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Gene-Edited Plants: Regulation and Issues for Congress

Plant biotechnology, which includes gene editing and genetic engineering, allows a more precise and efficient method for developing desirable traits in crops than conventional breeding methods that rely on natural genetic variation. Gene editing techniques offer the potential to modify specific genes in plants without introducing foreign genes as other methods of genetic engineering may. Gene-edited plants are regulated under the U.S. Coordinated Framework for Regulation of Biotechnology. The framework coordinates how different agencies regulate biotechnology products aiming to ensure their safety. It involves three federal agencies—the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). Over time, the three agencies have been directed by Executive Orders (E.O.s) to update their regulatory approaches to promote innovation in biotechnology and to protect human health and the environment. Potential congressional concerns could include examining whether current policies appropriately weigh the potential risks and rewards of new plant varieties developed using gene editing and whether regulatory agencies are efficiently coordinating their efforts.

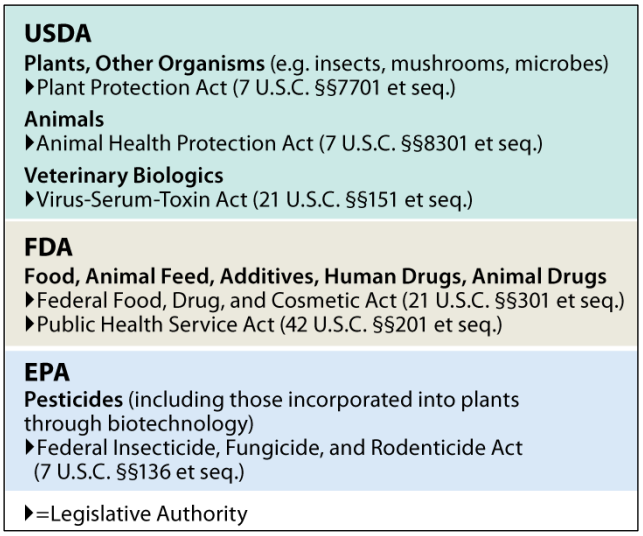
Background

Genetic engineering in agriculture involves the use of recombinant DNA technology to introduce specific genes or genetic material into an organism's genome. This process allows scientists to add to target organisms desired traits that may not be achievable through conventional breeding methods. Genetically engineered (GE) crops, also known as genetically modified (GM) crops, may carry desired characteristics, such as pest and herbicide resistance, and improved nutritional content. The commercialization of GE crops began in the 1990s. In the mid-2010s, gene editing tools like CRISPR-Cas9 used on plants entered agriculture, offering more precise and advanced methods for genetic modification. Gene editing allows targeted modifications of specific genes in plants to improve agronomic traits, such as yield, nutritional value, and disease resistance, without introducing foreign genes. Six gene-edited crop traits are approved for commercialization in the United States, including in soybean, canola, rice, maize, mushroom, and camelina.

Regulation and Oversight of Gene Editing in Plants

The regulation and oversight of gene editing in plants in the United States is facilitated by the U.S. Coordinated Framework for Regulation of Biotechnology. USDA, FDA, and EPA (**Figure 1**) collectively regulate the marketing and environmental release of gene-edited products. The framework relies on statutes predating newer types of biotechnology, such as gene editing. Each agency has established agency-specific regulations and policy documents outlining its regulatory approach to agricultural biotechnology products and emphasizing safety evaluation based on product characteristics rather than the process used to develop them.

Figure 1. Primary Legislative Authorities of Federal Regulation of Agricultural Biotechnology



Source: CRS.

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

USDA Oversight

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 organisms. These authorities were established primarily by the Plant Protection Act (7 U.S.C. §§7701 et seq.), 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 *SECURE Rule* (85 *Federal Register* 29790), which revised regulations for certain gene-edited and GE plants. Fully implemented in 2021, the rule exempts some plants from regulatory review, while others require review and permitting. Regulatory exemptions apply to categories of modified plants that could have been developed through conventional breeding techniques and thus are deemed unlikely to pose an increased plant pest risk compared to conventionally bred plants. Plants that were previously reviewed and deemed by APHIS to be low-risk plant-trait-mechanism of action combinations are also exempt from the regulations.

