

Animal and Plant Health Inspection Service, USDA

§ 330.100

or confiscate and destroy the refused shipments.

(Approved by the Office of Management and Budget under control number 0579-0207)

§ 322.35 Ports of entry.

A restricted article may be imported only at a port of entry staffed by an APHIS inspector. To find out if a specific port is staffed by an APHIS inspector, or for a list of ports staffed by APHIS inspectors, contact Permit Unit, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, Maryland 20737-1236; toll-free (877) 770-5990; fax (301) 734-8700.

PART 330—FEDERAL PLANT PEST REGULATIONS; GENERAL; PLANT PESTS, BIOLOGICAL CONTROL ORGANISMS, AND ASSOCIATED ARTICLES; GARBAGE

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AUTHORITY: 7 U.S.C. 1633, 7701-7772, 7781-7786, and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

SOURCE: 24 FR 10825, Dec. 29, 1959, unless otherwise noted.

Subpart A—General Provisions

SOURCE: Redesignated at 84 FR 2429, Feb. 7, 2019.

§ 330.100 Definitions.

The following terms, when used in this part, shall be construed, respectively, to mean:

Administrative instructions. Published documents relating to the enforcement of this part, and issued under authority thereof by the Administrator.

Administrator. The Administrator of the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture, or any employee of APHIS to whom authority has been delegated to act in the Administrator's stead.

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

Article. Any material or tangible object, including a living organism, that could harbor living plant pests or noxious weeds. The term includes associated articles such as soil and packaging.

Biocontainment facility. A physical structure or portion thereof, constructed and maintained in order to contain plant pests, biological control organisms, or associated articles.

Biological control organism. Any enemy, antagonist, or competitor used to control a plant pest or noxious weed.

Continental United States. The contiguous 48 States, Alaska, and the District of Columbia.

Continued curation permit. A permit issued prior to the expiration date for an import permit or interstate movement permit in order for a permittee to

continue research or other actions listed on the import or interstate movement permit. Continued curation permits do not allow acquisition of additional organisms for research and other authorized activities and only address retention of existing organisms for authorized uses.

Department. The United States Department of Agriculture.

Deputy Administrator. The Deputy Administrator of the Plant Protection and Quarantine Programs or any employee of the Plant Protection and Quarantine Programs delegated to act in his or her stead.

Enter (entry). To move into, or the act of movement into, the commerce of the United States.

EPA. The Environmental Protection Agency of the United States.

Export (exportation). To move from, or the act of movement from, the United States to any place outside the United States.

Garbage. That material designated as “garbage” in § 330.400(b).

Hand-carry. Importation of an organism that remains in one’s personal possession and in close proximity to one’s person.

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 of APHIS or the Commissioner of U.S. Customs and Border Protection to enforce the regulations in this part.

Interstate movement. Movement from one State into or through any other State; or movement within the District of Columbia, Guam, the U.S. Virgin Islands, or any other territory or possession of the United States.

Living. Viable or potentially viable.

Means of conveyance. Any personal or public property used for or intended for use for the movement of any other property. This specifically includes, but is not limited to, automobiles, trucks, railway cars, aircraft, boats, freight containers, and other means of transportation.

Move (moved and movement). To carry, enter, import, mail, ship, or transport; to 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 those activities.

Noxious weed. Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

Owner. The owner, or his or her agent, having possession of a plant pest, biological control organism, associated article, or any other means of conveyance, products, or article subject to the regulations in this part.

Permit. A written authorization, including by electronic methods, by the Administrator to move plant pests, biological control organisms, or associated articles under conditions prescribed by the Administrator.

Permittee. The person to whom APHIS has issued a permit in accordance with this part and who must comply with the provisions of the permit and the regulations in this part.

Person. Any individual, partnership, corporation, association, joint venture, or other legal entity.

Plant. Any plant (including any plant part) for or capable of propagation including trees, tissue cultures, plantlet cultures, pollen, shrubs, vines, cuttings, grafts, scions, buds, bulbs, roots, and seeds.

Plant pest. Any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: 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.

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

Plant Protection and Quarantine Programs. The Plant Protection and Quarantine Programs of the Animal and Plant Inspection Health Service.

Pure culture. A single species of invertebrate originating only from an identified/described population and free of disease and parasites, cryptic species, soil and other biological material except host material and substrate as APHIS deems appropriate. Examples of identified/described population are those originating from a specific laboratory colony or field collection from a specified geographic area, such as an entire country or States or provinces of a country.

Regulated garbage. That material designated as regulated garbage in § 330.400(c) and (d).

Responsible individual. One or more individuals who a permittee designates to appropriately oversee and control the staff, facilities, and/or site(s) at the location(s) specified on the permit as the ultimate destination of the plant pest, biological control organism, or associated article, to ensure compliance with the permit conditions during all phases of the activities being performed with the regulated articles authorized under a permit issued in accordance with this part for the movement or curation of a plant pest, biological control organism, or associated article. For the duration of the permit, the individual(s) must serve as a primary contact for communication with APHIS. The permittee may designate him or herself as the responsible individual. The responsible individual(s) must be at least 18 years of age and to be able meet with and provide information to an APHIS representative within a reasonable time frame. In accordance with section 7734 of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the act, omission, or failure of any responsible individual will also be deemed the act, omission, or failure of a permittee.

Secure shipment. Shipment of a regulated plant pest, biological control organism, or associated article in a container or a means of conveyance of sufficient strength and integrity to prevent leakage of contents and to withstand shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

Shelf-stable. The condition achieved in a product, by application of heat, alone or in combination with other ingredients and/or other treatments, of

being rendered free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50 °F or 10 °C).

Soil. The unconsolidated material from the earth's surface that consists of rock and mineral particles and that supports or is capable of supporting biotic communities.

