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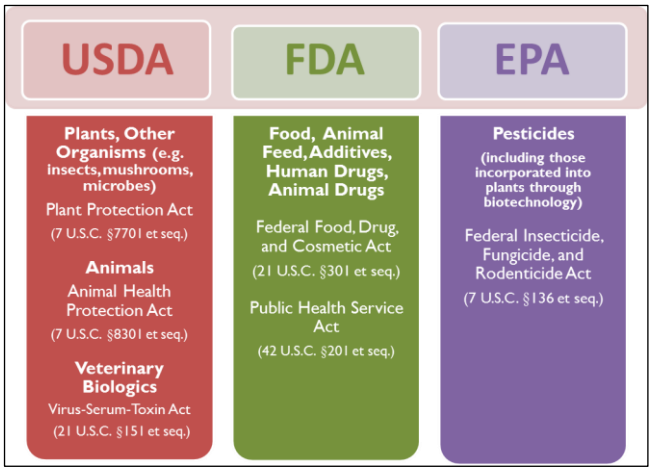
USDA's SECURE Rule to Regulate Agricultural Biotechnology

On May 18, 2020, the U.S. Department of Agriculture (USDA) published the final rule to revise its regulation of certain genetically engineered (GE) plants and other organisms (85 *Federal Register* 29790). USDA's Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule revises the regulations at Title 7, Section 340, of the *Code of Federal Regulations*. Phased implementation begins in June 2020, with full implementation by October 1, 2021.

The Coordinated Framework

USDA's SECURE rule is one component of the broader federal regulation of biotechnology products (e.g., GE plants, animals, and other organisms). The federal government's *Coordinated Framework for Regulation of Biotechnology* (the *Coordinated Framework*, 51 *Federal Register* 23302, June 26, 1986) outlines how USDA, the U.S. Food and Drug Administration (FDA), and the U.S. Environmental Protection Agency (EPA) apply existing statutes to regulate biotechnology products (**Figure 1**). A key principle of U.S. biotechnology policy is to regulate products according to their characteristics and unique features rather than the processes used to develop them.

Figure 1. Primary Legislative Authorities of Federal Biotechnology Regulation



Source: CRS.

Federal Regulation of Agricultural Biotechnology

Within the broader *Coordinated Framework*, USDA and EPA regulate the environmental release, transportation, and importation of GE agricultural products, including plants and other organisms (e.g., insects, mushrooms, microbes). FDA regulates GE material used in food products.

Within USDA, the Animal and Plant Health Inspection Service (APHIS) regulates new plants and other organisms according to their plant-pest and noxious weed risk under the Plant Protection Act (7 U.S.C. §7701 et seq.). *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 potential to exacerbate a plant pest's impact. FDA regulates agricultural products for their safety for human and animal consumption, and EPA regulates plant pesticides, including those incorporated through genetic engineering. The APHIS regulations (7 C.F.R. §340) specify what organisms APHIS regulates (most *regulated articles* are plants), processes to determine whether they are regulated, and how APHIS regulates them.

USDA's Previous Regulations

Prior to USDA's SECURE rule, product developers could seek a USDA determination of whether a new organism met the definition of *regulated article* through the APHIS *Am I Regulated?* process. A **petition process** allowed individuals to request non-regulated status for an organism that met the definition. In this process, APHIS assessed the plant-pest risk of each new GE plant variety separately—irrespective of its similarity to GE varieties that APHIS had approved in the past. Regulated articles required either **permits** for their importation, interstate transportation, or environmental release or use of a **notification process** in lieu of permits when the plant was not considered a noxious weed and met other standards.

USDA's New Regulations

USDA states that the final SECURE rule is the first "significant" revision of the APHIS regulations since their creation in 1987. Unlike the prior rule, USDA's SECURE rule does not assess the risk of every new GE variety. It applies APHIS's current understanding of plant-pest risk to exempt broad categories of new plants from review:

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

Major changes relate to exemptions, regulatory status review, and permitting, described in more detail below.

Exemption and Confirmation Process (§340.1)

USDA's SECURE rule exempts certain categories of modified plants (not other organisms) from the regulations because they could otherwise have been developed through conventional breeding. The rule identifies exemptions based on the type of GE modification. APHIS considers that such plants (e.g., certain genome-edited varieties) are "unlikely to pose an increased plant pest risk compared to conventionally bred plants." USDA's SECURE rule also exempts plants with a *plant-trait-mechanism of action combination* (i.e., combination of species, GE trait, and

how the GE trait was introduced) that APHIS has previously deregulated or determined need not be regulated. Developers can request a written confirmation from APHIS that a plant is not subject to the regulations. Exemptions do not include non-plant organisms. The exemption and confirmation process takes effect on August 17, 2020. It replaces the prior *Am I Regulated?* process.

