA rule establishes a process for determining that a PIP is eligible for the exemption that may require the developer to submit data sufficient for EPA to ensure that human dietary safety levels are not exceeded if the pesticidal substance is a known allergen, toxin, or toxicant.[30] Additionally, PIPs in this category are subject to certain recordkeeping and adverse effects reporting requirements.[31] The EPA rule also established a tolerance exemption for PIPs in this category.[32]

Under the second category, the term "loss-of-function" refers to the reduction or elimination of a gene's usual activity, making the plant less attractive to pests or disrupting a pest's ability to exploit the plant in the context of PIPs.[33] Instances in which the reduction or elimination of a gene's usual activity results in the intentional increase of another pesticidal gene are excluded from the exemption. Similar to the first exemption, the EPA rule also establishes a process for determining that a loss-of-function PIP is eligible for the exemption.[34] Additionally, loss-of-function is subject to certain recordkeeping and adverse effects reporting requirements.[35]

According to EPA, these exemptions are expected to reduce costs for the regulated community, increase research and development activities and the commercialization of new pest control options, and reduce the use of conventional pesticides.[36] EPA also has stated that the rule is consistent with Executive Order 14081 on advancing biotechnology, discussed below.[37]

Attempts to Update Federal Biotechnology Regulation: Selected Chronology

The Coordinated Framework for Regulation of Biotechnology was established in 1986.[38] Over time, successive administrations have directed the responsible agencies to update their rules and policies for regulating biotechnology products (also see "Efficacy of Regulatory Updates"). Presented below is a selected chronology of the ongoing efforts to update the framework.

- In 1992, the Office of Science and Technology Policy (OSTP) issued an update emphasizing a risk-based approach to overseeing biotechnology products.[39] That

[29] EPA, *Cost Analysis for the Final Rule Exempting Certain Plant-Incorporated Protectants (PIPs) from Registration*, May 2023, https://www.regulations.gov/document/EPA-HQ-OPP-2019-0508-0125, p. 4.

[30] 40 C.F.R Part 174, Subpart E. See 40 C.F.R. § 174.95 for documentation that specifically applies to an exemption for a PIP created through genetic engineering from a sexually compatible plant.

[31] 40 C.F.R. Part 174, Subpart D.

[32] 40 C.F.R. § 174.541.

[33] 40 C.F.R. § 174.3.

[34] 40 C.F.R Part 174, Subpart E. See 40 C.F.R. § 174.96 for documentation that specifically applies to an exemption for a loss-of-function PIP.

[35] 40 C.F.R. Part 174, Subpart D.

[36] EPA, "EPA Finalizes Rule to Accelerate Use of Plant-Incorporated Biotechnologies to Protect Against Pests," May 25, 2023, https://www.epa.gov/pesticides/epa-finalizes-rule-accelerate-use-plant-incorporated-biotechnologies-protect-against.

[37] Executive Order 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," 87 *Federal Register* 56849-56860, September 12, 2022.

[38] White House, OSTP, "Coordinated Framework for Regulation of Biotechnology," 51 *Federal Register* 23302, June 26, 1986.

[39] White House, OSTP, "Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of (continued...)

update changed the focus from the process of creation to the characteristics of the product and its introduction into the environment.

- On January 18, 2011, President Obama signed Executive Order 13563, "Improving Regulation and Regulatory Review," which laid out principles intended to guide agency actions related to public participation, integration, and innovation, the flexibility of approaches, science, and retrospective analyses of existing laws.[40]
- In 2015, OSTP directed USDA, FDA, and EPA to update the Coordinated Framework.[41] The goals were to clarify agency roles, develop a long-term strategy, and commission an independent analysis of the biotechnology landscape to enhance public confidence, promote innovation, and ensure efficient regulation while safeguarding health and the environment.[42]
- In 2016, the Biotechnology Working Group of the Emerging Technologies Interagency Policy Coordination Committee published the National Strategy for Modernizing the Regulatory System for Biotechnology, which outlined steps to assess the risks associated with future biotechnology products and support scientific underpinnings.[43] Concurrently, the National Academies of Sciences, Engineering, and Medicine (NASEM) was tasked to conduct a study to identify advances, potential risks, and scientific capabilities relevant to future biotechnology products.[44]
- In 2017, USDA, FDA, and EPA issued another update to the Coordinated Framework, clarifying agency responsibilities and promoting coordination through memoranda of understanding.[45]
- On June 11, 2019, President Trump issued Executive Order (E.O.) 13874, "Modernizing the Regulatory Framework for Agricultural Biotechnology Products." E.O. 13874 requested further modernizing of the regulatory framework and emphasizing the use of scientific evidence in decision-making. The executive order also encouraged trade in agricultural biotechnology products based on science and risk-based approaches.[46]
- In May 2020, responding to E.O. 13874, USDA's APHIS revised its regulations regarding the movement (importation, interstate movement, and environmental

