of such information may include, but is not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.

[70 FR 13278, Mar. 18, 2005, as amended at 77 FR 61077, Oct. 5, 2012; 82 FR 6206, Jan. 19, 2017]

§ 331.18 Inspections.

(a) Without prior notification, APHIS must be allowed to inspect any site at which activities regulated under this part are conducted and must be allowed to inspect and copy any records relating to the activities covered by this part.

(b) Prior to issuing a certificate of registration to an individual or entity, APHIS may inspect and evaluate their premises and records to ensure compliance with this part.

§ 331.19 Notification of theft, loss, or release.

(a) An individual or entity must immediately notify APHIS or CDC upon discovery of the theft or loss of a select agent or toxin. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

(1) The theft or loss of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information);

(ii) An estimate of the quantity stolen or lost;

(iii) An estimate of the time during which the theft or loss occurred;

(iv) The location (building, room) from which the theft or loss occurred; and

(v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report, the theft or loss.

(2) A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

(b) An individual or entity must notify APHIS or CDC immediately upon discovery of a release of a select agent or toxin outside of the primary barriers of the biocontainment area.

(1) The release of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information);

(ii) An estimate of the quantity released;

(iii) The time and duration of the release;

(iv) The location (building, room) from which the release occurred; and

(v) The number of individuals potentially exposed at the entity;

(vi) Actions taken to respond to the release; and

(vii) Hazards posed by the release.

(2) A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

[70 FR 13278, Mar. 18, 2005, as amended at 77 FR 61077, Oct. 5, 2012]

§ 331.20 Administrative review.

(a) An individual or entity may appeal a denial, revocation, or suspension of registration under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 30 calendar days of the decision.

(b) An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 180 calendar days of the decision.

(c) The Administrator's decision constitutes final agency action.

[77 FR 61077, Oct. 5, 2012]

PART 340—MOVEMENT OF ORGANISMS MODIFIED OR PRODUCED THROUGH GENETIC ENGINEERING

Sec.

AUTHORITY: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

SOURCE: 85 FR 29832, May 18, 2020, unless otherwise noted.

§ 340.1 Applicability of this part.

(a) The regulations in this part apply to those organisms described in § 340.2, but not to any organism that is exempt from this part under paragraph (b), (c), or (d) of this section.

(b) The regulations in this part do not apply to plants that have been modified such that they contain either a single modification of a type listed in paragraphs (b)(1) through (3) of this section, or additional modifications as determined by the Administrator, and described in paragraph (b)(4) of this section.

(1) The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or

(2) The genetic modification is a targeted single base pair substitution; or

(3) The genetic modification 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.

(4) The Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding. Such proposals may be Agency-initiated, and follow the process in paragraph (b)(4)(i) of this section, or in response to a request made in accordance with paragraph (b)(4)(ii) of this section.

(i) *APHIS-initiated proposals for exemptions.* APHIS will publish a notice in the FEDERAL REGISTER of the proposal by the Administrator to exempt plants with additional modifications. The notice will make available any supporting documentation, and will request public comment. After reviewing the comments, APHIS will publish a subsequent notice in the FEDERAL REGISTER announcing its final determination.

(ii) *Other parties' requests for exemptions.* Any person may request that the Administrator exempt plants developed with additional modifications that could be achieved through conventional breeding. To submit a request, the person must provide, in writing, information supporting the modification(s). Supporting information must include the following:

(A) A description of the modification(s);

(B) The factual grounds demonstrating that the proposed modification(s) could be achieved through conventional plant breeding;

(C) Copies of scientific literature, unpublished studies, or other data that support the request; and

(D) Any information known to the requestor that would be unfavorable to the request.

(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 Regulated'' 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 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 movement, or release into the environment of the GE organism); and information on the intended trait and the genotype of the intended trait. All permit applications must be signed by the responsible person.