In addition to the exemptions above, in November 2023, APHIS proposed five new exemptions for plants with

modifications achievable through conventional breeding (88 *Federal Register* 78285). These include modifications such as loss-of-function changes, deletions on chromosomes, multiple simultaneous or sequential modifications, and certain modifications to plants previously confirmed exempt through voluntary review. Developers uncertain whether their plants qualify for an exemption can request a determination from APHIS. APHIS asserts that these new regulations align with advancing technology and scientific understanding and facilitate innovation in agriculture while maintaining stringent safety standards. The period for public comments closed in December 2023, and APHIS has not announced its next steps.

FDA Oversight

FDA's authority to oversee gene-edited plants intended for human or animal consumption comes from the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§301 et seq.) and the Public Health Service Act (42 U.S.C. §§201 et seq.). New gene-edited plant varieties may undergo evaluation for potential impact on food allergenicity, toxicity, and nutritional composition.

In February 2024, FDA issued new guidance for industry on voluntary engagement before marketing food from gene-edited plants, aiming to clarify its policy toward such foods. FDA stated that it reaffirms applying a risk-based approach to foods from gene-edited plants, irrespective of the development method, and that it focuses on objective characteristics of the food and the intended use of the food (or its components). The guidance also outlines two processes through which the industry may voluntarily inform the FDA of the steps they have taken to ensure the safety of foods from their gene-edited plant varieties: voluntary premarket consultations and voluntary premarket meetings. FDA asserted that these processes would help ease the pathway to market for foods from gene-edited plants while keeping FDA safeguards in place.

EPA Oversight

EPA's authority comes 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, the EPA can register a pesticidal substance if it deems that it is effective and does not cause unreasonable adverse effects on the environment. This involves regulating plant-incorporated protectants (PIPs) and setting tolerances or exemptions for pesticidal substances in or on food. Typically, because EPA regulates biotechnology products for pesticidal purposes, it does not regulate gene-edited plants unless traits synthesize specific chemicals.

In May 2023, EPA issued a final rule (88 C.F.R. §§34756 et seq.) exempting certain categories of PIPs from registration requirements under FIFRA. EPA intends to consider expanding exemptions as biotechnology advances.

Changes to the Coordinated Framework for Regulation of Biotechnology

The three agencies that oversee agricultural products produced with biotechnology have periodically revised some of their regulations or other policy documents. The most recent changes occurred amid a broader debate about how the federal government should manage its roles in the biotechnology context, including those to protect consumers from risk and to support businesses and innovation. Some stakeholders, including some scientists and in industry, have called for updates to federal biotechnology regulations in light of scientific advances. Some stakeholders claim that because gene editing allows genetic changes in a more targeted way than the biotechnology approaches available when the Coordinated Framework was designed, the newer methods should not require the same regulatory scrutiny as products developed through less-targeted techniques. Other stakeholders, including consumer and environmental groups and other scientists, assert that all biotechnology products may present new risks, and unintended consequences, and should therefore be strictly or more strictly regulated.

In June 2019, the Trump Administration issued E.O. 13874, "Modernizing the Regulatory Framework for Agricultural Biotechnology Products" (84 *Federal Register* 27899). The order called for USDA, FDA, and EPA to collaborate in modernizing regulations for agricultural biotechnology products. It also required a review of existing policies and regulations, identification of areas for streamlining according to the E.O.'s guidance, implementation of changes, and appropriate exemptions for low-risk products. In September 2022, the Biden Administration issued E.O. 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy" (87 *Federal Register* 56849). This order instructed the agencies to further improve the clarity and efficiency of regulatory processes for biotechnology products and to increase coordination and communication among the federal regulatory agencies. The order aimed to streamline regulations to promote research, enhance biosecurity, and stimulate economic growth. According to APHIS, its actions, such as proposals for additional exemptions for five new categories of plants, align with the goals of E.O. 14081. Similarly, FDA's clarification of guidance for industry on voluntary engagement before marketing food from gene-edited plants is designed to align with E.O. 14081. Additionally, according to EPA, the changes to regulations regarding PIPs align regulations with advancing technology and scientific understanding, as directed by E.O. 14081.

Options for Congress include examining how executive branch efforts weigh the risks and potential rewards of new plant varieties developed using gene editing. Members might consider whether USDA, FDA, and EPA are effectively implementing this approach and whether the efforts of the agencies would benefit from additional congressional direction or amended authorities.

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