Biotechnology Products into the Environment Update to the Coordinated Framework," 57 *Federal Register* 6753, February 27, 1992.

[40] Executive Order 13563, "Improving Regulation and Regulatory Review," 76 *Federal Register* 3821, January 18, 2011.

[41] OSTP, "Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture Regarding Modernizing the Regulatory System for Biotechnology Products," July 2, 2015.

[42] White House, National Science and Technology Council (NSTC) and OSTP, "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," 80 *Federal Register* 60414, October 6, 2015.

[43] White House, NSTC, "National Strategy for Modernizing the Regulatory System for Biotechnology Products," September 2016.

[44] NASEM, "Preparing for Future Products of Biotechnology," National Academies Press, 2017.

[45] EPA, FDA, and USDA "Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology," 2017.

[46] Executive Order 13874, "Modernizing the Regulatory Framework for Agricultural Biotechnology Products," 84 *Federal Register* 27899, June 11, 2019.

release) of certain genetically engineered plants to focus on plant properties rather than production methods through its SECURE Rule, discussed above.[47]

- On September 12, 2022, President Biden issued Executive Order 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy."[48] The executive order aims to improve regulatory clarity and efficiency, enhance coordination among federal agencies, and encourage international regulatory cooperation. Among other things, agencies are directed to address ambiguities and provide information to stakeholders through an improved Unified Website for Biotechnology.[49] The order also prescribes the need for a "whole-of-government approach to advance biotechnology and biomanufacturing towards innovative solutions in health, climate change, energy, food security, agriculture, supply chain resilience, and national and economic security."[50]
- On May 25, 2023, in response to E.O. 14081, EPA announced changes to its regulations concerning genetically engineered plant-incorporated protectants (PIPs).[51] These changes exempt certain PIPs from registration and tolerance requirements while implementing a notification process for transparency. EPA intends to consider additional exemptions and expand the list of categories not requiring EPA confirmation as biotechnology progresses.

International Regulation of Gene-Edited Plants

The regulation of plants derived from gene editing varies across the globe. Various regulatory jurisdictions and countries have adopted different policies and regulatory frameworks for the use of gene editing techniques for plant products.[52]

The United States' regulatory approach is product-based, which focuses on the characteristics of the final product rather than the process used to create it. Generally speaking, if a gene-edited plant does not contain foreign DNA, the final product is considered no different from a product that was produced without gene editing. If the plant could have been produced with conventional breeding, then it would not be subject to the additional regulations that products that are produced through other types of biotechnology processes have to follow. Canada follows a similar product-

[47] APHIS first issued these regulations in 1987 under the authority of the Federal Plant Pest Act of 1957 and the Plant Quarantine Act of 1912, two acts that were subsumed into the Plant Protection Act (PPA, 7 U.S.C. §§ 7701 et seq.) in 2000, along with other provisions. Since 1987, APHIS has amended the regulations seven times (in 1988, 1990, 1993, 1994, 1997, 2005, and 2020) to institute exemptions from the requirement for permits to conduct activities for certain organisms, to institute the current notification process and petition procedure, and to exclude plants engineered to produce industrial compounds from the notification process. For more, see USDA APHIS, "Movement of Certain Genetically Engineered Organisms," May 18, 2020.

[48] Executive Order "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," 87 *Federal Register* 56849, September 12, 2022.

[49] For more information, also see CRS Report CRS Report R47274, *White House Initiative to Advance the Bioeconomy, E.O. 14081: In Brief*.