(2) *Information requirements for permit applications for interstate movement or importation.* Applications for permits for interstate movement or importation of GE organisms must include the following additional information:

(i) The origin and destination of the GE organism, including information on the addresses and contact details of the sender and recipient, if different from the responsible person;

(ii) The quantity of the GE organism, the method of shipment, and means of ensuring the security of the shipment against unauthorized release of the organism; and

(iii) The manner in which packaging material, shipping containers, and any other material accompanying the organism will be disposed of to prevent unauthorized release.

(3) *Information requirements for permit applications for release into the environment.* Applications for permits for release of GE organisms into the environment must include information on all proposed environmental release sites, including land area (size), Global Positioning System coordinates, addresses,

and land use history of the site and adjacent areas; and the name and contact information of a person at each environmental release site, if different from the responsible person. In the event that additional release sites are requested after the issuance of a permit, APHIS will evaluate and amend permits as appropriate, in accordance with paragraph (l) of this section.

(c) *Exemption for GE Arabidopsis thaliana.* A permit for interstate movement is not required for GE *Arabidopsis thaliana,* provided that it is moved as a secure shipment, the modified genetic material is stably integrated into the plant genome, and the modified material does not include the complete infectious genome of a plant pest.

(d) *Exemption for GE disarmed Agrobacterium* species. A permit for importation or interstate movement is not required for any GE disarmed *Agrobacterium* species, provided that it is moved as a secure shipment, the modified genetic material is stably integrated into the genome, and the modified material does not include the complete infectious genome of a plant pest.

(e) *Exemption for Drosophila melanogaster.* A permit for importation or interstate movement is not required for GE *Drosophila melanogaster,* provided that it is moved as a secure shipment and that any introduced genetic material is not designed to propagate through a population by biasing the inheritance rate.

(f) *Exemption for certain microbial pesticides.* A permit is not required for the movement of any GE microorganism product that is currently registered with the Environmental Protection Agency (EPA) as a microbial pesticide, so long as the microorganism is not a plant pest as defined in § 340.3.

(g) *Exemption of certain plant-incorporated protectants.* A permit is not required for the movement of any GE plant modified solely to contain a plant-incorporated protectant that is currently registered with EPA as a pesticide product pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*, FIFRA) or that is currently exempted from FIFRA pursuant to 40 CFR 174.21.

(h) *Administrative actions*—(1) *Review of permit applications.* APHIS will review the permit application to determine whether it is complete. APHIS will notify the applicant orally or in writing if the application is incomplete, and the applicant will be provided the opportunity to revise the application. Once an application is complete, APHIS will review it to determine whether to approve or deny the application.

(2) *APHIS assignment of permit conditions.* If a permit application is approved, the Administrator will issue a permit with conditions as described in paragraph (i) of this section. Prior to issuance of a permit, the responsible person must agree in writing, in a manner prescribed by the Administrator, that the responsible person and all agents of the responsible person are aware of, understand, and will comply with the permit conditions. Failure to comply with this provision will be grounds for the denial of a permit.

(3) *Inspections.* All premises associated with the permit are subject to inspection before and after permit issuance, and all materials associated with the movement are subject to sampling after permit issuance. The responsible person and agents must provide inspectors access to premises, facilities, release locations, storage areas, waypoints, materials, equipment, means of conveyance, documents, and records related to the movement of organisms permitted under this part. Failure to provide access for inspection prior to the issuance of a permit will be grounds for the denial of a permit. Failure to provide access for inspection following permit issuance will be grounds for withdrawal of the permit.

(4) *State or Tribal review and comment.* The Administrator will submit for notification and review a copy of the permit application, without confidential business information (CBI), and any permit conditions to the appropriate State or Tribal regulatory official. Timely comments received from the State or Tribal regulatory official will be considered by the Administrator prior to permit issuance.

(5) *Approval or denial of a permit.* Except in circumstances that could not

reasonably have been anticipated, APHIS will approve or deny the permit within:

(i) 45 days of receipt of a complete application for a permit for interstate movement or for importation; or

(ii) 120 days of receipt of a complete application for a permit for release into the environment.