State. Any of the States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the U.S. Virgin Islands, and all other territories or possessions of the United States.

Sterilization (sterile, sterilized). A chemical or physical process that results in the death of all living organisms on or within the article subject to the process. Examples include, but are not limited to, autoclaving and incineration.

Taxon (taxa). Any recognized grouping or rank within the biological nomenclature of organisms, such as class, order, family, genus, species, subspecies, pathovar, biotype, race, forma specialis, or cultivar.

Transit. Movement from and to a foreign destination through the United States.

United States. All of the States and territories.

U.S. Customs and Border Protection (CBP). U.S. Customs and Border Protection within the Department of Homeland Security.

[84 FR 29958, June 25, 2019]

§ 330.101 Policy.

The purpose of the regulations in this part is to prevent the dissemination of plant pests into the United States, or interstate, by regulating the movement of plant pests into or through the United States, or interstate, and the movement of means of conveyance, earth, stone and quarry products, garbage, and certain other products and articles into or through the United States, or from any Territory or possession into or through any other Territory or possession or the continental United States. The Deputy Administrator shall employ procedures to carry out this purpose which will impose a minimum of impediment to foreign

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commerce and travel whenever practicable, consistent with proper precaution against plant pest dissemination. The same policy is to be applied in the case of interstate commerce and travel.

§ 330.102 Basis for certain regulations.

Under the authority of the Plant Protection Act, the Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article (including baggage, mail, garbage, earth, stone, and quarry products) or means of conveyance if such actions are necessary to prevent the introduction into or the dissemination within the United States of a plant pest or noxious weed.

[66 FR 21058, Apr. 27, 2001]

§ 330.103 Documentation.

Any notifications, reports, and similar documentation not specified in the regulations in this part, but necessary to carry out the purpose of the regulations, will be prescribed in administrative instructions.

§ 330.104 Ports of entry.

Ports of entry for plant pests, means of conveyance, or other products or articles of any character whatsoever the entry or movement of which is regulated by the regulations in this part may be specified in administrative instructions or in the permits if permits are required by the regulations. The ports of entry shall be those named in 19 CFR 101.3(b)(1), except as otherwise provided by administrative instructions or by permits issued in accordance with this part, and except those ports of entry listed below.

LIST OF EXCEPTIONS TO CUSTOMS DESIGNATED
PORTS OF ENTRY

State	Port of entry
[Reserved]	[Reserved]

[24 FR 10825, Dec. 29, 1959, as amended at 72 FR 43523, Aug. 6, 2007]

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§ 330.105 Inspection.

(a) *Inspection of foreign arrivals.* In order to prevent the dissemination into the United States of plant pests and for the purpose of carrying out the regulations in this part, all plant pests; means of conveyance and their stores; baggage; mail; plants; plant products; soil; stone and quarry products under this part; garbage; and any other product or article of any character whatsoever which an inspector considers may be infested or infected by or contain a plant pest, arriving in the United States from any place outside thereof for entry into or movement through the United States shall be subject to inspection by an inspector at the port of first arrival, except that mail will be handled in accordance with the joint customs and postal regulations for inspecting and handling mail. No such plant pests; means of conveyance or their stores; baggage; mail; plants; plant products; soil; stone or quarry products under this part; garbage; or other products or articles which an inspector notifies the Customs authorities should be held for inspection shall be released by Customs officers for entry or onward movement until released by an inspector. The release of all means of conveyance, products and articles regulated under parts 319, 321, and 352 of this chapter shall be in accordance with the requirements of those parts and the applicable provisions in this part. Whenever it shall be deemed safe to modify the requirements of this section by exempting any class of means of conveyance, products or articles from the requirement that they be held for inspection and release of the inspector, the exemptions shall be specified in administrative instructions. Inspectors shall make local arrangements, in accordance with policies of the Plant Protection and Quarantine Programs, with the Collector of Customs for the release by Customs officers on behalf of the inspector of any class of means of conveyance, their stores, baggage, mail, or other products or articles when such arrangements do not increase unduly the danger of plant pest dissemination and will facilitate clearance of means of conveyance, baggage, mail, or other products or articles.

(b) *Inspection of domestic movements.* For the purpose of preventing the interstate movement of plant pests, provisions requiring inspection of means of conveyance and products or articles moving interstate may be issued as regulations in association with quarantines in part 301 or part 318 of this chapter or in this part.

NOTE: Notices appearing at 24 FR 4650, June 9, 1959, 24 FR 5363, July 2, 1959, 24 FR 6889, August 26, 1959, and 24 FR 7519, September 18, 1959, provide in part as follows: That means of conveyance subject to such inspection and release requirements and arriving at any port of entry outside the regularly assigned hours of duty of the Federal plant quarantine inspector, will be held for such inspection and release, until the regularly assigned hours of duty. However, notice is also hereby given that pursuant to the provisions of the Act of August 28, 1950 (7 U.S.C. 2260) such inspection service outside of the regularly assigned hours of duty may be made available to any interested person, upon a reimbursable basis and in accordance with applicable regulations, upon request to the Plant Quarantine Inspector in Charge at such port.

Information concerning regularly assigned hours of duty for Federal plant quarantine inspectors at each port where such inspection is available may be obtained locally by application to the Plant Quarantine Inspector in Charge at such port.

[24 FR 10825, Dec. 29, 1959, as amended at 62 FR 65009, Dec. 10, 1997; 84 FR 29960, June 25, 2019]

§ 330.106 Emergency measures.

