



Questions & Answers

Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) Rule

May 2020 (rev. June 2020)

Q: What is prompting this revision?

A: The United States Department of Agriculture’s (USDA) Animal and Plant Health Inspection Service’s (APHIS) plant biotechnology regulations have not been updated in a meaningful way for almost three decades. There have been major advances in the science of biotechnology during the past 30 years. Over that time APHIS has gained considerable experience in assessing the plant health risks of organisms developed using genetic engineering. The revisions to the regulations reflect these realities and ensure the introduction of a new/novel plant is safe for plant health.

Q: What are the goals of this revision?

A: The goals of the SECURE rule are to provide regulatory relief, enable innovation, and continue to protect plant health. The revisions allow APHIS to regulate organisms developed using genetic engineering in a manner that balances oversight and risk, based on the best available science. This is the first comprehensive revision of these regulations since they were established in 1987.

Q: What will be regulated under the new rule?

A: The new regulations focus regulatory oversight on organisms that pose a risk to plant health. Specifically, APHIS will regulate plants developed through genetic engineering when they pose a plausible plant pest risk to plant health. APHIS will also regulate plant pests (e.g., microbes and insects) and certain biological control organisms developed through genetic engineering.

Q: How is this final rule different from the current regulations?

A: Under the current regulations, regulatory oversight is focused on whether a plant pest is used in the development of the product. After 30 years of experience, we know that simply using a plant pest in the development of a plant does not necessarily cause it to pose a risk to plant health. Nonetheless, a time-consuming process is needed to remove regulatory oversight for organisms developed using genetic engineering that are unlikely to pose a plant pest risk. In addition, with advances in technology, developers are using more rapid and precise technologies, some of which do not use plant pests. This final rule puts in place a more efficient process to identify organisms that would be subject to regulation, focusing on the properties of the organism rather than on the use of a plant pest in its development. The final rule also enables APHIS to more quickly remove regulatory oversight for plants developed using genetic engineering that do not pose a plant health risk. These changes bring the biotechnology regulations up to speed and ensure they remain relevant into the future.

Q: What does “genetic engineering” mean?

A: The revised regulations define genetic engineering as techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome.

Q: What categories of plants developed using genetic engineering are exempt from regulation under the new rule?

A: The SECURE rule codifies Secretary Perdue’s statement on plant breeding innovation (issued March 2018) and exempts from regulation plants that could otherwise have been developed through conventional breeding techniques. Examples of genetic changes exempt from regulation include gene deletions and simple genetic transfers from one compatible plant relative to another. The new rule also exempts new varieties of plants that are the same as plants developed through genetic engineering that APHIS already reviewed and found unlikely to pose a plant pest risk. The new rule also provides mechanisms to adapt to future innovations that cannot yet be anticipated.

Q: Can developers rely on previously issued “Am I Regulated?” (AIR) responses to determine if their modified plant is exempt from the SECURE rule?

A: No. Plants that are the subject of previously issued AIR responses are not included in the § 340.1(c) exemption list because the plants were not evaluated under the petition process or the RSR process. Developers will not be able to use the AIR list in determining whether new modified plants they develop are subject to or exempt from the regulations. As described in § 340.1(d), only the plant specifically described in the AIR response retains its nonregulated status.

Q: Are there currently plants developed using genetic engineering that are not subject to regulation that will be subject to review in the final rule?

A: APHIS estimates that a small number of plants that were not regulated under the prior regulations may be regulated under the SECURE rule. In reviewing prior requests submitted through the “Am I Regulated?” process, APHIS found that about one percent of the plants might not qualify for an exemption or be found unlikely to pose an increased plant pest risk after an initial Regulatory Status Review and thus require regulation under SECURE.

Q: How does the final rule address genome editing techniques?

A: This final rule puts in place a more efficient process to identify organisms that would be subject to regulation, focusing on the properties of the organism rather than on the use of a plant pest in its development. Although plants developed using genome editing techniques are exempt from regulation if they could have otherwise been produced through conventional breeding techniques, the regulations focus on the plant pest risk presented by the product. Thus, some plants developed using genome editing techniques will be regulated if they pose a plausible plant

pest risk. The processes established in the final rule enables APHIS to efficiently remove many products from regulation and regulate a subset that present a risk to plant health.

Q: Have you sought input from stakeholders before publishing this final rule?

A: Yes. APHIS undertook an extensive outreach effort in developing the proposed rule, traveling the nation and meeting with the public, members of academia, state departments of agriculture, grower and commodity-related organizations, and non-governmental organizations. The Agency also considered comments received during public scoping and comment periods related to the 2008 and 2017 proposed rules, which were later withdrawn; comments on a 2018 Notice of Intent (NOI) to conduct a programmatic environmental impact statement (PEIS); comments on the proposed rule and the draft PEIS; certain provisions of the 2008 Farm Bill; and recommendations from the 2015 USDA Office of Inspector General (OIG) report on genetically engineered organisms. The Agency also met with foreign regulators and international stakeholders.

In issuing the final SECURE rule, APHIS carefully considered each of the thousands of comments received in response to proposed rule and the draft Programmatic Environmental Impact Statement (PEIS), and adopted changes that most appropriately addressed the concerns raised and would increase the efficiency and precision of APHIS' regulations.

