



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

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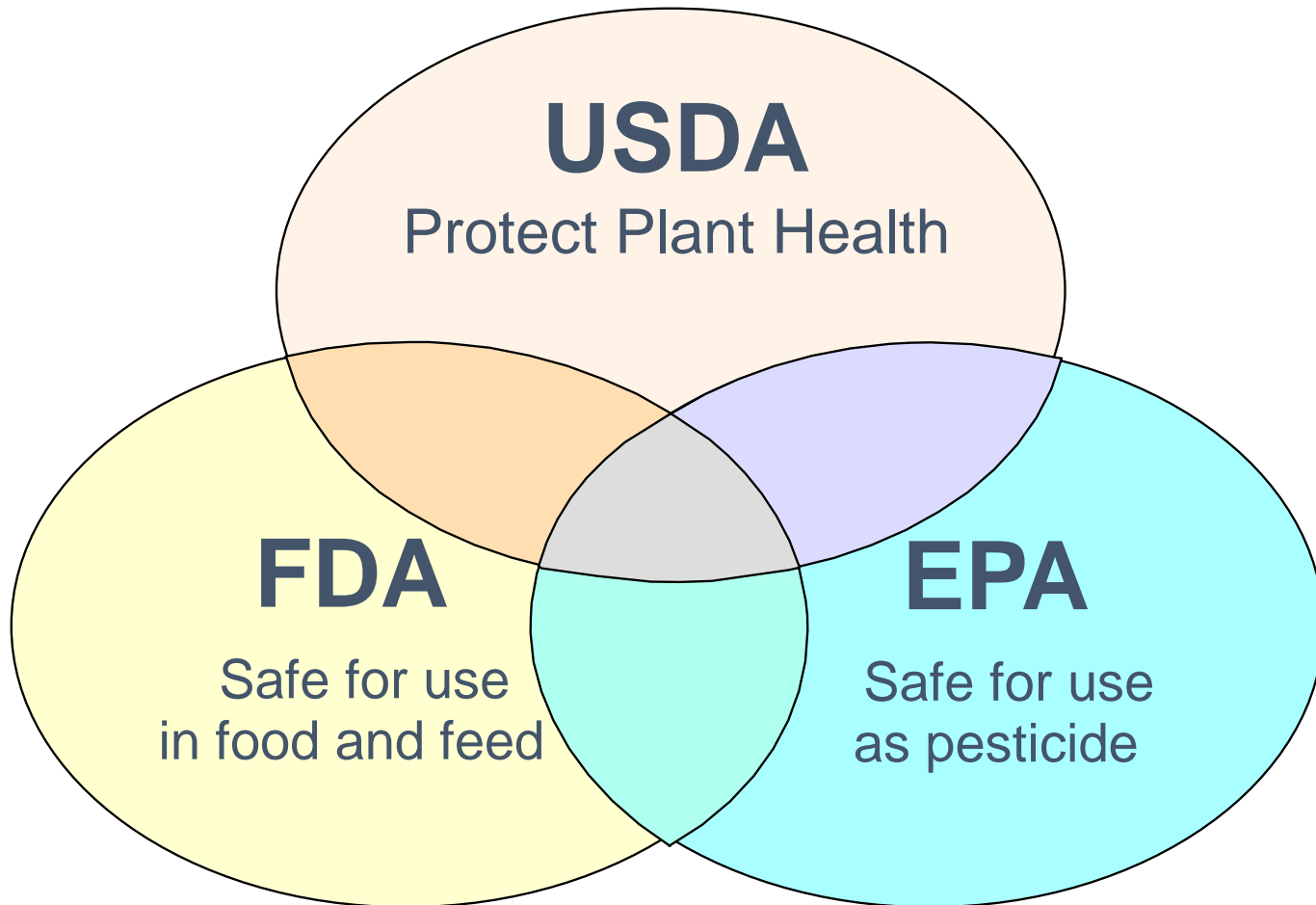
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# Regulation of Biotechnology Under the Coordinated Framework



## Overview – SECURE Rule

- Uses Plant Protection Act authority to regulate the import, interstate movement, and environmental release of plants and other organisms developed using genetic engineering (found at 7 CFR part 340)
- Represents a revised approach for U.S. regulation of plants
- Based on three decades of experience and advances in science and technology
- Establishes a clear, consistent, science-based and risk-based regulatory framework for biotechnology
- Provides regulatory relief and better focuses regulatory resources on areas of plausible risk

# Three Key Components

- Regulatory Exemptions for certain plants developed using genetic engineering
- Regulatory Status Review (RSR) for plants developed using genetic engineering
- Permitting for plants/organisms developed using genetic engineering

# Exemptions: Modifications Achievable through Conventional Breeding

- Provides three exemptions for plants modified in a manner that could otherwise be achieved through conventional breeding.
- A developer can use one of the three express exemptions to make a single targeted genetic modification to any plant species:
  1. A change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template;
  2. A targeted single base pair substitution; and
  3. Introduction of a gene known to occur in the plant's gene pool, or a change 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.