(a) *Procedures to prevent pest dissemination.* Whenever inspection of any means of conveyance, stores, baggage, mail, plants, plant products, earth, stone and quarry products, garbage, or other products or articles of any character whatsoever, arriving in the United States from a place outside thereof, or moving interstate, discloses a plant pest, or provides a reason to believe such a pest is present (other than one moving under permit in accordance with any conditions in the permit and the provisions in this part) which is new to, or not theretofore known to be widely prevalent or distributed within and throughout the United States, the inspector shall employ procedures necessary to prevent the dissemination of the plant pest. Such procedures shall also be employed with respect to means

of conveyance or products or articles of any character whatsoever which have moved into the United States or interstate and which the inspector has reason to believe were infested or infected by or contained any such plant pest at the time of such movement. The inspector may follow administrative instructions containing procedures prescribed for certain situations, or he may follow a procedure selected by him from administratively approved methods known to be effective. The procedure may involve seizure, quarantine, treatment in accordance with part 305 of this chapter, application of other remedial measures, exportation, return to shipping point of origin, destruction, or other disposal, but no means of conveyance, product, article, or plant pest owned by any person shall be destroyed, exported, or returned to shipping point of origin or ordered to be so handled, unless there is, in the opinion of the inspector, no less drastic action adequate to prevent the dissemination of the plant pest. In forming such an opinion that no less drastic action is adequate, the inspector shall be guided by applicable specific and general instructions received from officers of the Plant Protection and Quarantine Programs. In taking action with respect to any means of conveyance, product, article, plant pest, the inspector shall take cognizance of applicable requirements of the customs and postal laws and regulations.

(b) *Orders for remedial measures.* The inspector may order the owner of any means of conveyance, product, article, or plant pest, subject to disposal under paragraph (a) of this section, to treat, apply other remedial measures, destroy, or make other disposal thereof without cost to the Federal Government and in a manner specified in accordance with paragraph (a) of this section.

(c) *Failure to apply remedial measures.* If the measures required by the inspector are not applied promptly by the owner within the time limits specified by the inspector, the inspector shall apply measures necessary to prevent the dissemination of the plant pests.

(d) *Khapra beetle infestations of means of conveyance, or cargo or stores thereof;*

other infestations. As a means of preventing the dissemination into the United States, or interstate, of the khapra beetle (*Trogoderma granarium* Everts), the following procedures will be applicable when that insect is found, or there is reason to believe it is present, in a means of conveyance within paragraph (a) of this section, or in any cargo or stores in such a means of conveyance, or in any cargo or stores unloaded or landed, or being unloaded or landed, in the United States therefrom. These procedures will also apply with respect to other plant pests when the inspector finds they are necessary and sufficient to prevent the spread of such pests.

(1) *Infestation in storerooms and similar compartments of means of conveyance (except aircraft).* (i) When infestation is found only in stores or storerooms, galleys, pantries, or similar noncargo compartments of a means of conveyance, except aircraft, the inspector shall prescribe and supervise the application of such remedial measures as, in his opinion, will be effective under conditions that will not spread the infestation to other parts of the means of conveyance, or to adjacent piers or other installations. If, in the opinion of the inspector, fumigation is the only available safeguard to eliminate the infestation, he shall order the owner to arrange for immediate fumigation of the infested stores and portions of the means of conveyance.

(ii) If the means of conveyance is to leave the territorial limits of the United States directly for a port in another country within 24 hours of such order, the inspector may suspend compliance with the fumigation requirement pending departure from the United States. Pending fumigation or departure, the inspector may seal the openings of infested compartments, packages, or articles, if in his opinion the action is necessary to prevent plant pest dissemination while the means of conveyance remains in the territorial limits of the United States, as authorized in § 330.110. The inspector may extend the 24-hour period to 48 hours, if, in his judgment, such extension is warranted by plans of the owner to remove the means of conveyance from the territorial limits of the

United States within the extended period, the inability of the contractor to begin fumigation within the 24-hour period, or other reason deemed valid by the inspector. Further extension shall be given only under authority of the Deputy Administrator. Pending compliance with the requirement of fumigation, or the departure from the territorial limits of the United States directly for a port in another country, no stores, laundry, furnishings or equipment, or other articles or products whether in cargo or stores, shall be unloaded from the means of conveyance except as authorized by the inspector and under conditions prescribed by him. The owner of an infested means of conveyance under notice for fumigation which leaves the territorial limits of the United States without fumigation should arrange for the eradication of the infestation before returning to the same or another port in the United States. Upon return to a port in the United States and unless the infestation has been eliminated to the satisfaction of the inspector, the means of conveyance shall be subject to fumigation immediately upon arrival in the United States. Unloading or landing of any product or article shall not be permitted pending compliance with the fumigation requirement, except as authorized by the inspector and under conditions prescribed by him.

(iii) If the means of conveyance is to remain at the port where the infestation was found or is to be moved to another port in the United States, the inspector shall prescribe and supervise the application of the remedial measures at the port where the infestation is found, as provided in this paragraph, or he may authorize the means of conveyance to be moved to another port for fumigation or the application of other remedial measures under safeguards prescribed by him.

(iv) In all instances where the inspector prescribed procedures concerned with the application of remedial measures which involve (a) withholding permission to discharge articles or products; (b) permission to discharge after such permission has been withheld; (c) discontinuance of discharging; or (d) resumption of discharging after it has

been discontinued, the appropriate Customs officer shall be immediately notified in writing. The inspector shall also inform the Customs officers at the port where the infestation is found and at such other ports as may be necessary of the requirement for fumigation and/or permission to move coastwise to another U.S. port for fumigation or other remedial measures.