(iii) The 120-day period may be extended if preparation of an environmental assessment or environmental impact statement is necessary.

(i) *Permit conditions.* The standard conditions listed in this paragraph (i) will be assigned to all permits issued under this section. The Administrator may assign supplemental permit conditions as deemed necessary to ensure confinement of the GE organism. Prior to issuance of a permit or an amended permit, the responsible person will be required to agree in writing or electronically that he or she and his or her agents will comply with the conditions of the permit, as described in this paragraph (i). If the responsible person does not agree to the conditions, the amendment will be denied.

(1) The organism under permit must be maintained and disposed of in a manner so as to prevent its unauthorized release, spread, dispersal, and/or persistence in the environment.

(2) The organism under permit must be kept separate from other organisms, except as specifically allowed in the permit.

(3) The organism under permit must be maintained only in areas and premises specified in the permit.

(4) The identity of the organism under permit must be maintained and verifiable at all times.

(5) Authorized activities may be engaged in only while the permit is valid; the duration for which the permit is valid will be listed on the permit itself.

(6) Records related to activities carried out under the permit must be maintained by the responsible person and must be of sufficient accuracy, quality, and completeness to demonstrate compliance with all permit conditions and requirements under this part. APHIS must be allowed access to all records, to include visual inspection and reproduction (*e.g.,* photocopying, digital reproduction). The responsible person must submit reports and notices to APHIS, containing the information specified within the permit, at the times specified in the permit. At a minimum:

(i) Following an environmental release, environmental release reports must be submitted for all authorized release locations where the release occurred. Environmental release reports must contain details of sufficient accuracy, quality, and completeness to identify the location, shape, and size of the release and the organism(s) released into the environment. In the event no release occurs at an authorized location, an environmental release report of no environmental release must be submitted for all authorized locations where an environmental release did not occur. Unauthorized releases must be reported in accordance with paragraph (i)(9) of this section.

(ii) When the environmental release is of a plant, reports of volunteer monitoring activities and findings must be submitted for all authorized release locations where an environmental release occurred. If no monitoring activities are conducted, a volunteer monitoring report of no monitoring must be submitted indicating why no volunteer monitoring was done.

(7) Inspectors must be allowed access, during regular business hours, to all locations related to the permitted activities.

(8) The organism under permit must undergo the application of measures determined by the Administrator to be necessary to prevent its unauthorized release, spread, dispersal, and/or persistence in the environment.

(9) In the event of a possible or actual unauthorized release, the responsible person must contact APHIS as described in the permit within 24 hours of discovery and must subsequently supply a statement of facts in writing no later than 5 business days after discovery.

(10) The responsible person for a permit remains the responsible person for the permit unless a transfer of responsibility is approved by APHIS. The responsible person must contact APHIS to initiate any transfer. The new responsible person assumes all responsibilities for ensuring compliance with

the existing permit and permit conditions and for meeting the requirements of this part.

(j) *Denial or withdrawal of a permit.* Permit applications may be denied, or permits withdrawn, in accordance with this paragraph.

(1) *Denial of permits.* The Administrator may deny, either orally or in writing, any application for a permit. If the denial is oral, the Administrator will then communicate, as promptly as circumstances allow, the denial, and the reasons for it, in writing. The Administrator may deny a permit application if:

(i) The Administrator concludes that the proposed actions, *e.g.,* movements under permit, may not prevent the unauthorized release, spread, dispersal, and/or persistence in the environment of the organism; or

(ii) The Administrator determines that the responsible person or any agent of the responsible person has failed to comply with any material provision of this part, any other regulations issued pursuant to the Plant Protection Act (7 U.S.C. 7701 *et seq.*) or the Plant Protection Act itself;

(iii) In addition, no permit will be issued if the responsible person and his or her agents do not agree in writing, in accordance with paragraph (h)(2) of this section, to comply with the permit conditions or, in accordance with paragraph (h)(3) of this section, to allow inspection by APHIS.