[50] For more details on the Executive Order, the supporting federal investments announced by the Administration, and policy considerations for Congress regarding the implementation of the executive order, see CRS Report R47274, *White House Initiative to Advance the Bioeconomy, E.O. 14081: In Brief*.

[51] EPA, "Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies - Final Rule," May 31, 2023.

[52] For how the United Nations' Food and Agriculture Organization approaches gene editing, see Caixia Gao et al., "Gene Editing and Agrifood Systems," *FAO Report*, 2022.

based risk assessment and governs all plants with novel traits, including those introduced through genetic engineering and gene editing, under the same regulatory scheme. The United Kingdom, under a March 2023 law, is to start allowing the development, release, and marketing of gene-edited plants through a regulatory system different from that of plants developed through other biotechnology processes, such as older techniques of genetic engineering.[53]

Other countries have different regulations in place, focusing on the process used to develop the product and requiring extensive safety assessments and approval processes before gene-edited plants can be cultivated or approved for human consumption.

The European Union (EU) has long followed the process-based approach. However, there have been recent proposals to change its regulations. In 2021, the European Commission proposed a draft law that would exempt gene-edited plants from the laws applying to genetically engineered products, provided they are equivalent to what could be achieved with conventional plant breeding.[54] This proposal would apply to plants obtained using gene-editing techniques like CRISPR, as long as the modifications are comparable to those achieved with conventional breeding. The Commission expects to propose a legal framework for gene-edited plants and their food and feed products in 2023.[55]

Other countries apply risk assessments to gene-edited plants that fall in between the strictly product-based or process-based approaches, or have not finalized their decisions on how to regulate gene-edited products. For example, Hungary, Switzerland, and Norway are considering regulatory options that may be different from the region's regulations on gene editing and applying case-by-case assessment procedures for gene-edited products. Additionally, among the ten most populous countries (many being major agricultural producers), nine have expressed intentions to allow gene editing in commercial agriculture. During the last two years, China and India have taken steps to clarify their policies and allow the cultivation of gene-edited plants.[56]

Perspectives on Regulating Gene Editing as Genetic Engineering

Ongoing debates exist regarding the regulation of gene editing as compared to genetic engineering. These debates consider the biological, political, social, and legal differences between the two technologies.[57]

Those who argue against regulating gene editing and genetic engineering in the same way assert that the end products of gene editing are similar to those generated through conventional breeding techniques or that similar changes could occur naturally. Therefore, they assert that regulations and oversight imposed on regular genetically engineered products are unnecessary if the resulting gene-edited products are substantially equivalent in terms of safety and potential environmental impact. Furthermore, proponents of accelerated approvals for gene-edited products argue that

[53] Department for Environment Food and Rural Affairs, "Game-changing Genetic Technology Bill Passes into Law in England," March 24, 2023; United Kingdom Parliament, Genetic Technology (Precision Breeding) Act 2023, https://bills.parliament.uk/bills/3167.

[54] Brigitte Voigt, "EU Regulation of Gene-edited Plants—A Reform Proposal," *Frontiers in Genome Editing*, February 14, 2023.

[55] European Commission (EC), "European Green Deal: More Sustainable Use of Plant and Soil Natural Resources," July 5, 2023.

[56] Nadya Yeh, "After Decades of Bans, China Is Beginning to Plant Gene-edited Crops," *The China Project*, May 18, 2023.

[57] Aftab Ahmad et al., "An Outlook on Global Regulatory Landscape for Genome-edited Crops," *International Journal of Molecular Sciences*, p. 11753, October 29, 2021.

other regulatory processes are burdensome, stifle innovation, and hinder the development of beneficial gene-edited products.

Proponents of slower approvals for gene-edited plants raise concerns that accelerated regulatory approvals may compromise the safety of the environment, animals, and human health. One example they cite is the potential persistence of gene markers and gene-edited genes in subsequent generations of plants.[58] Additionally, opponents of regulating gene-edited and genetically engineered products differently emphasize the importance of transparency in regulating and labeling all products derived from genetic engineering, including those derived from gene editing. They argue that treating gene-edited and genetically engineered products differently can lead to consumer confusion.[59]

Issues Facing Congress

Congress may consider a range of issues and policy options concerning gene editing and genetic engineering in agriculture. Past Congresses have already passed certain legislation on this matter and may contemplate introducing more. In addition, Congress may choose to exercise its oversight, appropriations, and legislative powers regarding the following topics. Selected issues are discussed below, without any specific order.