(2) *Infestation in cargo compartments of means of conveyance (except aircraft).* When infestation is found in cargo compartments or in cargo of a means of conveyance, except aircraft, the inspector shall prescribe and supervise the application of such remedial measures as, in his opinion are necessary, with respect to the cargo and the portions of the means of conveyance which contain or contained or were contaminated by the infested cargo. If in the opinion of the inspector fumigation is the only available safeguard to eliminate the infestation, he shall order the owner to arrange for immediate fumigation of the infested portions of such means of conveyance and cargo. However, if such cargo compartments cannot be fumigated without fumigating the entire means of conveyance, the inspector may order the entire means of conveyance and cargo to be fumigated. The inspector shall notify the owner of the means of conveyance of such requirement and the owner shall arrange for immediate fumigation. Discharge of cargo shall be discontinued unless the inspector allows it to continue under safeguards to be prescribed by him. The provisions applicable to stores and storerooms in paragraph (d)(1)(ii) and (iii) of this section shall apply to cargo and cargo areas of such means of conveyance. Customs officers shall be informed as required in paragraph (d)(1)(iv) of this section.

(3) *Infestation in an aircraft.* If infestation is found in an aircraft, the inspector may apply seals as provided in § 330.110, and he may require such temporary safeguards as he deems necessary, including the discontinuance of further unloading or landing of any products or articles except as authorized by him. Upon finding such infestation in an aircraft the inspector shall promptly notify the Plant Protection and Quarantine Programs of all cir-

cumstances and the temporary safeguards employed, and the Plant Protection and Quarantine Programs will specify the measures for eliminating the infestation which will not be deleterious to the aircraft or its operating components. Any insecticidal application required shall be approved by the Deputy Administrator for use in aircraft. If the aircraft is to depart from the territorial limits of the United States within 24 hours after the infestation is found, the inspector shall permit such departure in lieu of the application of other measures and shall prior to departure break any seals that would prevent access to the aircraft or safe operation thereof. Other seals shall remain intact at time of departure and shall be broken by the aircraft commander or a crew member upon his order only after the aircraft is beyond the territorial limits of the United States. Extension of the 24-hour period shall be given only under authority of the Deputy Administrator. The owner of the aircraft under notice of khapra beetle infestation which leaves the territorial limits of the United States before the infestation has been eradicated should arrange for eradication before returning the aircraft to the United States. Upon return to the United States, if the infestation is not eliminated to the satisfaction of the inspector, the aircraft shall be subject to the same disinestation requirements and other safeguards immediately upon arrival in the United States. Customs officers shall be notified as required in paragraph (d)(1)(iv) of this section.

(4) *Precautions.* The owner of a means of conveyance required to be fumigated pursuant to this section shall arrange with a competent operator to apply the fumigant under the supervision of the inspector. The owner shall understand that if certain fumigants are used they may result in residues in or on foodstuffs which may render them unsafe for use as food items. He is hereby warned against such use unless as ascertains that the fumigated foodstuffs are fit for human consumption. It should also be understood by the owner that emergency measures prescribed by the inspector to safeguard against dissemination of infestation may have adverse effects on certain products and

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articles, and that the acceptance of fumigation as a requirement is an alternative to the immediate removal of the infested means of conveyance and any products and articles thereon, from the territorial limits of the United States. Products or articles in a means of conveyance, or compartments thereof, which may be exposed to methyl bromide or other remedial measures and may be adversely affected thereby, may be removed from the means of conveyance or compartments thereof prior to the application of the remedial measures if in the opinion of the inspector this can be done without danger of plant pest dissemination and under conditions authorized by him, for additional inspection and/or application of effective remedial measures.

[24 FR 10825, Dec. 29, 1959, as amended at 25 FR 8989, Sept. 20, 1960; 32 FR 6339, Apr. 21, 1967; 36 FR 24917, Dec. 24, 1971; 66 FR 21058, Apr. 27, 2001; 69 FR 12265, Mar. 16, 2004; 75 FR 4253, Jan. 26, 2010]

§ 330.107 Costs.

All costs (including those incurred under § 330.106 of this part by the government or the owner) incident to the inspection, handling, cleaning, safeguarding, treating, or other disposal of means of conveyance or products, articles, or plant pests under this part shall be borne by the owner. Services of the inspector during regularly assigned hours of duty at the usual places of duty shall be furnished without cost to the person requesting the services, unless a user fee is payable under § 354.3 of this chapter.

CROSS REFERENCE: See note following § 330.105.

[56 FR 14844, Apr. 12, 1991]

§ 330.108 Authority to issue administrative instructions.

The Deputy Administrator is authorized to issue the administrative instructions for which provision is made in the regulations in this part, for the purpose of preventing dissemination of plant pests into the United States or interstate. In addition, whenever the Deputy Administrator shall find that existing conditions as to pest risk involved in the movement of plant pests, means of conveyance, or other products

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or articles to which the regulations in this part apply, make it safe to modify by making less stringent the restrictions contained in any of such regulations, he shall publish such findings in administrative instructions, specifying the manner in which the regulations shall be made less stringent whereupon such modification shall become effective.

§ 330.109 Caution.

In applying treatments or taking other measures prescribed in administrative instructions or by the inspector, it should be understood that inexactness or carelessness may result in injury or damage.

§ 330.110 Seals.

(a) *Use authorized; form.* Whenever, in the opinion of the inspector, it is necessary, as a safeguard in order to prevent the dissemination of plant pests into the United States, or interstate, seals may be applied to openings, packages, or articles requiring the security provided by such seals. The words “openings, packages, or articles” shall include any form of container, shelf, bin, compartment, or other opening, package, or article which the inspector may have occasion to seal in lieu of more drastic action or otherwise, as a safeguard against plant pest dissemination. The seals may be automatic metal seals or labels or tags and will be provided by the Plant Protection and Quarantine Programs. When they consist of a label or tag, they will be printed in black ink on yellow paper and read substantially as follows: “Warning! The opening, package, or article to which this seal is affixed is sealed under authority of law. This seal is not to be broken while within the territorial limits of the United States except by, or under instructions of, an inspector.”

