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USDA’s SECURE Rule to Regulate Agricultural Biotechnology

In May 2020, citing 30 years of evidence, the U.S. Department of Agriculture (USDA) published a 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 revised the regulations at Title 7, Section 340, of the *Code of Federal Regulations* and further stated that new GE technologies, such as genome editing, do not engage with plant pests in any way. The rule was fully implemented in October 2021.

The Coordinated Framework

The federal government’s 1986 *Coordinated Framework for Regulation of Biotechnology* (Coordinated Framework) governs 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.

A key principle of the Coordinated Framework is to regulate products according to their characteristics and unique features rather than the processes used to develop them (e.g., whether or not they were developed with biotechnology). The Coordinated Framework was updated in 1992 and 2017 to better guide the federal agencies and summarize the statutes under which they regulate biotechnology products.

Regulation of Agricultural Biotechnology

Within the broader Coordinated Framework, EPA regulates plant pesticides, including those developed through genetic engineering. FDA regulates agricultural products for their safety for human and animal consumption. USDA’s primary engagement with the regulation of biotechnology-derived products has been through the Animal and Plant Health Inspection Service’s (APHIS’s) oversight of GE plants under the Plant Protection Act (PPA; 7 U.S.C. §§7701 et seq.). Under the PPA, APHIS regulates the importation, interstate movement, and environmental release (including field testing) of GE plants and organisms that may pose a plant-pest risk. *Plant-pest risk* is 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.

APHIS’s PPA regulations for GE organisms (7 C.F.R. §340) define regulated articles (i.e., the organisms subject to these PPA regulations; most are plants), processes to determine whether they are regulated, and how APHIS regulates them.

USDA’s Previous Requirements

Prior to USDA’s SECURE rule, product developers would seek a USDA determination of whether a new organism met the definition of a *regulated article* through the APHIS *Am I Regulated?* process. In this process, APHIS assessed the plant-pest risk of each new GE plant variety

separately—irrespective of its similarity to GE varieties approved in the past. Regulated articles required either permits for their importation, interstate transportation, environmental release, or the use of a notification process when the plant was not considered a noxious weed and met other standards. Developers could go through a separate petition process to request nonregulated status for an organism that met the regulated article definition.

USDA’s SECURE Rule

Unlike the prior requirements, USDA’s SECURE rule does not assess the risk of *every* new GE variety and provides changes to the exemptions, regulatory status review, and permitting steps of the process, based on APHIS’s current understanding of plant-pest risk (**Figure 1**). If exempted, developers can request a written confirmation from APHIS that a plant is not subject to the regulations (I). Plants that are not exempt must undergo a regulatory status review (II), which replaces the prior petition process. The review is followed by a new permitting process (III), which replaces the prior notification process.

Figure 1. The SECURE Rule Process



Source: CRS.

Exemptions and Confirmations (§340.1)

USDA’s SECURE rule exempts certain categories of engineered plants (not other organisms) from the regulations because USDA deems that they could otherwise have been developed through conventional breeding. 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., a combination of species, GE trait, and how the GE trait was introduced) that APHIS has previously deregulated or determined need not be regulated. Under the revised rules, developers self-determine if their product meets the exempt status and can request written confirmation from APHIS that a plant is not subject to the regulations. The exemption and confirmation process took effect in August 2020.

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 that APHIS has not previously evaluated and determined to be nonregulated. 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 also 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 took effect for all GE plants in October 2021.

Permitting (§340.5)

USDA's SECURE regulations require a permit for the importation, interstate movement, or environmental release of any GE organisms that may pose a plant-pest risk. These include plants and other organisms that do not meet the exemption criteria or are determined to pose a plausible plant-pest risk through the RSR process.

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 took effect in April 2021.

Reactions to the Changes

Initial stakeholder reaction to USDA's final SECURE rule has been mixed. Some exporter and consumer groups have criticized the rule, while some producer groups have supported it.

In a May 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.” 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.”

USDA states that the revised process has helped expedite the approval timing for new plants developed with biotechnology to about 41 days on average from submission, with small and medium-sized enterprises being the main clients. Although self-determination of exemptions provides flexibility in the approval process for developers, some have argued that it may provide less robust oversight of new GE and gene-edited varieties available in the market than the previous process.

In its five-year Strategic Plan for FY2023-FY2027, APHIS stated that one of its objectives is to ensure the safe development of agricultural biotechnology products using a science-based regulatory framework, including efficient permit review for GE organisms, clear communication of regulations to stakeholders, coordination with other agencies, and harmonization of regulatory oversight for biotechnology products.

Context for Regulatory Updates

USDA issued its SECURE rule 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 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 assert that genome-edited products should not require the same regulatory scrutiny as products developed through less-targeted techniques. Others have argued that all biotechnology products may present new risks and should be strictly regulated.

In 2019, the Trump Administration issued Executive Order (E.O.) 13874, “Modernizing the Regulatory Framework for Agricultural Biotechnology Products” (June 2019). The order called for USDA, FDA, and EPA to coordinate in modernizing the regulatory framework for agricultural plants and animals produced through biotechnology. It also asked 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.”

In 2022, the Biden Administration issued E.O. 14081, “Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy,” ordering the three agencies to further improve the clarity and efficiency of regulatory processes for biotechnology products and increase coordination and communication between federal regulatory agencies. FDA encourages developers of all new plant varieties to request premarket food safety consultations with the agency, which involves a discussion of the safety protocols and regulatory issues before the food is distributed in the market

In response to E.O. 14081, in May 2023, EPA announced changes to its regulations concerning genetically engineered plant-incorporated protectants (PIPs). 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. EPA's rule (88 C.F.R. §§34756 et seq.) went into effect in July 2023.

Congressional Interest

Congress may be interested in monitoring how USDA's revised regulatory requirements have affected the development and commercialization of GE and genome-edited products. Beyond that, Congress may consider monitoring how USDA, FDA, and EPA are assessing the effectiveness of the revised regulations, as underlined by the self-determination aspect of the exemption status of new GE and genome-edited products. Further, Congress may also oversee how well the three agencies are working together to harmonize the regulation of biotechnology products moving forward.

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