# Scientific Rationale For Exempting Modifications Achievable Through Conventional Breeding

- Plants developed through conventional breeding have a history of safe use related to plant pest risk;
- Exempt plants could have been developed through conventional breeding;
- There is no evidence that use of genetic engineering, in and of itself, introduces plant pest risk; and
- When a plant meets one of the exemptions it is not expected to pose any greater plant pest risk than a plant developed through conventional breeding.

# Exemptions: Additional Modifications Achievable through Conventional Breeding

- Ability to add to the list of modifications that plants can have and be exempt, e.g., to cover multiple modifications that are achievable through conventional breeding in a specific plant species
- APHIS can initiate or stakeholders can request the addition of a modification through a process that provides public notice and comment
- Ensures the regulations remain current with technology and science

## **Exemptions: Previously Reviewed Plants**

Plants modified to contain a plant-trait-MOA combination that is the same as one that was previously evaluated and determined by APHIS not to be regulated are also exempt from the regulations. Previous evaluations may have occurred under the:

- Current petition process; or
- Future Regulatory Status Review process



# Confirmation of Exemptions

- Developers may elect to seek confirmation from APHIS that the product meets an exemption and is not subject to the biotechnology regulations
- APHIS will provide a written response (“confirmation letter”) within 120 days of receiving a sufficiently detailed confirmation request
- APHIS will post the request and issued confirmation letters on its website, with redactions to protect Confidential Business Information, as appropriate

# Information Requirements For Confirmation

- A description of the plant's genus, species, and, if relevant, subspecies
- A clear statement of which regulatory exemption the requestor is claiming for the plant and why the plant qualifies for that exemption
- A description of the trait
- A description of the intended and/or actual genetic modification in the plant sufficient to enable APHIS to confirm the plant is eligible for the exemption

# Information Requirements For Confirmation

- Details about the scientific methodology used, or intended to be used, to verify the plant qualifies for the specified exemption
- Requirements focus on the information that is necessary to confirm the plant is not regulated
  - The confirmation process is not a risk assessment
- Optional information:
  - The function of the modified gene or genetic element
  - Molecular characterization data
  - DNA sequence data

# Regulatory Status Review (RSR)

- If a plant does not meet a regulatory exemption, the developer may seek a RSR for a plant developed using genetic engineering to determine whether or not it is regulated.
  
- RSR evaluates plant pest risk based on:
  - ✓ the biological properties of the plant;
  - ✓ the trait (or new characteristic); and
  - ✓ the mechanism of action (or how the modification caused the new trait to occur).
  
- RSR will include 1 or 2 steps, depending on the plant developed using genetic engineering

# RSR - Definitions

*Comparator plant.* A plant used as a comparison or reference for a plant developed using genetic engineering to determine if the plant being evaluated poses an increased plant pest risk.

*Trait.* An observable (able to be seen or otherwise identified) characteristic of an organism. (§ 340.3)

*Mechanism of Action (MOA).* The biochemical process(es) through which genetic material determines a trait. (§ 340.3)

*Plant pest risk.* The potential for direct or indirect injury to, damage to, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential for exacerbating the impact of a plant pest. (§ 340.3)

# Regulatory Status Review (RSR)

- Step 1 -- Evaluate the characteristics of the plant relative to an appropriate comparator plant to identify whether a plausible pathway to increased plant pest risk exists.
  - If APHIS does not identify a plausible pathway to increased plant pest risk, the plant is not subject to the regulations
  - If APHIS does identify a plausible pathway to increased plant pest risk, the developer may:
    - elect to take no further action
    - obtain a permit to allow movement and/or confined release
    - request that USDA complete step 2 in the process
- APHIS will complete Step 1 in 180 days

# Regulatory Status Review (RSR)

- The evaluation examines whether the trait and mechanism-of-action could change any of the following factors in a way that would plausibly increase plant pest risk:
  - The distribution, density, or development of the plant and its sexually compatible relatives
  - The production, creation, or enhancement of a plant pest or a reservoir for a plant pest
  - Harm to non-target organisms beneficial to agriculture
  - The weedy impacts of the plant and its sexually compatible relatives