(b) *Breaking of seals.* Seals may be broken: (1) By an inspector; (2) by a Customs officer for Customs purposes, in which case the opening, package, or article will be resealed with Customs seals; (3) by the owner or his agent when the means of conveyance, product, or article has left the territorial limits of the United States; (4) by any person authorized by the inspector or

the Deputy Administrator under conditions specified by the inspector or Deputy Administrator. No person shall break seals applied under authority of this section except as provided in this paragraph. The movement into or through the United States, or interstate, of any means of conveyance or product or article on which a seal, applied under this paragraph, has been broken in violation of this paragraph is hereby prohibited, except as authorized by an inspector.

(c) *Notice of sealing.* When an inspector seals any opening, product or article, he shall explain the purpose of such action to the owner or his representative and shall present him with a written notice of the conditions under which the seal may be broken, if requested to do so.

[25 FR 8990, Sept. 20, 1960, as amended at 36 FR 24917, Dec. 24, 1971]

§ 330.111 Advance notification of arrival of aircraft and watercraft.

The owner, operator, or other representative of any aircraft or watercraft entering the United States from a foreign country, or arriving in the continental United States from Hawaii or any territory or possession of the United States, shall provide every Plant Protection and Quarantine office (PPQ office) serving a port of arrival on the itinerary of the craft while in the United States with advance notification of intent to arrive at that port. This advance notification of arrival shall:

(a) Reach the appropriate PPQ office not less than 12 hours before the craft's estimated time of arrival at the port;

(b) Be communicated by radio, wire, telephone, or any other means; and

(c) Include the following information:

(1) The name or other identifying feature of the individual craft;

(2) The date and estimated time of arrival at the port;

(3) The location of arrival, providing the most site-specific data available, such as the dock, pier, wharf, berth, mole, anchorage, gate, or facility, and;

(4) The names of all foreign and non-Continental U.S. ports where any cargo, crew, or passenger destined for the continental United States has

boarded the craft since its most recent arrival at a port in the United States.

(d) If the craft's estimated time of arrival changes by more than one hour, the PPQ office that serves the port of arrival must be notified and provided with updated information immediately.

(e) If the craft's site of arrival changes after a PPQ office has received advance notification of arrival, both that PPQ office and the newly affected PPQ office shall be notified of this change immediately. This applies, too, to site-specific changes involving watercraft.

(f) If the craft's point of arrival is an anchorage, the PPQ office shall be notified, as soon as possible after the craft's arrival at the anchorage, of the specific site, such as berth, mole, pier, to which the craft will be moving, as well as of its estimated time of arrival at that site.

(g) Aircraft and watercraft meeting any of the following conditions are exempt from the provisions in this section, and need not provide advance notification of arrival:

(1) The craft is not regularly used to carry passengers or cargo for a fee;

(2) The aircraft is making a flight scheduled in the Official Airline Guide, North American Edition, or the Official Airline Guide, Worldwide Edition, unless the scheduled time of arrival changes by more than one hour or the plane is diverted to another landing port;

(3) An inspector has precleared the aircraft in Hawaii, a territory or possession of the United States, or a foreign port, having determined that the aircraft contained only articles that are not prohibited or restricted importation into the United States under the provisions of 7 CFR chapter III and 9 CFR chapter I; or

(4) Personnel of the United States armed forces, including the U.S. Coast Guard, in Hawaii, a territory or possession of the United States, or a foreign port, have precleared an aircraft, having determined that the aircraft contained only articles that are not prohibited or restricted importation into the United States under the provisions of 7 CFR chapter III and 9 CFR chapter I.

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(5) The owner, operator, or other representative of the aircraft or watercraft not leaving the United States has been informed in writing by a PPQ inspector that notification of intended arrival is not required at subsequent ports in the United States.

(Approved by the Office of Management and Budget under control number 0579–0054)

[52 FR 49344, Dec. 31, 1987]

Subpart B—Movement of Plant Pests, Biological Control Organisms, and Associated Articles

SOURCE: 84 FR 29960, June 25, 2019, unless otherwise noted.

§ 330.200 Scope and general restrictions.

(a) *Restrictions.* No person shall import, move interstate, transit, or release into the environment plant pests, biological control organisms, or associated articles, unless the importation, interstate movement, transit, or release into the environment of the plant pests, biological control organisms, or associated articles is:

(1) Authorized under an import, interstate movement, or continued curation permit issued in accordance with § 330.201; or

(2) Authorized in accordance with other APHIS regulations in this chapter; or

(3) Explicitly granted an exception from permitting requirements in this subpart; or

(4) Authorized under a general permit issued by the Administrator.

(b) *Plant pests regulated by this subpart.* For the purposes of this subpart, and except for an organism that has undergone genetic engineering as defined in § 340.3 of this chapter, APHIS will consider an organism to be a plant pest if the organism directly or indirectly injures, causes damage to, or causes disease in a plant or plant product, or if the organism is an unknown risk to plants or plant products, but is similar to an organism known to directly or indirectly injure, cause damage to, or cause disease in a plant or plant product. Plant pests that have undergone genetic engineering, as de-

defined in § 340.3 of this chapter, are subject to the regulations of part 340 of this chapter.

(c) *Biological control organisms regulated by this subpart.* For the purposes of this subpart, biological control organisms include:

(1) Invertebrate predators and parasites (parasitoids) used to control invertebrate plant pests;

(2) Invertebrate competitors used to control invertebrate plant pests;

(3) Invertebrate herbivores used to control noxious weeds;

(4) Microbial pathogens used to control invertebrate plant pests;

(5) Microbial pathogens used to control noxious weeds;

(6) Microbial parasites used to control plant pathogens; and

(7) Any other types of biological control organisms, as determined by APHIS.

