



# APHIS Biotechnology Regulations – Regulatory Exemptions

SCRA 2023

Deshui Zhang, PhD  
September 21, 2023



# 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.

2

A targeted single base pair substitution.

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

## TYPE 2

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.

# Confirming Exempt Status

**Developers may voluntarily request a letter confirming exempt status**

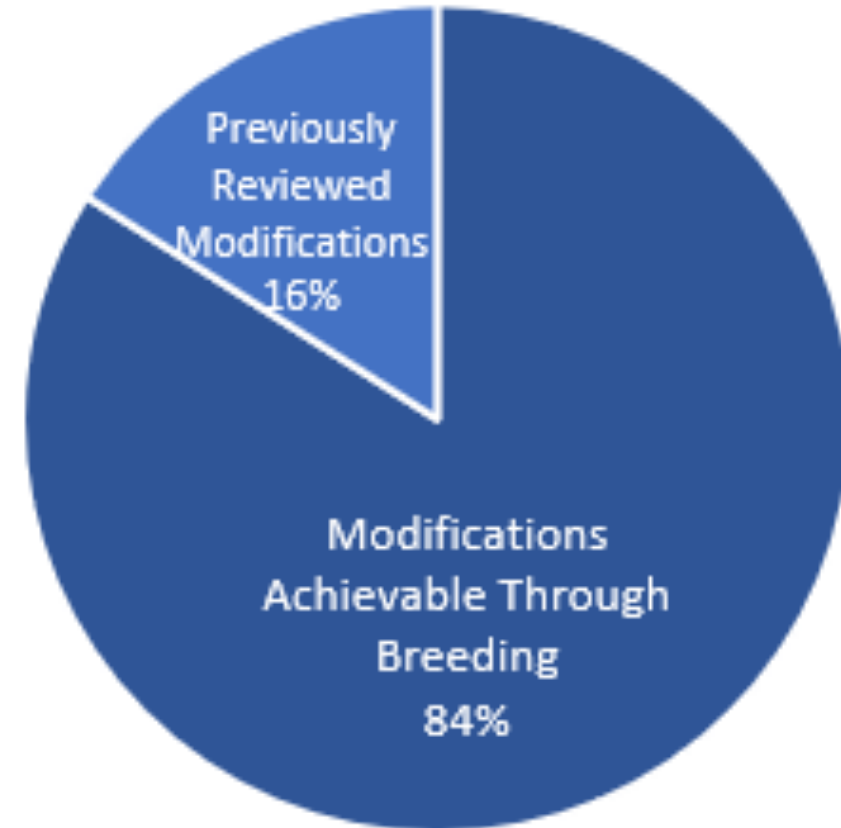
**Requests and responses are posted on USDA website**

[ConfirmationRequests@usda.gov](mailto:ConfirmationRequests@usda.gov)