(2) *Withdrawal of permits.* The Administrator may withdraw, either orally or in writing, any permit that has been issued. If the withdrawal is oral, the Administrator will communicate, as promptly as circumstances allow, the withdrawal, and the reasons for it, in writing. The Administrator may withdraw a permit if:

(i) Following issuance of the permit, the Administrator receives information that would have provided grounds for APHIS to deny the original permit application;

(ii) The Administrator determines that actions taken under the permit have resulted in the unauthorized release, spread, dispersal, and/or persistence in the environment of the organism under permit; or

(iii) The Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with any material provision of this part or with any other regulations issued pursuant to the Plant Protection Act (7 U.S.C. 7701 *et seq.*). This includes failure to comply with the conditions of any permit issued.

(k) *Appeal of denial or withdrawal of permit.* Any person whose permit application has been denied or whose permit has been withdrawn may appeal the decision in writing to the Administrator.[1] The applicant must submit in writing an acknowledgment of the denial or withdrawal, and a statement of intent to appeal, within 10 days after receiving written notification of the denial or withdrawal. The applicant may request additional time to prepare the appeal. The appeal must state all of the facts and reasons upon which the person relies to assert that the permit was wrongfully denied or withdrawn. The Administrator will grant or deny the appeal in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict.

(l) *Amendment of permits*—(1) *Amendment at responsible person's request.* If the responsible person determines that circumstances have changed since the permit was initially issued and wishes the permit to be amended accordingly, the responsible person must request the amendment by contacting APHIS directly. The responsible person will have to provide supporting information justifying the amendment. APHIS will review the amendment request, and will amend the permit if APHIS determines that relatively minor changes are necessary. Requests for more substantive changes will require a new permit application. Prior to issuance of an amended permit, the responsible person will be required to agree in

[1] The Office of the Administrator, as established in §371.2 of this chapter, will review appeals involving the denial or withdrawal of a permit. Appeals may be sent to Office of the Administrator, United States Department of Agriculture, Jamie L. Whitten Building, Room 312–E, 1400 Independence Ave. SW, Washington, DC 20250.

writing or electronically that he or she and his or her agents will comply with the conditions of the amended permit. If the responsible person does not agree to the conditions, the amendment will be denied.

(2) *Amendment initiated by APHIS.* APHIS may amend any permit and its conditions at any time, upon determining that the amendment is needed to address plant pest risks presented by the organism or the activities allowed under the permit. APHIS will notify the responsible person of the amendment to the permit and, as soon as circumstances allow, the reason(s) for it. The responsible person may have to agree in writing or electronically that he or she and his or her agents will comply with the conditions of the amended permit before APHIS will issue it. If APHIS requests such an agreement, and the responsible person does not accept it, the existing permit will be withdrawn.

(m) *Shipping under a permit.* (1) All shipments of organisms under permit must be secure shipments. Organisms under permit must be shipped in accordance with the regulations in 49 CFR part 178.

(2) The container must be accompanied by a document that includes the names and contact details for the sender and recipient.

(3) For any organism to be imported into the United States, the outmost container must bear information regarding the nature and quantity of the contents; the country (or countries) and locality (localities) where collected, developed, manufactured, reared, cultivated, and cultured (as applicable); the name and address of the shipper, owner, or person shipping or forwarding the organism; the name, address, and telephone number of the consignee; the identifying shipper's mark and number; and the permit number authorizing the importation. For organisms imported under permits by mail, the container must also be addressed to a plant inspection station listed in the USDA Plants for Planting Manual, which can be accessed at: *https://www.aphis.usda.gov/import__export/plants/manuals/ports/downloads/plants__for__planting.pdf.* All imported containers of organisms under permits must be accompanied by an invoice or packing list indicating the contents of the shipment.

(4) Following the completion of the shipment, all packaging material, shipping containers, and any other material accompanying the organism will be devitalized consistent with supplemental permit conditions, or disposed of to prevent unauthorized release.