(d) *Biological control organisms not regulated by this subpart.* Paragraph (c) of this section notwithstanding, biological control organisms that have undergone genetic engineering, as defined in § 340.3 of this chapter, as well as products that are currently under an EPA experimental use permit, a Federal Insecticide Fungicide and Rodenticide Act (FIFRA) section 18 emergency exemption, or products that are currently registered with EPA as a microbial pesticide product, are not regulated under this subpart. Additionally, biological control organisms that are pesticides that are not registered with EPA, but are being transferred, sold, or distributed in accordance with EPA's regulations in 40 CFR 152.30, are not regulated under this subpart for their interstate movement or importation. However, an importer desiring to import a shipment of biological control organisms subject to FIFRA must submit to the EPA Administrator a Notice of Arrival of Pesticides and Devices as required by CBP regulations at 19 CFR 12.112. The Administrator will provide notification to the importer indicating the disposition to be made of shipment upon its entry into the customs territory of the United States.

[84 FR 29960, June 25, 2019, as amended at 85 FR 29832, May 18, 2020]

§ 330.201 Permit requirements.

(a) *Types of permits.* APHIS issues import permits, interstate movement permits, continued curation permits, and transit permits for plant pests, biological control organisms, and associated articles.¹

(1) *Import permit.* Import permits are issued to persons for secure shipment from outside the United States into the territorial limits of the United States. When import permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States. When import permits are issued to corporate persons, these persons must maintain an address or business office in the United States with one or more designated individuals for service of process.

(2) *Interstate movement permit.* Interstate movement permits are issued to persons for secure shipment from any State into or through any other State. When interstate movement permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States. When interstate movement permits are issued to corporate persons, these persons must maintain an address or business office in the United States with a designated individual for service of process.

(3) *Continued curation permits.* Continued curation permits are issued in conjunction with and prior to the expiration date for an import permit or interstate movement permit, in order for the permittee to continue the actions listed on the import permit or interstate movement permit. When continued curation permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States. When continued curation permits are issued to corporate persons, these persons must maintain an address or busi-

ness office in the United States with one or more designated individuals for service of process.

(4) *Transit permits.* Transit permits are issued for secure shipments through the United States. Transit permits are issued in accordance with part 352 of this chapter.

(b) *Applying for a permit.* Permit applications must be submitted by the applicant in writing or electronically through one of the means listed at http://www.aphis.usda.gov/plant_health/permits/index.shtml in advance of the action(s) proposed on the permit application.

(c) *Completing a permit application.* A permit application must be complete before APHIS will evaluate it in order to determine whether to issue the permit requested. To facilitate timely processing, applications should be submitted as far in advance as possible of the date of the proposed permit activity. Guidance regarding how to complete a permit application, including guidance specific to the various information blocks on the application, is available at http://www.aphis.usda.gov/plant_health/permits/index.shtml.

(d) *APHIS action on permit applications.* APHIS will review the information on the application to determine whether it is complete. In order to consider an application complete, APHIS may request additional information that it determines to be necessary in order to assess the risk to plants and plant products that may be posed by the actions proposed on the application. When it is determined that an application is complete, APHIS will commence review of the information provided.

(1) *State or Tribal consultation and comment; consultation with other individuals.* APHIS will share a copy of the permit application, and the proposed permit conditions, with the appropriate State or Tribal regulatory officials, and may share the application and the proposed conditions with other persons or groups to provide comment.

(2) *Initial assessment of sites and facilities.* Prior to issuance of a permit, APHIS will assess all sites and facilities that are listed on the permit application, including private residences,

¹Persons contemplating the shipment of plant pests, biological control organisms, or associated articles to places outside the United States should make arrangements directly, or through the recipient, with the country of destination for the export of the plant pests, biological control organisms, or associated articles into that country.

biocontainment facilities, and field locations where the organism² or associated article will be held or released. As part of this assessment, all sites and facilities are subject to inspection. All facilities must be determined by APHIS to be constructed and maintained in a manner that prevents the dissemination or dispersal of plant pests, biological control organisms, or associated articles from the facility. The applicant must provide all information requested by APHIS regarding this assessment, and must allow all inspections requested by APHIS during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, excluding holidays). Failure to do so constitutes grounds for denial of the permit application.

(3) *Issuance of a permit.* APHIS may issue a permit to an applicant if APHIS concludes that the actions indicated in the permit application are not likely to introduce or disseminate a plant pest, biological control organism, or noxious weed within the United States in a manner that exposes plants and plant products to unacceptable risk. Issuance will occur as follows:

(i) Prior to issuing the permit, APHIS will notify the applicant in writing or electronically of all proposed permit conditions. The applicant must agree in writing or electronically that he or she, and all his or her employees, agents, and/or officers, will comply with all permit conditions and all provisions of this subpart. If the organism or associated article will be contained in a private residence, the applicant must state in this agreement that he or she authorizes APHIS to conduct unscheduled assessments of the residence during normal business hours if a permit is issued.

(ii) APHIS will issue the permit after it receives and reviews the applicant's agreement. The permit will be valid for no more than 3 years. During that period, the permittee must abide by all permitting conditions, and the use of the organism or associated article must conform to the intended use on the permit. Moreover, the use of organisms derived from a regulated parent

organism during that period must conform to the intended use specified on the permit for the parent organism.

(iii) All activities carried out under the permit must cease on or before the expiration date for the permit, unless, prior to that expiration date, the permittee has submitted a new permit application and a new permit has been issued to authorize continuation of those actions.

(iv) At any point following issuance of a permit but prior to its expiration date, an inspector may conduct unscheduled assessments of the site or facility in which the organisms or associated articles are held, to determine whether they are constructed and are being maintained in a manner that prevents the dissemination of organisms or associated articles from the site or facility. The permittee must allow all such assessments requested by APHIS during normal business hours. Failure to allow such assessments constitutes grounds for revocation of the permit.