Labeling Disclosure and Standards

The debate over labeling foods that include ingredients that have been genetically engineered has been longstanding. At the heart of the debate, some stakeholders express worries about the health implications of consuming genetically engineered foods, as well as other unforeseen long-term health effects. Others maintain that genetically engineered foods approved for consumption are as safe as their conventional counterparts. The debate also touches upon consumers' right to information, with many advocating for mandatory labeling, while opponents argue that such labels might mislead consumers into thinking that genetically engineered products are inherently harmful.

In 2016, Congress passed the United States Grain Standards Reauthorization Act of 2020 (P.L. 116-216), which instructed USDA's Agricultural Marketing Service (AMS) to establish a mandatory national standard for disclosing foods created with genetic engineering or bioengineered foods. The implementation of the National Bioengineered Food Disclosure Standard (NBFDS) began on January 1, 2022, and it defined bioengineered foods as those that contain detectable genetic material modified through specific lab techniques, which cannot be achieved through conventional breeding or found in nature.[60]

[58] For example, concerns have been raised regarding epigenetic variations of gene-edited plants, see Yanfei Mao, Jose Ramon Botella, Yaoguang Liu, and Jian-Kang Zhu, "Gene Editing in Plants: Progress and Challenges," *National Science Review* 6, no. 3, pp. 421-437, 2019. For more examples of concerns raised with accelerating regulatory reforms see Jennifer Kuzma, "Regulating Gene-edited Crops-Advocates of Second-generation Genetically Modified Crops are Making Choices Likely to Trigger Another Round of Public Opposition," *Issues in Science and Technology*, 2018.

[59] Food Marketing Institute (FMI), "Consumer Acceptance of Gene Edited Foods," March 12, 2019. In 2020, the Food Marketing Institute formally rebranded to use the acronym FMI. The organization adopted the tagline, The Food Industry Association and FMI stands for Food Marketplace Inc." For more details, see https://www.fmi.org/about-us/history.

[60] For more details, see CRS Report R46183, *The National Bioengineered Food Disclosure Standard: Overview and Selected Considerations*.

Figure 4. Disclosure Symbols of the Standard

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

Notes: Foods that meet the criteria in the Standard must display the "bioengineered" symbol. The "derived from bioengineering" symbol may be displayed on foods that do not meet the bioengineered food definition yet derive from bioengineered food (e.g., refined foods that do not contain detectable modified DNA). For background and more information, see CRS Report R46183, *The National Bioengineered Food Disclosure Standard: Overview and Selected Considerations*.

USDA's Agriculture Marketing Service, which is responsible for its implementation, has said that the goal of the standard was to provide consistent information to consumers, to enhance transparency:

> By providing a uniform national standard for labeling bioengineered foods, we can increase transparency in our food system and give consumers information about the bioengineered status of their foods.[61]

Stakeholders had proposed that the labeling should explicitly cover all foods derived from biotechnology, including gene editing, that may not fit the legal definition of bioengineering. These suggestions were not incorporated into the enacted law. Under the standard, gene-edited products or ingredients are not required to be labeled on a food product because the statutory definition of *bioengineered food* in the standard does not explicitly mention gene editing and other new plant breeding techniques. Specifically, gene editing is exempt from labeling requirements when gene-edited products (a) do not contain recombinant DNA or (b) when their modifications could be achieved through conventional breeding or found in nature.

Since the labeling standards went into effect, some consumer groups and grocery stores have complained that the labels are confusing, specifically with respect to the term "bioengineered."[62] Congress has considered legislation regarding the NBDS and the applications of the labeling standard. The legislation included provisions that would require the labeling of genetically engineered salmon and other animals and added provisions into annual appropriations legislation to require their labeling in FY2021-FY2023.[63]

[61] Anna Waller, USDA AMS, "Overview of the National Bioengineered Food Disclosure Standard," Webinar, December 2020.

