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IN FOCUS

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USDA's Regulation of Agricultural Biotechnology

The U.S. Department of Agriculture (USDA) regulates certain organisms developed using genetic engineering (GE) under its authority to prevent the introduction and dissemination of plant pests. In May 2020, USDA's Animal and Plant Health Inspection Service (APHIS) finalized the "Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE)" rule, which revised 7 C.F.R. Part 340. The rule was fully implemented in October 2021. In December 2024, the U.S. District Court for the Northern District of California prospectively vacated the SECURE rule. Following the court's decision, APHIS announced that it would reestablish regulatory and nonregulatory processes under the pre-2020 biotechnology regulations at 7 C.F.R. Part 340 (2019).

As of 2026, USDA biotechnology oversight operates under these earlier regulations while APHIS evaluates potential regulatory revisions. In the Spring 2025 Unified Agenda of Regulatory and Deregulatory Actions (Unified Agenda), APHIS listed an anticipated interim final rule, "Regaining Lost Efficiencies for Products of Biotechnology." The listing indicates that USDA intends to alter regulatory processes following the vacatur of the SECURE rule, with publication projected for 2026.

This In Focus describes USDA's statutory authority over agricultural biotechnology, the evolution of its implementing regulations, and the current regulations following the vacatur of the 2020 SECURE rule. It also outlines how USDA's role fits within the broader Coordinated Framework for the Regulation of Biotechnology and highlights issues that may be of interest to Congress as agencies evaluate regulatory changes.

The Coordinated Framework of the Regulation of Biotechnology

The federal government's 1986 *Coordinated Framework for Regulation of Biotechnology* (Coordinated Framework) describes how USDA, the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA) regulate biotechnology products under existing statutes. Rather than acting upon a single biotechnology statute, the framework relies on agencies' preexisting legal authorities. Under the Coordinated Framework, USDA regulates certain biotechnology products for plant health risks; EPA regulates pesticides (including plant-incorporated protectants, PIPs); and FDA oversees food and feed safety. A central principle of the Coordinated Framework is that products are regulated based on their characteristics and potential risks rather than the processes used to develop them. Depending on their intended use and characteristics, more than one agency may have jurisdiction.

USDA's Authority Under the Plant Protection Act

USDA's regulation of agricultural biotechnology occurs primarily through APHIS under the Plant Protection Act (PPA; 7 U.S.C. §§7701 et seq.). The PPA authorizes USDA to regulate the importation, interstate movement, and environmental release of organisms that are plant pests or if there is reason to believe they are plant pests.

Under APHIS biotechnology regulations at 7 C.F.R. Part 340 (2019), a "regulated article" includes organisms altered or produced through GE that (1) contain genetic material derived from a plant pest or (2) are determined by APHIS to be a plant pest or likely to pose a plant-pest risk. *Plant-pest risk* refers to the potential for injury, damage, or disease to plants or plant products.

Pre-2020 Biotechnology Regulations (Currently in Effect)

APHIS is using the biotechnology regulations that were in place prior to May 2020 (i.e., pre-2020 biotechnology regulations). The sections below outline the main elements of that framework.

"Am I Regulated?" Process

Under the pre-2020 biotechnology regulations, developers may submit an inquiry through APHIS's "Am I Regulated?" (AIR) process to determine whether an organism meets the definition of a regulated article. If APHIS determines that the organism is not a regulated article, the organism is not subject to regulation under 7 C.F.R. Part 340.

Permits and Notifications

If an organism is a regulated article, APHIS oversight applies to its importation, interstate movement, and environmental release. Such activities require either a permit or, in certain cases, a notification process if qualified. Permits and notifications are intended to ensure confinement and oversight of regulated articles during field testing and movement.

Petitions for Nonregulated Status

Developers of regulated articles may petition APHIS for a determination of nonregulated status. In evaluating a petition, APHIS assesses whether the "organism is unlikely to pose a greater plant pest risk relative to its comparator." If APHIS determines that the organism is not a plant pest, it must grant nonregulated status and lacks authority under the PPA to continue regulating the organism.

APHIS publishes notices in the *Federal Register* to solicit public comment on petitions and makes its determinations publicly available.