(4) *Denial of a permit application.* APHIS may deny an application for a permit if:

(i) APHIS concludes that the actions proposed in the permit application would present an unacceptable risk to plants and plant products because of the introduction or dissemination of a plant pest, biological control organism, or noxious weed within the United States; or

(ii) The actions proposed in the permit application would be adverse to the conduct of an APHIS eradication, suppression, control, or regulatory program; or

(iii) A State or Tribal executive official, or a State or Tribal plant protection official authorized to do so, objects to the movement in writing and provides specific, detailed information that there is a risk the movement will result in the dissemination of a plant pest or noxious weed into the State, APHIS evaluates the information and agrees, and APHIS determines that such plant pest or noxious weed risk cannot be adequately addressed or mitigated; or

(iv) The applicant does not agree to observe all of the proposed permit conditions that APHIS has determined are

²Includes biological control organisms and plant pests.

necessary to mitigate identified risks; or

(v) The applicant does not provide information requested by APHIS as part of an assessment of sites or facilities, or does not allow APHIS to inspect sites or facilities associated with the actions listed on the permit application; or

(vi) APHIS determines that the applicant has not followed prior permit conditions, or has not adequately demonstrated that they can meet the requirements for the current application. Factors that may contribute to such a determination include, but are not limited to:

(A) The applicant, or a partnership, firm, corporation, or other legal entity in which the applicant has a substantial interest, financial or otherwise, has not complied with any permit that was previously issued by APHIS.

(B) Issuing the permit would circumvent any order denying or revoking a previous permit issued by APHIS.

(C) The applicant has previously failed to comply with any APHIS regulation.

(D) The applicant has previously failed to comply with any other Federal, State, or local laws, regulations, or instructions pertaining to plant health.

(E) The applicant has previously failed to comply with the laws or regulations of a national plant protection organization or equivalent body, as these pertain to plant health.

(F) APHIS has determined that the applicant has made false or fraudulent statements or provided false or fraudulent records to APHIS.

(G) The applicant has been convicted or has pled *nolo contendere* to any crime involving fraud, bribery, extortion, or any other crime involving a lack of integrity.

(5) *Withdrawal of a permit application.* Any permit application may be withdrawn at the request of the applicant. If the applicant wishes to withdraw a permit application, he or she must provide the request in writing to APHIS. APHIS will provide written notification to the applicant as promptly as circumstances allow regarding reception of the request and withdrawal of the application.

(6) *Cancellation of a permit.* Any permit that has been issued may be canceled at the request of the permittee. If a permittee wishes a permit to be canceled, he or she must provide the request in writing to APHIS-PPQ. Whenever a permit is canceled, APHIS will notify the permittee in writing regarding such cancellation.

(7) *Revocation of a permit.* APHIS may revoke a permit for any of the following reasons:

(i) After issuing the permit, APHIS obtains information that would have otherwise provided grounds for it to deny the permit application; or

(ii) APHIS determines that the actions undertaken under the permit have resulted in or are likely to result in the introduction into or dissemination within the United States of a plant pest or noxious weed in a manner that presents an unacceptable risk to plants or plant products; or

(iii) APHIS determines that the permittee, or any employee, agent, or officer of the permittee, has failed to comply with a provision of the permit or the regulations under which the permit was issued.

(8) *Amendment of permits—(i) Amendment at permittee's request.* If a permittee determines that circumstances have changed since the permit was initially issued and wishes the permit to be amended accordingly, he or she must request the amendment, either through APHIS' online portal for permit applications, or by contacting APHIS directly via phone or email. The permittee may have to provide supporting information justifying the amendment. APHIS will review the amendment request, and may amend the permit if only minor changes are necessary. Requests for more substantive changes may require a new permit application. Prior to issuance of an amended permit, the permittee may be required to agree in writing that he or she, and his or her employees, agents, and/or officers will comply with the amended permit and conditions.

(ii) *Amendment initiated by APHIS.* APHIS may amend any permit and its conditions at any time, upon determining that the amendment is needed to address newly identified considerations concerning the risks presented

by the organism or the activities being conducted under the permit. APHIS may also amend a permit at any time to ensure that the permit conditions are consistent with all of the requirements of this part. As soon as circumstances allow, APHIS will notify the permittee of the amendment to the permit and the reason(s) for it. Depending on the nature of the amendment, the permittee may have to agree in writing or electronically that he or she, and his or her employees, agents, and/or officers, will comply with the permit and conditions as amended before APHIS will issue the amended permit. If APHIS requests such an agreement, and the permittee does not agree in writing that he or she, and his or her employees, agents, and/or officers, will comply with the amended permit and conditions, the existing permit will be revoked.

(9) *Suspension of permitted actions.* APHIS may suspend authorization of actions authorized under a permit if it identifies new factors that cause it to reevaluate the risk associated with those actions. APHIS will notify the permittee in writing of this suspension explaining the reasons for it and stating the actions for which APHIS is suspending authorization. Depending on the results of APHIS' evaluation, APHIS will subsequently contact the permittee to remove the suspension, amend the permit, or revoke the permit.

(10) *Appeals.* Any person whose application has been denied, whose permit has been revoked or amended, or whose authorization for actions authorized under a permit has been suspended, may appeal the decision in writing to the Administrator within 10 business days after receiving the written notification of the denial, revocation, amendment, or suspension. The appeal shall state all of the facts and reasons upon which the person relies to show that the application was wrongfully denied, permit revoked or amended, or authorization for actions under a permit suspended. The Administrator shall grant or deny the appeal, stating the reasons for the decision as promptly as circumstances allow.

(Approved by the Office of Management and Budget Under Control Number 0579–0054)

§ 330.202 Biological control organisms.