## Regulatory Status Review (RSR)

- Step 2 – Further evaluate the identified factors of concern to determine the likelihood and consequence of the plausible increased plant pest risk with a Plant Pest Risk Assessment
  - Publish the results in the *Federal Register*
  - Solicit and review comments from the public
  - If APHIS finds the plant developed using genetic engineering is unlikely to pose an increased plant pest risk, the plant is not subject to the regulations
  - If APHIS does not make such a finding, the plant will remain regulated
  
- APHIS will complete its entire evaluation within 15 months
  
- Developers can request a re-review based upon scientifically valid evidence relating to plant pest risk



# Pausing the RSR Process

- APHIS will pause the RSR process after Step 1 until receiving a response from the requestor
- APHIS will pause the process while awaiting a response to completeness review in Step 2
- APHIS will otherwise not pause the RSR process after a complete request is submitted
- A requestor can request a pause in the RSR process at any time, e.g., if data from a laboratory or field study is needed to inform a PPRA, the RSR process can be paused until the data is provided to APHIS

## Benefits of the Two-Step RSR Process

- Two-step process enables APHIS to rapidly identify a plant developed using genetic engineering that is not subject to the regulations.
- APHIS can focus more staff resources and oversight emphasis on areas that present the greatest potential risks to plant health.
- Process will save developers regulatory costs, increase regulatory certainty, and continue to protect plant health.

# Permitting

- Permitting is required for any plant or organism subject to the regulations that is moved interstate or released into the environment (confined field trials).
- The permitting conditions are specified in the regulations.
- APHIS may add supplemental permitting conditions to protect plant health, as appropriate.

# Permitting

- APHIS will approve or deny an application for a movement permit within 45 days, and an application for a permit for an environmental release in 120 days.
- APHIS will conduct inspections to assess compliance with the permitting conditions, and require the maintenance and submission of certain records.

# Implementation Timing

- The SECURE Rule was final and effective as of May 18, 2020, with phased implementation for key provisions.
- As of June 16, 2020, APHIS no longer accepted new “Am I Regulated” requests.
- On August 17, 2020, the exemptions took effect and APHIS started accepting confirmation requests.

# Implementation Timing

- On April 5, 2021, APHIS will begin accepting new RSR requests for certain crops (corn, soybean, cotton, potato, tomato, and alfalfa). The new permitting regulations take effect.
- On October 1, 2021, the RSR process will be fully implemented for all crops. APHIS will no longer accept any petitions under the previous regulations.
- Phased approach to implementation allows developers adequate time to make changes to business processes and management information systems to comply with the SECURE Rule.

## Summary of SECURE

- Plants with modifications that could have otherwise been produced through conventional breeding are not regulated because they are unlikely to pose an increased plant pest risk relative to conventionally bred plants
- Other plants are regulated based on whether they pose a plausible increased plant pest risk until APHIS determines they are unlikely to pose an increased plant pest risk
- Plant pest risk is assessed based on the properties of the plant, the trait and the mechanism of action, not the technique used to produce the plant

## Summary of SECURE

- Notifications will no longer be issued; permits will be issued for all movement of plants produced through genetic engineering
- The determination of the regulatory status of non-exempt plants will be done through the new Regulatory Status Review (RSR) process



# Summary of SECURE

- Will better focus regulatory resources on protecting plant health
- Likely decrease unauthorized releases
- Will reduce costs for developers and spur innovation
- Will facilitate the availability of new varieties of crops that are safe for plant health and currently not available, such as vegetables and cereals:
  - Maintain conservation tillage (soil, air and water resources) through effective weed control.
  - Reduce insecticide and fungicide use through development of crop plants resistant to pests and pathogens.
  - Reduce fertilizer inputs through development of crop plants with higher nutrient utilization efficiency.
  - Reduce water use via plants with decreased water requirements.
  - Provide food plants with improved nutrient profiles.

# Stakeholder Outreach

- Information on the SECURE rule, including presentations and guidance on the confirmation process, can be found on the APHIS website
  
- APHIS has hosted numerous stakeholder webinars on the SECURE rule and confirmation process
  - Additional webinars are planned, with a focus on the RSR process
  
- APHIS has held meetings with individual stakeholders, including developers and government representatives, as requested, to discuss the SECURE rule



# Thank You

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**Website (About the Secure Rule)**

<https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/secure-rule/secure-about>