APHIS Biotechnology Regulations – Regulatory Exemptions

SCRA 2023

Deshui Zhang, PhD
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Three Regulatory Processes

1. **EXEMPTIONS AND CONFIRMATIONS**
   Determine whether your plant meets the criteria for an exemption with the option for requesting confirmation of plant’s exempt status.

2. **REGULATORY STATUS REVIEW**
   Request a regulatory status review (RSR) to determine if a plant developed using genetic engineering poses a plant pest risk.

3. **PERMITTING**
   Apply for a permit for a regulated organism that does not undergo or pass the RSR.

Processes 1 & 2 apply only to plants.
Regulatory Exemptions: Two Types

TYPE 1

Modified plants that could otherwise have been developed through conventional breeding techniques, and for this first type of exemptions, a plant may only be modified to contain a single targeted genetic modification.

1. A change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template.


3. 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.

NOTE: Additional Modifications Achievable through Conventional Breeding: Ability to add to the list of modifications that are exempt. The USDA can initiate, or stakeholders can request this through a process that provides public notice and comment.
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.

- The exemptions are science- and risk-based, provide regulatory relief to developers, and allow USDA to focus resources on plausible risks
Regulatory Exemptions: Two Types

Plants modified to contain the same plant-trait-mechanism of action (MOA) combination as in another plant of the same species previously reviewed and determined by APHIS not to be regulated under the:

1. Regulatory Status Review process; or

2. Legacy Petition process.
Developers may voluntarily request a letter confirming exempt status

Requests and responses are posted on USDA website

ConfirmationRequests@usda.gov
Regulatory Exemptions

- 55 letters confirming a modified plant’s exempt status (on average, within 51 days of receiving a complete submission)
- 84% - Modifications achievable through conventional breeding
- 16% - Same plant-trait-mechanism of action combination previously reviewed and found not regulated

As of 14 September 2023
Institution Type

- Small and Medium Sized Enterprises: 87%
- Academic Institutions: 6%
- Large Institutions: 7%

Plant Species

- Tomato: 10
- Pennycress: 8
- Soybean: 6
- Sorghum: 4
- Rice: 2
- Potato: 2
- Petunia: 2
- Coyote tobacco: 2
- Cotton: 2
- Corn: 2
- Citrus: 2
- Camelina sativa: 2
- Brassica juncea: 2
- Blackberry: 2
- Barley: 1
- Banana: 1
- Apple: 1
- Alfalfa: 1

As of 14 September 2023
Traits Confirmed as Exempt from Regulation

Herbicide, Insect, and Disease Resistance Traits

Product Quality Traits

Agronomic Property Traits

Other
Additional Resources

APHIS BRS Homepage
https://www.aphis.usda.gov/aphis/our focus/biotechnology

Revised Rule (7 CFR part 340)

CR Guide

Table of Confirmation Letters
Thank you!