Regulatory Status Review (§340.4)

The regulatory status review (RSR) process replaces the prior petition process. Product developers may request a permit or an RSR for a new GE plant (not other organisms) that APHIS has not previously evaluated and determined to be non-regulated. Under the RSR process, APHIS evaluates whether the plant requires additional oversight based on its characteristics—its plant-pest risk—rather than the method used to develop it. If APHIS determines that the plant is not regulated, then later GE varieties using the same plant-trait-mechanism of action combination would not be regulated. If APHIS cannot determine that the plant does not pose a plant-pest risk, then it would require a permit. The RSR process is to be implemented for new GE corn, soybeans, cotton, potatoes, tomatoes, and alfalfa beginning April 5, 2021, and for all GE plants by October 1, 2021.

Permitting (§340.5)

USDA's SECURE regulations require a permit for the importation, interstate movement, or environmental release of any GE organism that may pose a plant-pest risk. These include plants that do not meet the exemption criteria or are determined to pose a plausible plant-pest risk through the RSR process, and other organisms. Developers may request a permit instead of an RSR, or they may request both. The RSR and permitting processes replace the former rule's notification process. The changes take effect April 5, 2021.

Stakeholder Reactions

Initial stakeholder reaction to USDA's final SECURE rule has been mixed. Some exporter and consumer groups criticized the new rule, while some producer groups supported it. In a May 14, 2020 statement, 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." On the same date, the Center for Science in the Public Interest stated that "a majority of genetically engineered and gene edited plants now will escape any oversight," and "government regulators and the public will have no idea what products will enter the market and whether those products appropriately qualified for an exemption from oversight."

Among supporters, the National Farm Bureau Federation stated that "the revised rule will encourage innovation of new plant breeding techniques while safeguarding our food supply." The National Corn Growers Association stated that the new rule provides "a modern framework to better address the innovations in and challenges facing modern agriculture."

Context for Regulatory Updates

USDA issued its SECURE rule in the midst of a broader debate about how the federal government should manage its roles, including those to protect consumers from risk and to support businesses and innovation. Some stakeholders have long called for updates to federal biotechnology regulations in light of scientific advances. *Genome editing*, which allows scientists to alter the characteristics of an organism through genetic changes in a more targeted way than previous biotechnology approaches permitted, was developed decades after the *Coordinated Framework* was designed. Some have argued that genome-edited products should not require the same regulatory scrutiny as products developed through less-specific techniques. Others have argued that products of all biotechnology may present new risks and should be strictly regulated.

The federal government revised the *Coordinated Framework* in 1992 and 2017. These updates did not involve changes to the underlying legislation and did not change the long-standing federal policy of evaluating risks and regulating products based on their characteristics rather than the processes used to develop them. The 2017 update states:

> It is the characteristics of the biotechnology product, the environment into which it will be introduced, and the application of the product that determine its risk (or lack thereof).

Following the 2017 update, USDA addressed its position on the regulation of genome-edited plants in a March 28, 2018, statement, stating it did not—and did not plan to—"regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or developed using plant pests."

The following year, the Trump Administration issued Executive Order (E.O.) 13874, *Modernizing the Regulatory Framework for Agricultural Biotechnology Products* (June 11, 2019). This E.O. called for USDA, FDA, and EPA to coordinate in modernizing the regulatory framework for agricultural plants and animals produced through biotechnology. It called for the agencies to review existing policies and regulations, identify those that could be streamlined in accordance with the E.O.'s policy guidance, begin to implement such changes, and exempt low-risk products from regulation "as appropriate." The SECURE rule meets this obligation for USDA. FDA and EPA have not yet revised their agricultural GE product regulations.

Congressional Interest

Congress may be interested in how any future changes to FDA and EPA regulation of GE plants align with the changes introduced through USDA's SECURE rule. As implementation of USDA's rule begins and potential updates of FDA and EPA regulations are made, Congress may consider whether the statutes underlying the *Coordinated Framework* continue to provide appropriate regulatory guidance or whether they require revision.

USDA's rule could also raise new concerns in international trade. Some have questioned whether certain U.S. trading partners would accept the revised regulatory requirements as sufficient to meet their own regulations for importing U.S. GE products. Congress may choose to monitor U.S. trading partner responses.

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