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Regulatory Exemptions and Confirmations

Last Modified:



Developers can request a confirmation from APHIS that a modified plant qualifies for an exemption and is not subject to the regulations in 7 CFR part 340.

Under APHIS biotechnology regulations, certain categories of modified plants are exempt from regulation because they could otherwise have been developed through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants. Plants that have a plant-trait-mechanism of action combination that has been previously reviewed and determined by APHIS to be unlikely to pose a plant pest risk and therefore to be not regulated are also exempt from the regulations.

When developers request a confirmation from APHIS, we will provide a written response (“confirmation letter”) within 120 days of receiving a sufficiently detailed confirmation request. APHIS will post both the confirmation requests and the issued confirmation letters on its website, with redactions to protect Confidential Business Information and Personal Identifying Information, as appropriate.

*As part of 2020 revisions to the regulations, “Am I Regulated?” responses issued under the legacy regulations that indicated the nonregulated status of specific plants are considered valid exemptions from the current regulations for the particular requestor and specific plant(s).

Qualifications for Exemptions

A developer may review the regulations to assess whether a plant belongs to one of the exempt categories.

A plant that contains a single modification of a type in one of the following three categories is exempt from regulation:

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

APHIS can expand the exemptions related to modifications that could otherwise be achieved through conventional breeding to ensure the regulations remain current with technology and science. Stakeholders can also request expansion through a process that provides public notice and comment.

A plant that contains a plant-trait-mechanism of action (MOA) combination that APHIS has already evaluated under the legacy or current regulations and determined are not subject to the regulations.

Exemption and Confirmation Request Guides and Resources

- [BRS Guide for Requesting a Confirmation of Exemption](#) (315.07 KB)
- [Guide for Submitting Confidential Business Information](#) (431.95 KB)
- [Guidance for Preparing Proposals to Exempt Plants with Additional Modifications from Regulation Pursuant to 7 CFR § 340.1\(b\)\(4\)](#) (431.95 KB)
- [Table of Confirmation Letters](#)
- [Plant-Trait-Mechanism of Action \(MOA\) Table](#)
- [Submit a Confirmation Request](#)
- [Submit a Question About Confirmations](#)

Related Links

- [Previous AIR Letters of Inquiry and APHIS Responses](#)
- [Questions and Answers About Confirmations](#)
- [Confirmations Webinar Presentation](#)
- [Learn More About the Biotechnology Regulations](#)

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