



## **Policy Update: USDA Releases Revised Rule on Genetically Engineered Plants Amid Overhaul of Biotechnology Regulations**

*Lewis-Burke Associates LLC – May 18, 2020*

On May 18, the U.S. Department of Agriculture (USDA) and the Animal and Plant Health Inspection Service (APHIS) released the final version of the agency's update to the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework). APHIS initially released a proposed rule in 2019, but withdrew it following significant stakeholder comments. This revision, called the Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule, pertains to the importation, interstate movement, and environmental release of genetically engineered organisms under the *Plant Protection Act (PL 106-224)*. USDA is one of three agencies party to the Coordinated Framework, alongside the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA).

Updating Parts 330, 340, and 372 of the Code of Federal Regulations (CFR), the SECURE rule is intended to align regulations with advances in genetic engineering and increased understanding of the risks associated with plant pests. Carrying out instructions from the June 2019 "Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products," this rule seeks to reduce the regulatory burdens for producers, sellers, and innovators and is the first comprehensive revision to the Coordinated Framework since its introduction in 1987.

While the current statute explicitly lists taxa that should be considered plant pests, the revised rule represents a new approach to biotechnology regulation guided by an emphasis on risk as opposed to process, with APHIS choosing to exempt products that could have been created through conventional or traditional breeding. USDA will review risk with the following criteria:

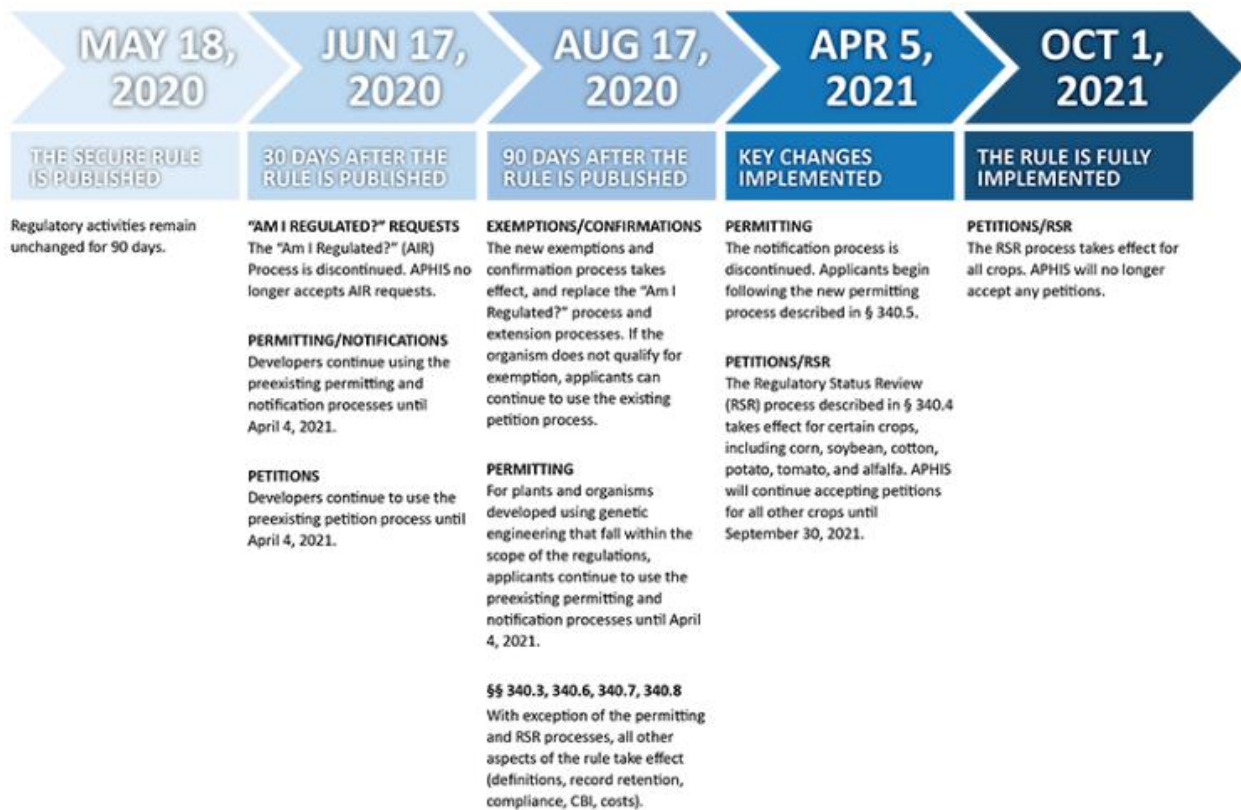
- “(i) The biology of the comparator plant(s) and its sexually compatible relatives;
- (ii) The trait and mechanism-of-action of the modification(s); and
- (iii) The effect of the trait and mechanism-of-action on:
  - a. The distribution, density, or development of the plant and its sexually compatible relatives;
  - b. The production, creation, or enhancement of a plant pest or a reservoir for a plant pest;
  - c. Harm to non-target organisms beneficial to agriculture; and
  - d. The weedy impacts of the plant and its sexually compatible relatives.”

The revised exemptions will be applied to plant products that have been modified in the following ways:

- “The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or
- The genetic modification is a targeted single base pair substitution; or
- The genetic modification introduces a gene known to occur in the plant's gene pool, or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool.”

The rule also gives the APHIS Administrator the power to propose additional exemptions based on what could be achieved through conventional breeding and also includes specific exemptions for microbial pesticides. Products that do not meet exemption are required to apply for permits through APHIS per Section 340.5 of the rule. In addition to increased exemptions, the rule creates a new Regulatory Status Review provision (Section 340.4) that allows APHIS or any member of the public to request a regulatory status review or re-review of a genetically engineered plant previously found to be subject to regulation to determine if that plant product should be granted an exemption.

Following the federal rulemaking process, this rule will go into effect 90 days after being published the federal register. After the first 30 days, APHIS will begin to transition its stakeholder engagement process by ending the “Am I Regulated?” process. At the end of 90 days, the rule will go into effect with Sections 340.4 and 340.5, which pertain to the new Regulatory Status Review and Permitting processes and will go into effect on April 5, 2021. On April 5, 2021, the Permitting process will be open to all crops and the Regulatory Status Review process will open for corn, soybean, cotton, potato, tomato, and alfalfa, while other crops will continue to use the preexisting petition process through September 30, 2021.



A - Implementation Timeline of SECURE Rule (Source: APHIS)

The FDA and EPA are in the process of fulfilling their responsibilities under the Executive Order, with the EPA on track to release their new rules on agricultural biotechnology later this summer; the FDA has yet to release a proposed timeline for updated rules.

Sources and Additional Information:

- The Federal Register posting of the SECURE Rule can be found at <https://www.federalregister.gov/d/2020-10638>.
- USDA's press release of the rule can be found at <https://www.usda.gov/media/press-releases/2020/05/14/usda-secure-rule-paves-way-agricultural-innovation>.
- The APHIS Biotechnology Regulatory Services resource guide on the SECURE rule can be found at [https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/secure-rule/secure-about/340\\_2017\\_perdue\\_biotechreg](https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/secure-rule/secure-about/340_2017_perdue_biotechreg).
- The Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products can be found at <https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-regulatory-framework-agricultural-biotechnology-products/>.
- The original proposed rule can be found at <https://www.federalregister.gov/d/2019-11704>.