[62] For example, after the enactment of the NBFDS, the Non-GMO project stated that USDA's decision not to regulate or label gene-edited products under the federal labeling law "signals a clear strategic shift further away from transparency in the food system." For more on the stakeholders' views and reactions to the NBFDS, see Theresa Selfa, Sonja Lindberg, and Carmen Bain, "Governing Gene Editing in Agriculture and Food in The United States: Tensions, Contestations, and Realignments," *Elementa: Science of the Anthropocene*, October 4, 2021, p. 00153.

[63] Bills that would have required labeling of genetically engineered salmon regardless of when it was approved include H.R. 270 and S. 1940 (117th Congress), H.R. 1103 (116th Congress), and S. 282 (116th Congress). Past annual appropriations provisions include §778 of the Consolidated Appropriations Act, 2021 (P.L. 116-260), which requires that "the acceptable market name of any engineered animal approved prior to the effective date of the National (continued...)

Congress may continue using its oversight authorities to (a) monitor the implementation of the standard and (b) address the concerns on how existing genetically engineered products and gene-edited products fit under the national labeling standard.[64] If the discrepancies in labeling requirements for genetically engineered vs. gene-edited products have important implications, and harmonization of labeling requirements is needed, Congress may amend the standard or take other actions such as establishing an independent or scientific body to oversee and review the standard.

Additionally, some argue that consumers' demands for labels in biotechnology-derived food are motivated by an underlying distrust of the agrifood systems or a lack of education about new food technologies.[65] In 2017, Congress appropriated $7.5 million to support the "Agricultural Biotechnology Education and Outreach Initiative." This program required FDA to educate and engage the public regarding agricultural biotechnology, as well as biotechnology-derived food and animal feed ingredients. Congress provided annual appropriations for funding the program for two more years in FY2018 and FY2019 in the amount of $1.5 and $3 million per year respectively. FDA states that it "is currently working on this initiative in coordination with USDA and EPA."[66]

Additionally, in 2018, Congress included in the Agriculture Improvement Act of 2018 (P.L. 115-334), known as the 2018 farm bill, a provision called "the Public Education on Biotechnology in Food and Agriculture Sectors" provision.[67] The goal of this program was to enhance public awareness about the use of biotechnology in these sectors. This was to be achieved through a national science-based education campaign that covered topics like the science and regulatory review process for biotechnology products, the history and effects of plant and animal breeding, and the impacts of biotechnology on food security, nutrition, and the environment. The initiative aimed to provide transparent, accessible, and user-friendly information to the public, ensuring they were well-informed about the role and implications of biotechnology in their food and the broader agricultural landscape. Congress may monitor the effectiveness of the outreach initiative and decide whether to allocate additional annual appropriations to the agencies for consumer education and outreach initiatives intended to increase public trust in biotechnology and facilitate public understanding of biotechnology and its potential benefits and risks.[68]

Bioengineered Food Disclosure Standard (February 19, 2019) shall include the words 'genetically engineered' prior to the existing acceptable market name"; §765 of the Consolidated Appropriations Act, 2023 (P.L. 117-328) and §778 of the Consolidated Appropriations Act, 2021 (P.L. 116-260).

[64] For example, the 117th Congress considered S. 1940 and H.R. 270, which would have mandated that the market name of genetically engineered salmon must include "Genetically Engineered" or "GE" as a prefix to the existing name and require an independent scientific organization to review FDA's environmental assessment for the approval of AquAdvantage Salmon, a genetically engineered salmon.

[65] Sinja A., Lindberg, David J. Peters, and Christopher L. Cummings, "Gene-Edited Food Adoption Intentions and Institutional Trust in the United States: Benefits, Acceptance, and Labeling," *Rural Sociology*, 2023.

[66] In the Consolidated Appropriations Act of 2017 (P.L. 115-31), Congress directed FDA to conduct "consumer outreach and education regarding agricultural biotechnology and biotechnology-derived food products and animal feed, including through publication and distribution of science-based educational information on the environmental, nutritional, food safety, economic, and humanitarian impacts of such biotechnology, food products, and feed." Since then, additional funding for the program has been provided in the FY2018 and FY2019 Appropriations bills P.L. 115-141 and P.L. 116-6). For more information, see FDA, "Agricultural Biotechnology Education and Outreach Initiative," August 3, 2022.

