

(iii) *Timeframe for Agency review of requests for additional exemptions.* After APHIS receives all information required under paragraph (b)(4)(ii) of this section, APHIS will complete its review of the request and render a determination within 12 months, except in circumstances that could not reasonably have been anticipated.

(iv) *Denial of requests.* If APHIS disagrees with the conclusions of the request or determines that there is insufficient evidence that the modification could be achieved through conventional breeding methods, APHIS will deny the request and notify the requestor in writing regarding this denial.

(v) *Agreement with requests.* If APHIS initially determines that the modification could be achieved through conventional breeding methods, APHIS will publish a notice in the FEDERAL REGISTER and request public comments in accordance with the process set forth in paragraph (b)(4)(i) of this section. After reviewing the comments, APHIS will publish a subsequent notice in the FEDERAL REGISTER announcing its final determination.

(vi) *website posting.* A list specifying the additional modifications will be posted on the APHIS website at <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>.

(c) The regulations in this part do not apply to a plant with:

(1) A plant-trait-mechanism of action combination that has previously undergone an analysis by APHIS in accordance with §340.4 and has been determined by APHIS not to be regulated under this part, or

(2) A plant-trait-mechanism of action combination found in a plant that APHIS determined to be deregulated in response to a petition submitted prior to October 1, 2021, pursuant to §340.6 as that section was set forth prior to August 17, 2020. All plants determined by APHIS to be deregulated pursuant to §340.6 as that section was set forth prior to August 17, 2020 will retain their nonregulated status under these regulations.

(d) The regulations in this part do not apply to plants determined by APHIS not to require regulation under this part pursuant to the “Am I Regu-

lated” process. All plants determined by APHIS not to require regulation under this part pursuant to the “Am I Regulated” process will retain their nonregulated status under these regulations.

(e) Developers may request confirmation from APHIS that a plant is not within the scope of this part. APHIS will provide a written response (confirmation letter) within 120 days of receiving a sufficiently detailed confirmation request, except in circumstances that could not reasonably have been anticipated.

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

§340.2 Scope of this part.

Except under a permit issued by the Administrator in accordance with §340.5, no person shall move any GE organism that:

(a) Is a plant that has a plant-trait-mechanism of action combination that has not been evaluated by APHIS in accordance with §340.4 or that, as a result of such evaluation, is subject to the regulations; or

(b) Meets the definition of a *plant pest* in §340.3; or

(c) Is not a plant but has received deoxyribonucleic acid (DNA) from a plant pest, as defined in §340.3, and the DNA from the donor organism either is capable of producing an infectious agent that causes plant disease or encodes a compound that is capable of causing plant disease; or

(d) Is a microorganism used to control plant pests, or an invertebrate predator or parasite (parasitoid) used to control invertebrate plant pests, and could pose a plant pest risk; or

(e) Is a plant that encodes a product intended for pharmaceutical or industrial use.

§340.3 Definitions.

Terms used in the singular form in this part shall be construed as the plural, and vice versa, as the case may demand. The following terms, when used in this part, shall be construed, respectively, to mean:

Access. The ability during regular business hours to enter, or pass to and from, a location, inspect, and/or obtain

or make use or copies of any records, data, or samples necessary to evaluate compliance with this part and all conditions of a permit issued in accordance with § 340.5.

Administrator. The Administrator of the Animal and Plant Health Inspection Service (APHIS) or any other employee of APHIS to whom authority has been or may be delegated to act in the Administrator's stead.

Agent. A person who is designated by the responsible person to act in whole or in part on behalf of the permittee to maintain control over an organism under permit during its movement and to ensure compliance with all applicable permit conditions and the requirements in this part. Multiple agents may be associated with a single responsible person or permit. Agents may be, but are not limited to, brokers, farmers, researchers, or site cooperators. An agent must be at least 18 years of age and be a legal resident of the United States.

Animal and Plant Health Inspection Service (APHIS). An agency of the United States Department of Agriculture (USDA).

Article. Any material or tangible object that could harbor plant pests.

Contained facility. A structure for the storage and/or propagation of living organisms designed with physical barriers capable of preventing the escape of the organisms. Examples include but are not limited to laboratories, growth chambers, fermenters, and containment greenhouses.

Donor organism. The organism from which genetic material is obtained for transfer to the recipient organism.

Environment. All the land, air, and water; and all living organisms in association with land, air, and water.

Gene pool. Germplasm within which sexual recombination is possible as a result of hybridization, including via methods such as embryo culture or bridging crosses.

Genetic engineering. Techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome.

Import (importation). To move into, or the act of movement into, the territorial limits of the United States.

Inspector. Any individual authorized by the Administrator or by the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

Interstate. From one State into or through any other State or within the District of Columbia, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Mechanism of action (MOA). The biochemical process(es) through which genetic material determines a trait.

Move (moving, movement). To carry, enter, import, mail, ship, or transport; aid, abet, cause, or induce the carrying, entering, importing, mailing, shipping, or transporting; to offer to carry, enter, import, mail, ship, or transport; to receive to carry, enter, import, mail, ship, or transport; to release into the environment; or to allow any of the above activities to occur.

Organism. Any active, infective, or dormant stage of life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.

Permit. A written authorization, including by electronic methods, by the Administrator to move organisms regulated under this part and associated articles under conditions prescribed by the Administrator.

Person. Any individual, partnership, corporation, company, society, association, or other organized group.

Plant. Any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a bulb, a root, or a seed.

Plant pest. Any living stage of a protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied

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