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

Biotechnology Regulatory Services
Animal and Plant Health Inspection Service

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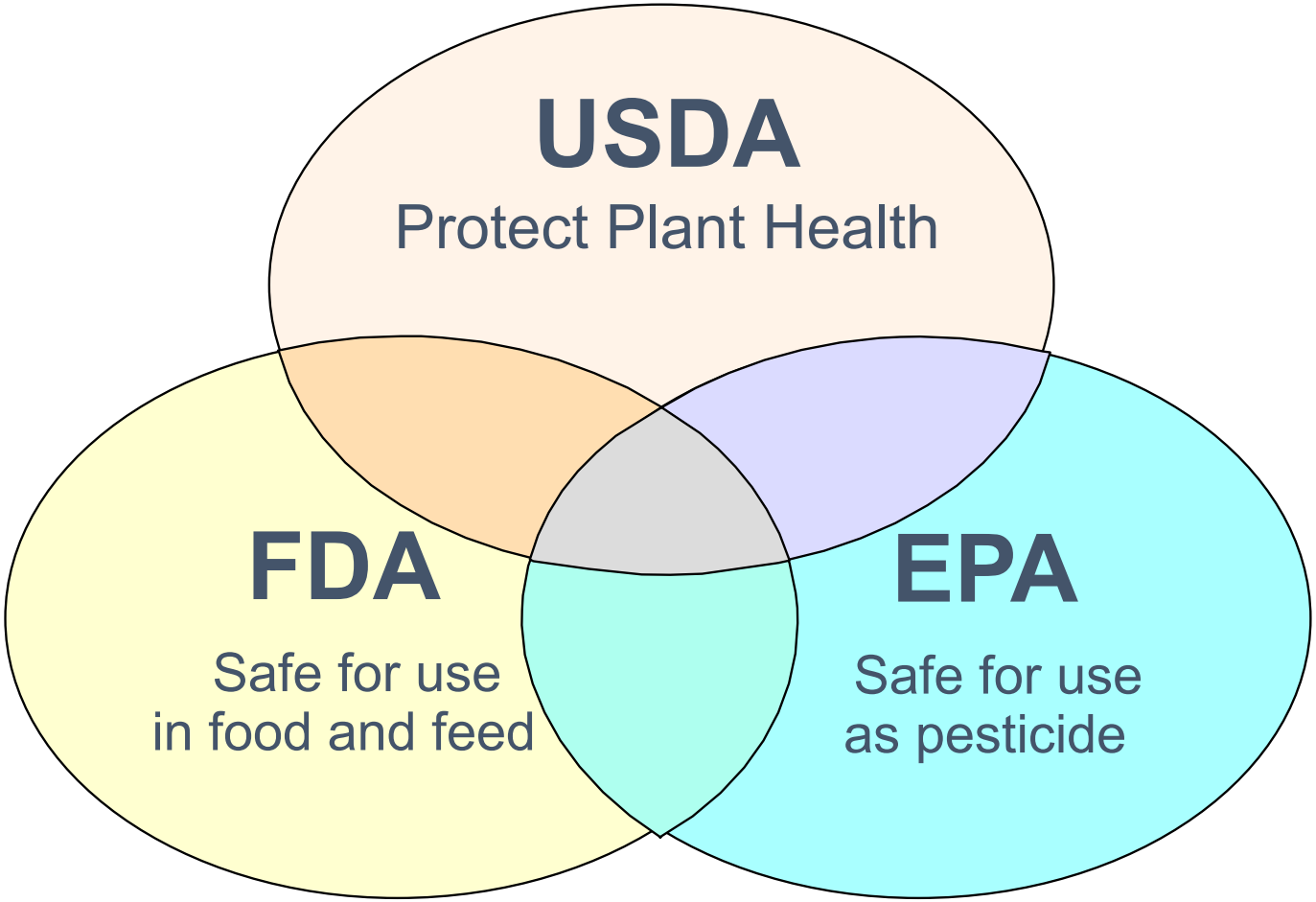
Regulation of Biotechnology Under the Coordinated Framework



Modernizing the Regulatory Framework for Agricultural Biotechnology Products

(June 11, 2019)