[67] See H.Rept. 115-661, Sec. 7608.

[68] For the goals, current efforts, and additional background see FDA, "Agricultural Biotechnology Education and Outreach Initiative," August 3, 2022.

Efficacy of Regulatory Updates

As noted above, the regulatory bodies and agencies have attempted updates to the Coordinated Framework for Biotechnology Regulation. In September 2022, President Biden issued Executive Order 14081, which established "the National Biotechnology and Biomanufacturing Initiative" (NBBI). The goals of the initiative include streamlining regulations in order to advance research, bolster biosecurity measures, and stimulate economic growth.[69] Congress may exercise its oversight authorities and use the annual appropriation process to monitor and assess the implementation of the efforts undertaken by the agencies to revise the regulations.

In addition to monitoring how the agencies' revised regulatory requirements have affected the development and commercialization of gene-edited products, Members of Congress may also oversee how USDA, FDA, and EPA are collecting feedback on the effectiveness of the revised regulations. For example, EPA's latest PIPs regulations have caused some to raise questions relating to the developer's authority on making the decision whether a plant-incorporated protectant should be exempt and why certain genetically engineered and gene-edited plants would be considered exempt while others are not. Critics have also claimed that only PIPs that meet the scientific low-risk criteria should be exempt and demand that EPA discloses a list of all exempt PIPs.[70] Legislation introduced in the 117th Congress would have amended EPA's provisions in relation to the FIFRA Act, including an amendment requiring EPA to provide a notice of at least 270 days in advance in the *Federal Register* before making changes to a pesticide registered under the FIFRA Act (H.R. 9035), and an amendment of FIFRA to prohibit local regulations relating to the sale, distribution, labeling, application, or use of any pesticide or device subject to regulation by a state or EPA (H.R. 7266).

Differences in Regulation and Global Trade

Differing regulations and labeling requirements in relation to genetically engineered and gene-edited products around the world can lead to important trade issues, such as restricted market access for the products and inconsistencies in standards across nations.[71] Recognizing these challenges, Congress established the "Biotechnology and Agricultural Trade Program" in the 2018 farm bill.[72] The program's core mission is to alleviate trade barriers confronting U.S. biotech products in international markets. These barriers emerge from diverse regulations and varied perceptions of biotech products among countries. The program was also intended to support private sector endeavors to boost biotech trade, educate international audiences on biotech product safety, and devise strategies to navigate trade impediments.

Several international agreements touch on agricultural biotechnology. For instance, the U.S.-Mexico-Canada Agreement (USMCA) became the first to address agricultural products derived

[69] According to the U.S. Department of Health and Human Services (HHS), NBBI will use biotechnology and biomanufacturing to promote groundbreaking research, development, and infrastructure in biotechnology while minimizing risks. HHS is expected to lead the strategic progress of biosafety and biosecurity innovation within the expanding bioeconomy. For more information, see U.S. Department of Health and Human Services, "Fact Sheet: HHS Takes Action on Executive Order Launching a National Biotechnology and Biomanufacturing Initiative," September 14, 2022.

[70] Theresa Selfa, Sonja Lindberg, and Carmen Bain, "Governing Gene Editing in Agriculture and Food in The United States: Tensions, Contestations, and Realignments," *Elementa: Science of the Anthropocene*, p. 00153, October 4, 2021.

[71] For more details, see CRS In Focus IF11399, *Enforcing International Trade Obligations in USMCA: The State-State Dispute Settlement Mechanism*.

[72] "Biotechnology and agricultural trade program," 7 U.S.C. 5679, P.L. 115-334.

through genetic engineering techniques.[73] Furthermore, the U.S.-China Phase One trade agreement saw China making commitments in the realm of agricultural biotechnology.[74] Yet, despite these advances, concerns over countries' adherence to these agreements persist. One example is the trade dispute between Mexico and the United States regarding genetically engineered corn, which revolves around Mexico's plan to phase out imports of U.S. genetically engineered corn by 2024.[75] The U.S. and Canadian governments have raised concerns over Mexico's presidential decree banning the use of genetically engineered corn in tortillas and the gradual substitution of its use in all products for human and animal consumption.[76] The U.S. government asserts that Mexico's biotechnology policies and actions are not based on science, hinder agricultural innovation, and are inconsistent with its obligations under the United States-Mexico-Canada Agreement (USMCA), a free trade pact that took effect in 2020 and replaced the North American Free Trade Agreement (NAFTA).[77]

