



Guidance for Requesting a Confirmation of Exemption from Regulation under 7 CFR part 340

The contents of this presentation do not have the force and effect of law and are not meant to bind the public in any way. This presentation is intended only to provide clarity to the public regarding existing requirements under the law or agency regulations.

June 24, 2020

Introduction to the Confirmation of Exemption Process

- 7 CFR part 340 governs the movement of certain organisms that are modified or produced through genetic engineering.
- Certain plants are exempt from the regulations (§ 340.1).
- Developers may request confirmation that their plant is exempt
 - Not mandatory
 - Responses generally within 120 days
 - Posted on the APHIS-BRS website
- Consult prior to your first submission, if possible.

Exemptions

- There are **four** exemptions defined in § 340.1.
- The **first three** exemptions cover modified plants that could otherwise have been developed through conventional breeding techniques (§ 340.1(b)(1-3)).

The First Three Exemptions

These exemptions cover plants modified to contain a single targeted genetic modification of one of the three types listed:

- **Exemption 1**

- A change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template (§ 340.1(b)(1)).

- **Exemption 2**

- Is a targeted single base pair substitution (§ 340.1(b)(2)).

- **Exemption 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 (§ 340.1(b)(3)).

The Fourth Exemption

This exemption (§ 340.1(c)) covers plants modified to contain a plant-trait-MOA combination that is the same as that in another plant of the same species previously reviewed and determined by APHIS not to be regulated under either the:

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

Your Letter Must Include

- Requestor's name and contact information, including email address; AND
- A description of the plant's genus, species, and, if relevant, subspecies or ecotypes; AND
- A citation to the claimed regulatory exemption for the plant, a clear statement of why the plant qualifies for that exemption; AND
- A description of the trait (it is helpful to also include a description of the phenotype of the plant).

Your Letter Must Include

For **modified plants that could otherwise have been developed through conventional breeding techniques** provide:

- A description of the intended and/or actual genetic modification sufficient to enable APHIS to confirm the final plant is eligible for the exemption, AND
- The type of genetic modification (e.g., insertion, deletion, single base pair substitution, allele replacement or alteration), AND
- The targeted gene or genetic element, and the method used to produce the modification (§ 340.1(b)(1) or (b)(2)), OR
- The gene or genetic or structural element, the donor organism or the organism on which the modification is based, and the method used to produce the modification (§ 340.1(b)(3)).

Your Letter Must Include

For **previously reviewed plant/trait/MOA combinations** under § 340.1(c) provide:

- A description of the intended and/or actual genetic modification sufficient to enable APHIS to confirm the final plant is eligible for the exemption, AND
- The trait(s) and associated MOA(s), including a molecular description of the inserted genetic material, and the method used to produce the modification.

Your Letter Must Include

- Describe the scientific methodology you used, or intend to use, to verify the plant qualifies for the requested exemption.
- Provide sufficient information to enable APHIS to assess the efficacy of the methodology.

Your Letter May Include Supporting Information and Data

- Function of the modified gene or genetic element
- Molecular characterization data (e.g., Southernns)
- DNA sequence data
 - Sequence data should encompass the modification.
 - Any sequencing strategy and methodology should be clearly presented.

Off-Target Mutations

- **APHIS will not** review off-target mutations that occur during development of an exempt plant.
 - (1) The rate of off-target mutation is low relative to the background mutation rate that occurs in conventional breeding, which raises no plant pest risk concern, and
 - (2) Deleterious off-target mutations are likely to be lost unless they are closely genetically linked to the targeted modification.

- **APHIS will** focus review on the targeted modification.

- **APHIS does not** consider the unintended retention of exogenous DNA that was inserted as part of the modification process to be an off-target mutation.



Request for Confirmation of Exemption

If you are seeking confirmation that your plant is exempt from the regulations in 7 CFR part 340, electronically submit your confirmation request as a letter to:

Bernadette Juarez

APHIS Deputy Administrator

Biotechnology Regulatory Services

ConfirmationRequests@usda.gov

APHIS' Reply

Will vary slightly depending on:

- Whether the modification to the plant is actual or intended;
- Whether the requestor provides a description of both the confirmatory methods and the results;
- Whether the requestor provides a description of the confirmatory methods and supporting data for the results.

Confidential Business Information

- If your confirmation request, as well as any follow-up documentation you provide, does not contain Confidential Business Information (CBI), it must be marked “**No CBI.**”

- If your confirmation request, or any documentation you provide, contains CBI, you must correctly mark and submit:
 - a CBI copy;
 - a CBI-deleted copy; and,
 - a detailed justification for each CBI claim.

- Refer to **CBI Submission Guidance** on BRS’ website



Questions?

Future questions --

ConfirmationRequests@usda.gov

Thank you!