- The President issued an Executive Order on modernizing regulatory systems for agricultural biotechnology products
- Regulatory approaches for agricultural biotechnology products should be proportional to the risks such products pose
- Regulatory decisions based on scientific and technical evidence
- Regulatory determinations based on risks associated with the product and its intended end use

USDA Secretary Perdue's Statement on Plant Breeding Innovations

(March 28, 2018)

- USDA regulatory oversight should focus on the product, not the method used to produce it
- Established USDA policy to treat similar products in a similar manner – modifications that could otherwise be achieved through conventional breeding techniques should be treated similarly to conventionally bred plants from a regulatory perspective
- These principles laid the foundation for the SECURE Rule

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
- Regulatory Status Review for plants developed using genetic engineering
- Permitting for plants/organisms developed using genetic engineering

Exemptions: Modifications Achievable through Conventional Breeding

Allow a single 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; or

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 are exempt, e.g., to cover multiple modifications that are achievable through conventional breeding in a specific plant species
- USDA 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

- Plant/trait/mechanism-of-action combinations previously evaluated and designated as not subject to the regulations are also exempt from the regulations

Confirmation of Exemptions

- Developers may elect to seek confirmation from USDA that the product meets an exemption and is not subject to the biotechnology regulations

- USDA will provide a written response ("confirmation letter") within 120 days of receiving a sufficiently detailed confirmation request

- USDA will post the request and issued confirmation letters on its website, with redactions to protect Confidential Business Information, as appropriate

Confirmation Process is Based on Experience with "Am I Regulated?" Process

- "Am I Regulated?" (AIR) process was retired on June 16, 2020 and is no longer used under the SECURE Rule
- The AIR process determined whether or not the organism developed using genetic engineering met the definition of a "regulated article" under the previous regulations
- Regulated article was defined as: *Developed through genetic engineering and the donor, recipient, or vector agent is a plant pest*
- Data requirements were minimal – those necessary to confirm the organism was not a regulated article
  - In contrast, a petition for the deregulation of a plant developed using genetic engineering requires a data package to confirm that it is not a plant pest

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 USDA 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

- Optional information:
  - The function of the modified gene or genetic element
  - Molecular characterization data
  - DNA sequence data

- Requirements focus on the information that is necessary to confirm the plant is not regulated
  - The confirmation process is not a risk assessment

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).

Regulatory Status Review (RSR)

- RSR will include 1 or 2 steps, depending on the plant developed using genetic engineering:

- 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 USDA does not identify a plausible pathway to increased plant pest risk, the plant is not subject to the regulations

  - If USDA 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

- USDA 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 USDA 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 USDA does not make such a finding, the plant will remain regulated
- USDA will complete its entire evaluation within 15 months
- Developers can request a re-review based upon scientifically valid evidence relating to plant pest risk

Benefits of the Two-Step RSR Process

- Two-step process enables USDA to rapidly identify a plant developed using genetic engineering that is not subject to the regulations.

- USDA 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.
- USDA may add supplemental permitting conditions to protect plant health, as appropriate.
- USDA 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.
- USDA will conduct inspections to assess compliance with the permitting conditions, and require the maintenance and submission of certain records.

Implementation Timing – Next Steps

- The SECURE Rule is final and effective as of May 18, 2020, with phased implementation for key provisions.
- As of June 16, 2020, USDA no longer accepts new “Am I Regulated” requests.
- On August 17, 2020, the exemptions took effect and USDA started accepting confirmation requests.
- On April 5, 2021, USDA will begin accepting new RSR requests for certain crops (corn, soybean, cotton, potato, tomato, and alfalfa). The new permitting regulations take effect.

Implementation Timing – Next Steps

- On October 1, 2021, the RSR process will be fully implemented for all crops. USDA 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 the SECURE Rule

- 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 there is a plausible pathway to increased plant pest risk until USDA determines they are unlikely to pose a plant pest risk

- Plant pest risk is assessed based on the plant, the trait and the mechanism of action, not the technique used to produce the plant

International Engagement

- International communications and outreach are vital to the SECURE Rule

- It is important to us that your government understands the features of the SECURE Rule
  - SECURE Rule will not disrupt trade
  - The final rule has been notified to the WTO

- We look forward to continued conversations with our international stakeholders regarding the SECURE Rule

- We are happy to answer any questions

Thank You

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