USDA's Previous SECURE Rule (2020-2024)

In contrast, USDA's SECURE rule did not require APHIS to assess the risk of every new GE plant variety. Rather than requiring a case-by-case review of all GE plants, the rule established exemptions and a new review process based on APHIS's assessment of plant-pest risk. (**Figure 1**). Certain GE plants were exempt from regulation if APHIS determined they could have been developed through conventional breeding and were unlikely to pose increased plant-pest risk. Developers could request written confirmation that a plant was not subject to regulation. For nonexempt plants, the rule established a Regulatory Status Review (RSR) process involving a risk-based screening approach to determine whether a plant required continued oversight. The SECURE rule also retained permitting requirements for organisms that did not qualify for exemptions or were determined to pose plausible plant-pest risks.

Figure 1. The Vacated SECURE Rule Process

Source: Figure created by CRS.

Anticipated Regulatory Revisions (2026)

USDA reviews each new transformation event through a petition process and may conduct separate reviews for products that are also regulated by other federal agencies, such as EPA. In the Unified Agenda, APHIS listed an anticipated interim final rule titled "Regaining Lost Efficiencies for Products of Biotechnology" (RIN 0579-AE84), indicating that USDA intends to alter regulatory processes following the vacatur of the SECURE rule. According to APHIS, the anticipated rule would consider exemptions or simplified procedures for certain low-risk plants and microorganisms, including some commonly used in laboratory development. It would also address permitting requirements, such as movement and shipping requirements, the use of multiyear permits, whether prior regulatory determinations could apply to similar future transformation events, and ways to reduce review where another federal agency regulates the product. APHIS discussed the anticipated rule at the Biotechnology Regulatory Services Annual Meeting in February 2026. The rule has not been published, and specific regulatory details are not available.

Why Did Regulations Change in 2020?

USDA's SECURE rule was issued in the context of broader debates about how federal biotechnology oversight should adapt to scientific advances. Since the Coordinated Framework was established in 1986, biotechnology techniques have evolved (e.g., newer genome-editing methods, such as CRISPR/Cas9). These developments prompted debate over whether certain genome-edited plants should be regulated in the same manner as earlier transgenic organisms. Genome editing techniques that developed after the Coordinated Framework was established have prompted differing views on whether newer products warrant the same regulatory treatment as earlier GE organisms.

Both the Trump Administration in 2019 and the Biden Administration in 2022 directed federal agencies to modernize biotechnology regulation. Executive Order 13874 (2019) and Executive Order 14081 (2022) emphasized regulatory efficiency, coordination, and clarity while maintaining safety standards. In turn, some agencies updated their approaches. EPA revised its oversight of certain PIPs, exempting certain low-risk PIPs from registration and tolerance requirements and establishing a notification process for transparency, with additional exemptions anticipated as biotechnology advances. FDA continues to operate a voluntary consultation process for foods derived from GE plants and reaffirmed this approach in updated guidance issued in February 2024.

Reactions to USDA's SECURE Rule

Stakeholder reaction to the SECURE rule was mixed. Some consumer and public interest organizations argued the rule narrowed federal oversight: the Center for Science in the Public Interest stated that "a majority of GE and gene-edited plants now will escape any oversight." The National Feed and Grain Association stated that the rule "takes an overly broad approach that does not deliver adequate transparency and could contribute to future trade disruptions," and the National Corn Growers Association welcomed the revisions but anticipated further streamlining. USDA reported that the revised process expedited certain reviews, averaging approximately 41 days, with small and medium-sized enterprises comprising a substantial share of applicants. Some stakeholders contended that self-determined exemptions could reduce oversight compared with the prior regulations.

Potential Congressional Interest

Congress has received recommendations identifying biotechnology as an area of strategic importance for U.S. economic competitiveness, food security, and national security from multiple sources, including executive branch initiatives and reports from the National Security Commission on Emerging Biotechnology (NSCEB). These sources have highlighted the role of regulatory clarity and predictability in supporting innovation while maintaining public trust and effective oversight.

Congress may consider overseeing USDA's implementation of the pre-2020 biotechnology regulations following the vacatur of the SECURE rule and monitoring the agency's anticipated rulemaking. In doing so, Congress may consider how regulatory uncertainties may affect the development, review, and commercialization of biotechnology products and the efficiency and extent of interagency coordination among USDA, EPA, and FDA. Congress may clarify, amend, or reaffirm USDA's role with respect to newer biotechnology techniques and the sufficiency of agricultural biotechnology oversight under current statutes and regulations.

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