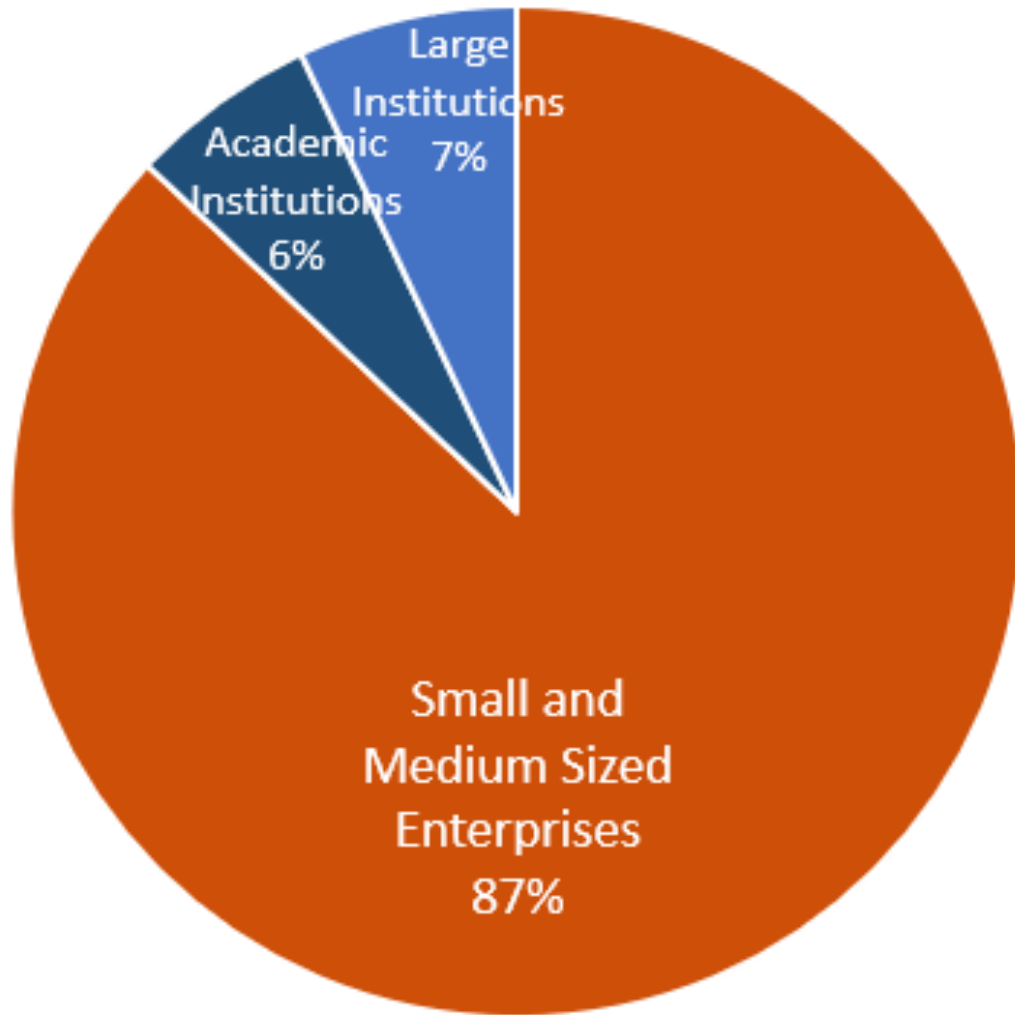
# Regulatory Exemptions

- 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

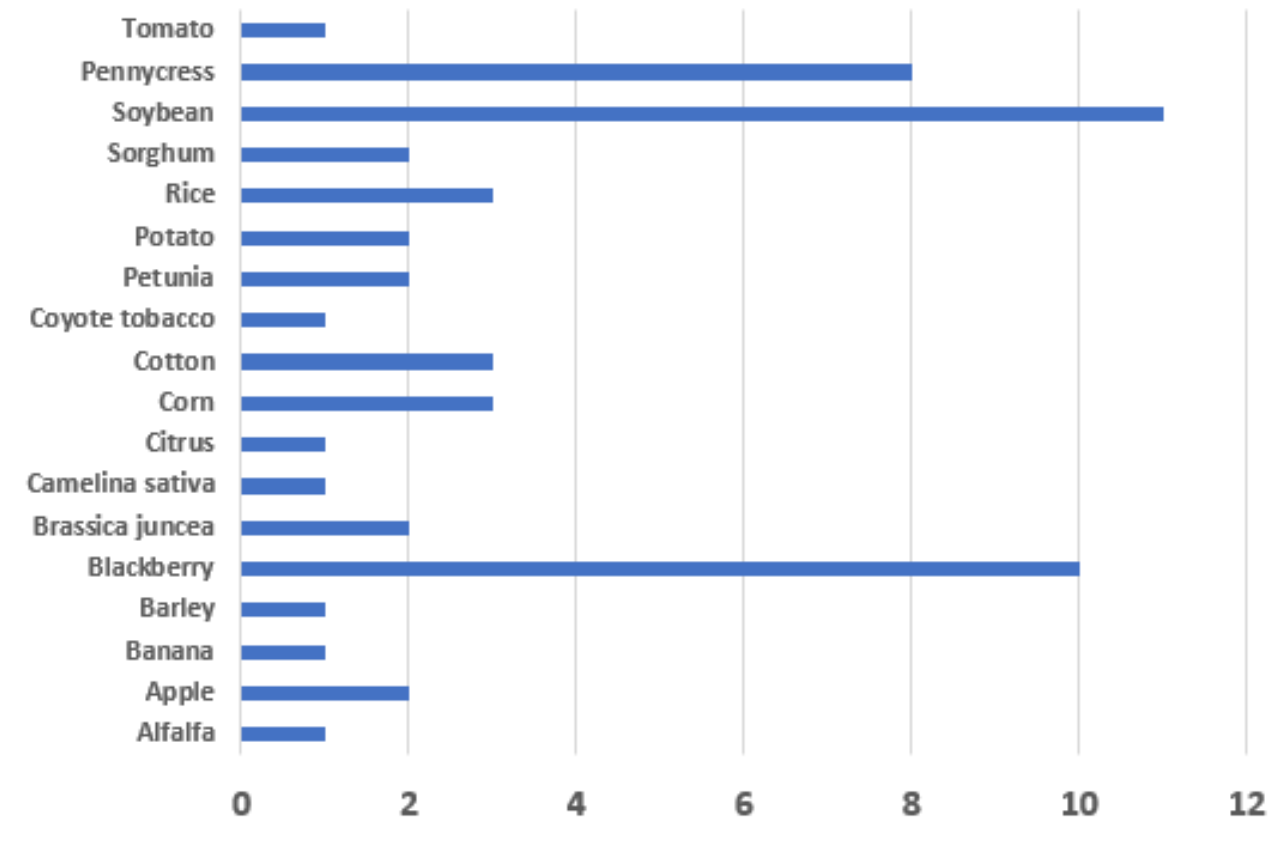


*As of 14 September 2023*

## Institution Type



## Plant Species



*As of 14 September 2023*

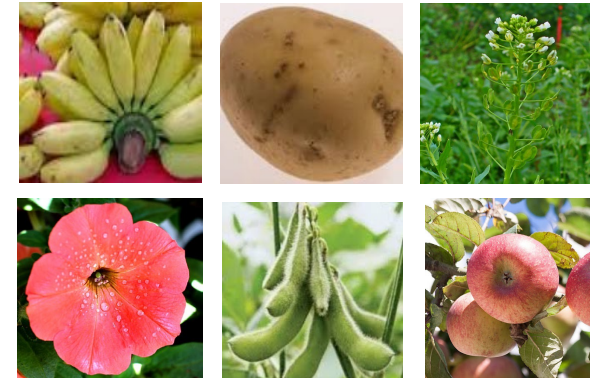


# Traits Confirmed as Exempt from Regulation

## Herbicide, Insect, and Disease Resistance Traits



## Product Quality Traits



## Agronomic Property Traits



## Other





# Additional Resources

APHIS BRS Homepage

<https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>

Revised Rule (7 CFR part 340)

<https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-340?toc=1>

CR Guide

<https://www.aphis.usda.gov/brs/pdf/requesting-confirmation-of-exemption.pdf>

Table of Confirmation Letters

<https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/confirmations/responses/cr-table>





**Thank you!**