Congress may consider assessing the potential impacts of regulations on gene-edited plants on market access for agricultural producers and evaluate any trade barriers that may arise due to limited export opportunities and possible hindrances to the free flow of goods.[78] As the funding for the Biotechnology and Agricultural Trade Program is about to come to an end with the expiration of the 2018 farm bill, Congress may assess whether the program's implementation is satisfactory and consider including a re-authorization provision in the upcoming farm bill.

Research Investments in Gene Editing

Congress may continue to be interested in better understanding the intricacies of using biotechnology in agriculture and in exploring the potential uses of gene editing by supporting research and development. The 2018 farm bill established "the Agricultural Genome to Phenome Initiative or AG2PI," a program dedicated to deepening our understanding of genetic information and observable traits (phenotypes) in both crops and animals.[79] The initiative aims to foster collaboration among a diverse group of experts, including crop and livestock scientists, as well as professionals from fields like data science, statistics, engineering, and social sciences.[80] The 2018 farm bill also directed USDA's National Institute of Food and Agriculture (7 U.S.C. §§ 5924 et

[73] 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.

[74] 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.

[75] Cassandra Garrison, "Mexico to Fight US Dispute Over GM Corn After Formal Consultations Fail," *Reuters*, June 2, 2023.

[76] Office of the United States Trade Representative, "United States Requests USMCA Dispute Settlement Consultations on Mexico's Agricultural Biotechnology Measures," June 2, 2023, and Government of Canada, "Ministers Bibeau and Ng Statement on Mexican Measures that Impact Agricultural Innovation," *Agriculture and Agri-Food Canada*, June 9, 2023.

[77] For additional background on the Mexico-U.S. trade consultations, see CRS Report R45661, *Agricultural Provisions of the U.S.-Mexico-Canada Agreement* and CRS Report R45661, *Agricultural Provisions of the U.S.-Mexico-Canada Agreement* and CRS In Focus IF11399, *Enforcing International Trade Obligations in USMCA: The State-State Dispute Settlement Mechanism*.

[78] For more information, see Justus Wesseler and Nicholas Kalaitzandonakes, "Present and Future EU GMO Policy," *EU Bioeconomy Economics and Policies*: Volume II, pp. 245-256, 2019.

[79] CRS Report R47313, *Next Farm Bill Primer Series: A Guide to Agriculture and Food Programs in the 2018 Farm Bill*.

[80] More information about the competitive grants is available at USDA NIFA, "Agricultural Genome to Phenome Initiative (AG2PI)," last visited June 23, 2023.

seq.) to establish a competitive grant program to support collaborative research aimed at expanding knowledge about the genomes and other characteristics of crops and animals important to the agricultural sector. It also aimed to increase understanding of how various factors such as weather impact the growth and productivity of specific varieties of crops and species of animals.

Congress approved $40 million for each fiscal year from FY2019 through FY2023 to be appropriated for the program. Congress may monitor the overall implementation or impacts of the AG2PI and assess whether it has fulfilled the specified objectives, including researching important crops and animals, deepening our understanding of agricultural genetics, and using genetics to combat diseases. A bill was introduced in the 118th Congress (H.R. 3905) with the goal of re-authorizing the AG2PI through FY2028; Congress may also re-authorize funding for the program by including provisions for it in the upcoming farm bill with permanent funding.

Off-Target Effects and Environmental Concerns

The relationship between genetically engineered plants and the potential environmental risks is ongoing.[81] Stakeholders have long raised concerns regarding the introduction of products created with genetic engineering into the environment and the possible unforeseen consequences, including harm to biodiversity and ecosystem stability.[82] These concerns, some of which persist today, stem from potential gene flow between genetically engineered products and wild relatives, the development of resistance in pests, and the unintended impacts on non-target organisms.[83]