Q: Have you considered the economic impact of the final rule?

A: Yes. An extensive economic analysis was conducted, which considered the future scope and effect of the regulation on businesses. The SECURE rule will stimulate innovation and technical advancement leading to additional competitiveness for American agriculture. The revised regulations will also provide greater trade opportunities for farmers and for rural economies. In accordance with Executive Order 13771, APHIS estimates the net private sector savings for the SECURE rule at \$8.3 million.

Q: Will more organisms developed using genetic engineering be regulated under the final rule?

A: We expect the number of organisms developed using genetic engineering that remain subject to the regulations will be lower. The final rule focuses on the properties of the organism rather than the use of a plant pest in its development. Although initially this could result in a larger and more diverse group of products being subject to regulation, the final rule establishes regulatory off ramps for products that we know do not pose plant pest risk. Moreover, in contrast to the current regulations, once a specific plant developed through genetic engineering is found not to require regulation, new varieties of the plant containing the same genetic modification would similarly not be regulated.

Q: What roles does the final rule play in food safety?

A: The final rule is issued under the Plant Protection Act and does not involve food safety or impact the voluntary food safety consultation process implemented by the U.S. Food and Drug

Administration. All food safety assurances currently provided by the FDA are unchanged by this final rule. This rule in no way negatively impacts food safety.

Q: Under the final rule, how will developers be able to show their product is not regulated?

A: A key feature of the final rule takes into account the challenges of accessing foreign agriculture markets. We included specific provisions for developers to request a formal written communication from APHIS that provides the status of a plant with respect to our regulations.

Q: Would developers still be required to comply with EPA and FDA regulations?

A: Yes. Issuance of the final rule does not affect the regulatory oversight currently provided by both the Food and Drug Administration and the Environmental Protection Agency.

Q: Is a permit required for a plant that has been modified to produce a plant-incorporated protectant (PIP) that is regulated by EPA under an Experimental Use Permit (EUP)?

A: Yes. Unless APHIS has reviewed the plant pursuant to an RSR request and determined it to not be regulated under 7 CFR part 340, permits will be required for a plant modified to produce a PIP that is regulated by EPA under an EUP. USDA and EPA regulations serve different purposes. USDA is responsible for regulating organisms developed using genetic engineering that could pose a plant pest risk to the health of plants. EPA is responsible for ensuring that any type of pesticide engineered and used in living plants would not pose unreasonable risk to human health and the environment during their time-limited registration. As part of the registration process for a pesticide, testing of an unregistered product is necessary to demonstrate the safety of the product. EPA authorizes the distribution and sale of the product for testing purposes by means of an EUP. An APHIS permit is required for a plant modified to produce a PIP until the PIP receives EPA's commercial registration.

Q: Is a plant exempt from the permit requirements in SECURE because it contains a PIP that is registered by EPA as a pesticide or that is exempt from EPA regulation, also exempt from the requirement for a RSR in order to be listed as a plant-trait-MOA combination eligible for exemption under § 340.1(c)?

A: No. EPA's time-limited PIP registration expires if it is not renewed, and a plant may later be found not to be exempt from EPA regulation. Therefore, plants producing commercially registered PIPs or exempt PIPs must still undergo a RSR for the plant-trait-MOA combination to be eligible for exemption under § 340.1(c), unless they met another exemption in § 340.1 of the SECURE rule. However, as long as the PIP commercial registration remains in effect, a plant solely producing a PIP that is registered by EPA or exempt from EPA regulation would not require a permit from USDA.

Q: After the final rule is published, will there be a transition process from the current rule to the new rule?

A: Yes. The SECURE rule's provisions take effect on key dates over the next 18 months. You can review a complete overview of the implementation process for the new rule on the [SECURE webpage](#).

Q: How will the international community learn about the final rule?

A: We believe that improved international regulatory compatibility is needed for products developed using genetic engineering, both in approach and timing, to avoid trade disruption and foster agricultural innovation. For this reason, we spoke with trading partners in foreign governments to share our proposed policy direction. We will continue to coordinate and communicate with trading partners going forward.

Q: What are the next steps?

A: Along with this final rule, APHIS published the supporting Programmatic Environmental Impact Statement (PEIS). Under the final rule, actions will be accompanied by appropriate environmental analysis based on the degree of environmental impact as described in the final PEIS. APHIS is launching an extensive outreach effort to ensure that trading partners and international regulators are apprised of the mechanics and merits of the SECURE Rule. APHIS will also undertake dedicated outreach efforts to ensure that stakeholders and innovators understand the features and attributes of the revised regulatory processes.

Q: Does the final rule impact labeling requirements under the National Bioengineered Food Disclosure Standard (NBFDS)?

A: No. Although both the SECURE rule and NBFDS evaluate products based, in part, on what is possible through conventional breeding, SECURE is a regulatory rule that considers plant pest risk, while the NBFDS is a marketing standard intended to provide consumers with more information about their food. A correlation between products exempt under SECURE and those that do not require a bioengineered food disclosure under the NBFDS is likely; however, products are subject to a separate evaluation under each of the respective frameworks.