

with any of the foregoing, that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product.

Plant pest risk. The potential for direct or indirect injury to, damage to, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential for exacerbating the impact of a plant pest.

Plant product. (1) Any flower, fruit, vegetable, root, bulb, seed, or other plant part that is not included in the definition of plant; or

(2) Any manufactured or processed plant or plant part.

Recipient organism. The organism whose nucleic acid sequence will be modified through the use of genetic engineering.

Release into the environment (environmental release). The use of an organism outside the physical constraints of a contained facility.

Responsible person. The individual responsible for maintaining control over a GE organism under permit during its movement and for ensuring compliance with all conditions contained in any applicable permit as well as with other requirements in this part and in the Plant Protection Act (7 U.S.C. 7701 *et seq.*). This individual must sign the permit application, and must be at least 18 years of age, and must be a legal resident of the United States.

Secure shipment. Shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

State. Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territories or possessions of the United States.

State or Tribal regulatory official. State or Tribal official with responsibilities for plant health, or any other duly designated State or Tribal official, in the State or on the Tribal lands where the movement is to take place.

Trait. An observable (able to be seen or otherwise identified) characteristic of an organism.

Unauthorized release. The intentional or accidental movement of an organism under a permit issued pursuant to this part in a manner not authorized by the permit; or the intentional or accidental movement without a permit of an organism that is subject to the regulations in this part.

§ 340.4 Regulatory status review.

(a)(1) Any person may submit a request to APHIS for a regulatory status review, pursuant to paragraph (b)(3) of this section.

(2) Any person may request re-review of a GE plant previously found to be subject to this part after an initial review was conducted, provided that the request is supported by new, scientifically valid evidence bearing on the plant pest risk associated with movement of the plant.

(3) APHIS may also initiate a regulatory status review or re-review of a GE plant to identify whether it is subject to regulation under this part.

(4) Information submitted in support of a request for a regulatory status review or re-review must meet the requirements listed in paragraphs (a)(4)(i) through (iii) of this section.

(i) A description of the comparator plant(s), to include genus, species, and any relevant subspecies information;

(ii) The genotype of the modified plant, including a detailed description of the differences in genotype between the modified and unmodified plant; and

(iii) A detailed description of the new trait(s) of the modified plant.

(iv) Detailed information on how to meet the above-listed requirements can be found on the APHIS website at <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>. If APHIS proposes revisions to the detailed information on the APHIS website, APHIS will make the proposed revisions available for notice and public comment prior to implementation.

(b)(1) When APHIS receives a request for a regulatory status review of a GE plant, APHIS will conduct an initial review to determine whether there is a plausible pathway by which the GE

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plant, or any sexually compatible relatives that can acquire the engineered trait from the GE plant, would pose an increased plant pest risk relative to the plant pest risk posed by the respective non-GE or other appropriate comparator(s), based on the following factors:

(i) The biology of the comparator plant(s) and its sexually compatible relatives;

(ii) The trait and mechanism-of-action of the modification(s); and

(iii) The effect of the trait and mechanism-of-action on:

(A) The distribution, density, or development of the plant and its sexually compatible relatives;

(B) The production, creation, or enhancement of a plant pest or a reservoir for a plant pest;

(C) Harm to non-target organisms beneficial to agriculture; and

(D) The weedy impacts of the plant and its sexually compatible relatives.

(2) APHIS will complete the initial review within 180 days of receiving a request for a regulatory status review that meets the requirements specified in paragraph (a)(4) of this section, except in circumstances that could not reasonably have been anticipated. If APHIS does not identify a plausible pathway by which the GE plant or its sexually compatible relatives would pose an increased plant pest risk relative to the comparator(s) in the initial review, the GE plant is not subject to the regulations in this part. APHIS will post the plant, trait, and general description of the MOA on its website.

(b)(3)(i) If APHIS does identify a plausible pathway by which the GE plant or its sexually compatible relatives would pose an increased plant pest risk relative to the comparator(s) in the initial review, the requestor may apply for a permit and/or request that APHIS conduct an evaluation of the factor(s) of concern identified in the initial review to determine the likelihood and consequence of the plausible increased plant pest risk. APHIS may request additional information as needed to evaluate the factor(s) of concern.

(ii) For those GE plants for which such an evaluation is conducted, APHIS will publish the results of the evaluation in the FEDERAL REGISTER

and will solicit and review comments from the public. Except in circumstances that could not reasonably have been anticipated, APHIS will complete these steps within 15 months of receiving a request for a regulatory status review that meets the requirements specified in paragraph (a)(4) of this section.

(iii) If APHIS finds that the GE plant and its sexually compatible relatives are unlikely to pose an increased plant pest risk relative to their comparator(s), the GE plant is not subject to this part. APHIS will publish its evaluation of the plant-trait-MOA combination in a subsequent FEDERAL REGISTER document and will also post it on the APHIS website. If APHIS does not make such a finding, the GE plant will remain regulated under this part, and its movement will be allowed only under permit in accordance with § 340.5.

(c) This section is applicable beginning April 5, 2021 for GE corn, soybean, cotton, potato, tomato, and alfalfa, and on October 1, 2021 for all GE plants.

(Approved by the Office of Management and Budget under control number 0579–0471)

§ 340.5 Permits.

(a) *Permit requirement.* A permit from APHIS is required for the movement of all GE organisms subject to the regulations under this part.

(b) *Permit application requirements.* All applications for permits must be submitted in accordance with the requirements of this section. The responsible person must apply for and obtain a permit through APHIS' website. The application must also include the following information:

(1) *General information requirements for all permit applications.* All permit applications must include the name, title, and contact information of the responsible person and agent (if any); the country (or countries) and locality (or localities) where the organism was collected, developed, manufactured, reared, cultivated, and cultured (as applicable); the organism's genus, species and any relevant subspecies and common name information; the intended activity (*i.e.*, importation, interstate