(n) *Applicability date:* This section is applicable beginning April 5, 2021.

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

§ 340.6 Record retention, compliance, and enforcement.

(a) *Recordkeeping.* Responsible persons and their agents are required to establish, keep, and make available to APHIS the following records:

(1) Records and reports required under § 340.5(i);

(2) Addresses and any other information (*e.g.*, GPS coordinates, maps) needed to identify all locations where the organism under permit was stored or used, including all contained facilities and environmental release locations;

(3) A copy of the APHIS permit authorizing the permitted activity; and

(4) Legible copies of contracts (including amendments to contracts) between the responsible person and agents that conduct activities subject to this part for the responsible person, and copies of documents relating to agreements made without a written contract.

(b) *Record retention.* Records indicating that an organism under permit that was imported or moved interstate reached its intended destination must be retained for at least 2 years. All other records related to a permit must be retained for 5 years following the expiration of the permit, unless a longer retention period is determined to be needed by the Administrator and is documented in the supplemental permit conditions.

(c) *Compliance and enforcement.* (1) Responsible persons and their agents must comply with all of the requirements of this part. Failure to comply with any of the requirements of this

part may result in any or all of the following:

(i) Denial of a permit application or withdrawal of a permit in accordance with § 340.5(j);

(ii) Application of remedial measures in accordance with the Plant Protection Act (7 U.S.C. 7701 *et seq.*); and

(iii) Criminal and/or civil penalties in accordance with the Plant Protection Act (7 U.S.C. 7701 *et seq.*).

(2) Prior to the issuance of a complaint seeking a civil penalty, the Administrator may enter into a stipulation, in accordance with § 380.10 of this chapter.

(d) *Liability for acts of an agent.* For purposes of enforcing this part, the act, omission, or failure of any agent for a responsible person may be deemed also to be the act, omission, or failure of the responsible person.

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

§ 340.7 Confidential business information.

Persons including confidential business information (CBI) in any document submitted to APHIS under this part should do so in the following manner. If there are portions of a document deemed to contain confidential business information, those portions must be identified, and each page containing such information must be marked ''CBI Copy.'' A second copy of the document must be submitted with all such CBI deleted, and each page where the CBI was deleted must be marked ''CBI Deleted.'' In addition, any person submitting CBI must justify how each piece of information requested to be treated as CBI is a trade secret or, if not a trade secret, is either commercial or financial information that is privileged or confidential.

§ 340.8 Costs and charges.

The services of the inspector related to carrying out this part and provided during regularly assigned hours of duty and at the usual places of duty will be furnished by APHIS without cost to the responsible person.[1] The U.S. Department of Agriculture will not be responsible for any costs or charges incidental to inspections or compliance with the provisions of this part, other than for the services of the inspector.

PART 351—IMPORTATION OF PLANTS OR PLANT PRODUCTS BY MAIL

AUTHORITY: 7 U.S.C. 7711–7714, 7721, 7754, and 7755; 7 CFR 2.22, 2.80, and 371.3.

Sec.

CROSS REFERENCE: For customs regulations governing importation of plants and plant products, see 19 CFR part 12.

AUTHORITY: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

§ 351.1 Joint treatment generally.

The entry into the United States of certain plants, plant products, and soil is prohibited or restricted through various orders, quarantines, and regulations promulgated by the Administrator of the Animal and Plant Health Inspection Service (APHIS) under the authority of the Plant Protection Act (7 U.S.C. 7701–7772). To assist in enforcing the aforementioned orders, quarantines, and regulations, the Plant Protection and Quarantine Programs of APHIS have made provisions with the U.S. Postal and Customs Services to ensure closer inspection of prohibited or restricted imported articles.

[66 FR 21059, Apr. 27, 2001]

§ 351.2 Location of inspectors.

Inspectors of the Plant Protection and Quarantine Programs and customs officers are stationed at the following locations:

[1] The Department's provisions relating to overtime charges for an inspector's services are set forth in part 354 of this chapter.