Congressional Research Service
Informing the legislative debate since 1914

IN FOCUS

Updated November 30, 2024

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 compared to conventional breeding, which relies on natural genetic variation. Gene editing techniques can modify specific genes in plants without introducing foreign genes, unlike other genetic engineering methods. Gene-edited plants are regulated under the U.S. Coordinated Framework for the Regulation of Biotechnology. The framework coordinates how three agencies—the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA)—regulate biotechnology products in order to ensure safety. Executive orders (E.O.s) direct these agencies to update their regulatory approaches to foster innovation while protecting human health and the environment. Potential issues for Congress include evaluating current policies, determining the potential risks and benefits of gene-edited plants, and reviewing whether the coordination among USDA, FDA, and EPA is effective. Options include reviewing the agencies' regulatory efforts, considering updated authorities or clearer definitions, streamlining low-risk innovation, and assessing the level of funding for research.

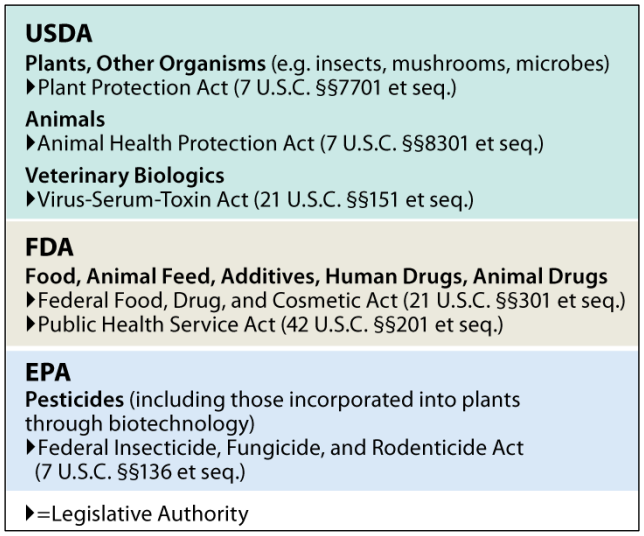
Background

Genetic engineering in agriculture involves using recombinant DNA technology to introduce specific genes or genetic material into an organism's genome, enabling the development of traits not achievable through conventional breeding. The commercialization of genetically engineered crops began in the 1990s, and by the mid-2010s, gene editing tools like CRISPR-Cas9 were applied to plants. These tools allow for more precise, targeted genetic modifications to improve traits, such as yield, nutritional value, and disease resistance, without introducing foreign genes. Several gene-edited crops have been approved for commercialization in the United States, including soybean, canola, rice, maize, mushroom, tomatoes, and camelina.

Regulation and Oversight of Gene Editing in Plants

The regulation and oversight of gene editing in plants is facilitated by the U.S. Coordinated Framework for the 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 for 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 2020, APHIS published the "Movement of Certain Genetically Engineered Organisms" final rule (also called the *SECURE Rule*; 85 *Federal Register* 29790), revising regulations for certain gene-edited and genetically engineered plants. Fully implemented in 2021, the rule exempts some plants from regulatory review while requiring permits for others. Exemptions apply to plants that could have been developed through conventional breeding and are unlikely to pose increased plant pest risks, as well as to previously reviewed, low-risk plant-trait-mechanism combinations. In November 2023, APHIS proposed five new exemptions for plants with modifications achievable through conventional breeding, such as loss-of-function changes and deletions on chromosomes (88 *Federal Register* 78285). Other modifications include multiple simultaneous or sequential changes and adjustments to plants previously confirmed exempt from regulation. In November 2024, APHIS announced a final notice expanding the exemptions to allow plants with up to 12 modifications to qualify (89 *Federal Register* 89569).

According to the agency, the updates align with scientific advancements and foster innovation while maintaining safety standards.

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 impacts 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 FDA of the steps it has taken to ensure the safety of foods from their gene-edited plant varieties: voluntary premarket consultations and voluntary premarket meetings. FDA asserts 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.). Under FIFRA, EPA can register a pesticidal substance if it deems it to be effective and not a cause of 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 *Federal Register* 34756) exempting certain categories of PIPs from registration requirements under FIFRA. EPA has stated that the agency is open to considering additional PIP category exemptions and expanding exemptions as biotechnology advances.

Changes to the Coordinated Framework for the Regulation of Biotechnology

USDA, FDA, and EPA have periodically revised some of their regulations or other policy documents. Some of the revisions 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 scientists and industry leaders, have called for updates to federal biotechnology regulations in light of scientific advances. Some of these 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 therefore should 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), calling for USDA, FDA, and EPA to collaborate in the modernization process. 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 the regulatory process for biotechnology products" and to increase coordination and communication among the federal regulatory agencies. Its aim was to streamline regulations to promote research, enhance biosecurity, and stimulate economic growth. USDA, FDA, and EPA assert that their subsequent regulatory actions, discussed above, align with these orders. In May 2024, USDA, FDA, and EPA released a plan for regulatory reform under the Coordinated Framework for the Regulation of Biotechnology, focusing on modified plants, animals, microorganisms, human drugs, and broader issues. The plan aims to clarify and streamline oversight of genetically engineered products, stating that USDA, FDA, and EPA intend to update the framework by December 2024 and to begin conducting biannual reviews to ensure it remains up to date.

Issues for Congress

Options for Congress include examining the effectiveness of USDA, FDA, and EPA efforts to regulate gene-edited products, particularly new plant varieties, and considering whether these agencies need additional direction or amended authorities to increase or decrease regulatory scrutiny. Congress may also consider clarifying related definitions in statute, amending processes based on deemed risk, or changing research funding or agency capacity. Oversight hearings could assess how and whether the implementation of the regulatory revisions achieve the goals of balancing safety and scientific advancements in new biotechnology products. In addition, as differences in regulations and labeling requirements between countries could potentially lead to important trade issues, 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 as a result of limited export opportunities and possible hindrances to the free flow of goods.

Eleni G. Bickell, Analyst in Agricultural Policy

IF12618

Disclaimer