Supporters of gene editing, leveraging technologies like CRISPR, argue that the newer technologies offer greater precision and control, enabling more targeted modifications and the potential for products with fewer unintended effects on the environment. Some stakeholders contend that gene-edited plants could still pose ecological and environmental risks,[84] emphasizing the need for comprehensive risk assessments to ensure a thorough evaluation of potential effects on ecosystems and biodiversity. For instance, while CRISPR systems are more precise, they have not eliminated the potential for off-target effects. Off-target impacts can affect treatment outcomes and have led to genotoxicity or chromosomal rearrangements when applied in fields like therapeutics and farm animal breeding.[85] Although off-target mutations have been observed mostly in animals and human cells,[86] studies also indicate possible off-target effects when used in plants such as Arabidopsis, rice, and tomato, but these effects can generally be corrected in subsequent generations.[87]

Biotechnology advancements have implications for food production, sustainability, innovation, and consumer well-being. Many in Congress have been interested in understanding and regulating their potential as well as examining the ethical, social, and environmental

[81] Aftab Ahmad et al., "CRISPR Crops," *Regulatory, Ethical, and Social Aspects of CRISPR Crops*, pp. 261–287, 2021.

[82] Suzanne I. Warwick., Hugh J. Beckie, and Linda M. Hall, "Gene Flow, Invasiveness, and Ecological Impact of Genetically Modified Crops," *Annals of the New York Academy of Sciences* 1168.1, 72-99, 2009.

[83] Krishan Kumar et al., "Genetically Modified Crops: Current Status and Future Prospects," *Planta* 251, pp. 1-27, 2020.

[84] Jennifer Kuzma, "Regulating Gene-Edited Crops-Advocates of Second-generation Genetically Modified Crops are Making Choices Likely to Trigger Another Round of Public Opposition," *Issues in Science and Technology*, 2018.

[85] Keith R. Anderson et al., "CRISPR Off-target Analysis in Genetically Engineered Rats and Mice," *Nature Methods* 15.7, pp. 512-514, 2018.

[86] Alexey V. Deykin et al., "Using CRISPR/Cas9 for Generation the cd209 Knockout Is a Way to Get Cattle Breeds Resistant to the Bovine Leukemia Virus (BLV)," *E3S Web of Conferences,* Vol. 176, EDP Sciences, 2020.

[87] Aftab Ahmad et al., "An Outlook on Global Regulatory Landscape for Genome-Edited Crops," *International Journal of Molecular Sciences,* p. 11753, October 29, 2021.

considerations. For example, Congress has authorized annual appropriations for USDA to award grants "for biotechnology risk assessment research" for FY2020-FY2023 (P.L. 116-94, P.L. 116-260, P.L. 117-103, and P.L. 117-328). Additional bills introduced in Congress have had differing priorities for assessing the potential risks associated with biotechnology and gene editing.[88]

As gene editing technologies evolve, new issues may emerge of interest to Congress. Some of these possible issues may involve managing the coexistence and legal challenges of organic, conventional, and gene-edited plants and their long-term impact on ecosystems and biodiversity, which could lead to conflicts between growers, trading partners, the industry, and consumers.[89]

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[88] See, for example, H.R. 774 - Manufacturing Economy and National Security Act or the MEANS Act. This bill would establish the Office of Manufacturing Security and Resilience within the Department of Commerce to make grants and loans to support domestic manufacturing of critical goods and services, industrial equipment, and manufacturing technology. Genomics and synthetic biology are included in the "key technology focus areas" for the grants and loans in H.R. 2993 & S. 1368, the Preventing PLA Acquisition of United States Technology Act of 2023. These bills would restrict scientific research and technical exchanges, including those relating to genetic engineering, between certain U.S. entities and certain entities in China.

The 117th Congress established the National Security Commission on Emerging Biotechnology through Section 1091 of the FY2022 National Defense Authorization Act (P.L. 117-81). The Commission is tasked with evaluating emerging biotechnology's potential implications for U.S. strategic competitiveness, particularly with China, and for the U.S. military and international security. In the 116th Congress, H.R. 8045- Genome Editing Threat Assessment Act, would have required the Department of Homeland Security (DHS) to comprehensively assess the potential security risks related to genome modification and editing. The assessment would have determined the risk of gene editing being used to intentionally spread infectious diseases. This bill was not enacted.

[89] Caixia Gao et al., "Gene Editing and Agrifood Systems," *FAO Report*, 2022.