(a) *General conditions for importation, interstate movement, and release of biological control organisms.* Except as provided in paragraph (b) of this section, no biological control organism regulated under this subpart may be imported, moved in interstate commerce, or released into the environment unless a permit has been issued in accordance with § 330.201 authorizing such importation, interstate movement, or release, and the organism is moved or released in accordance with this permit and the regulations in this subpart. The regulations in 40 CFR parts 1500 through 1508, part 1b of this title, and part 372 of this chapter may require APHIS to request additional information from an applicant regarding the proposed release of a biological control organism as part of its evaluation of a permit application. Further information regarding the types of information that may be requested, and the manner in which this information will be evaluated, is found at http://www.aphis.usda.gov/plant_health/permits/index.shtml.

(b) *Exceptions from permitting requirements for certain biological control organisms.* APHIS has determined that certain biological control organisms have become established throughout their geographical or ecological range in the continental United States, such that the additional release of pure cultures derived from field populations of taxa of such organisms into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products. Lists of biological control organisms for invertebrate plant pests and for weeds are maintained on the PPQ Permits and Certifications website at <https://www.aphis.usda.gov/aphis/resources/permits>.

(1) *Importation and interstate movement of listed organisms.* Pure cultures of organisms excepted from permit requirements, unless otherwise indicated, may be imported or moved interstate within the continental United States without further restriction under this subpart.

(2) *Release of listed organisms.* Pure cultures of organisms on the list may be released into the environment of the

continental United States without further restriction under this subpart.

(c) *Additions to the list of organisms granted exceptions from permitting requirements for their importation, interstate movement, or release.* Any person may request that APHIS add a biological control organism to the list referred to in paragraph (b) of this section by submitting a petition to APHIS via email to pest.permits@usda.gov or through any means listed at http://www.aphis.usda.gov/plant_health/permits/index.shtml. The petition must include the following information:

(1) Evidence indicating that the organism is indigenous to the continental United States throughout its geographical or ecological range, or evidence indicating that the organism has produced self-replicating populations within the continental United States for an amount of time sufficient, based on the organism's taxon, to consider that taxon established throughout its geographical or ecological range in the continental United States; or

(2) Evidence that the organism's geographical or ecological range includes an extremely limited area of or none of the continental United States based on its inability to maintain year to year self-replicating populations despite repeated introductions over a sufficient range of time; or

(3) The petition would include evidence that the organism cannot establish anywhere in the continental United States; or

(4) Results from a field study where data were collected from representative habitats occupied by the biological control organism. Studies must include sampling for any direct or indirect impacts on target and non-target hosts of the biological control organism in these habitats. Supporting scientific literature must be cited; or

(5) Any other data, including published scientific reports, that suggest that subsequent releases of the organism into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products.

(d) *APHIS review of petitions*—(1) *Evaluation.* APHIS will review the petition to determine whether it is complete. If APHIS determines that the petition is

complete, it will conduct an evaluation of the petition to determine whether there is sufficient evidence that the organism exists throughout its geographical or ecological range in the continental United States and that subsequent releases of pure cultures of field populations of the organism into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products.

(2) *Notice of availability of the petition.* If APHIS determines that there is sufficient evidence that the organism exists throughout its geographical or ecological range in the continental United States and that subsequent releases of pure cultures of the organism into the environment of the continental United States will present no additional plant pest risk to plants or plant products, APHIS will publish a notice in the FEDERAL REGISTER announcing the availability of the petition and requesting public comment on that document.

(3) *Notice of determination.* (i) If no comments are received, or if the comments received do not lead APHIS to reconsider its determination, APHIS will publish in the FEDERAL REGISTER a subsequent notice describing the comments received and stating that the organism has been added to the list referred to in paragraph (b) of this section.

(ii) If the comments received lead APHIS to reconsider its determination, APHIS will publish in the FEDERAL REGISTER a subsequent notice describing the comments received and stating its reasons for determining not to add the organism to the list referred to in paragraph (b) of this section.

(e) *Removal of organisms from the list of exempt organisms.* Any biological control organism may be removed from the list referred to in paragraph (b) of this section if information emerges that would have otherwise led APHIS to deny the petition to add the organism to the list. Whenever an organism is removed from the list, APHIS will publish a notice in the FEDERAL REGISTER announcing that action and the basis for it.

(Approved by the Office of Management and Budget under control number 0579-0187)

§ 330.203 Soil.

(a) *Requirements.* The Administrator has determined that, unless it has been sterilized, soil is an associated article, and is thus subject to the permitting requirements of § 330.201, unless its movement:

(1) Is regulated pursuant to other APHIS regulations in this chapter; or

(2) Does not require such a permit under the provisions of paragraph (b)(1) or (c)(1) of this section.

(b) *Conditions governing the importation of soil—*(1) *Permit.* Except as provided in § 319.37–10 of this chapter and except for soil imported from areas of Canada not regulated by the national plant protection organization of Canada for a soil-borne plant pest, soil may be imported into the United States if an import permit has been issued in accordance with § 330.201 and if the soil is imported under the conditions specified on the permit.

(2) *Additional conditions for the importation of soil via hand-carry.* In addition to the condition of paragraph (b)(1) of this section, soil may be hand-carried into the United States only if the importation meets the conditions of § 330.205.

(3) *Additional conditions for the importation of soil intended for the extraction of plant pests.* In addition to the condition of paragraph (b)(1) of this section, soil may be imported into the United States for the extraction of plant pests if the soil will be imported directly to an APHIS-approved biocontainment facility.

(4) *Additional conditions for the importation of soil contaminated with plant pests and intended for disposal.* In addition to the condition of paragraph (b)(1) of this section, soil may be imported into the United States for the disposal of plant pests if the soil will be imported directly to an APHIS-approved disposal facility.

(5) *Exemptions.* The articles listed in this paragraph (b) are not soil, provided that they are free of organic material. Therefore, they may be imported into the United States without an import permit issued in accordance with § 330.201, unless the Administrator has issued an order stating otherwise. All such articles are, however, subject to inspection at the port of first ar-

rival, subsequent reinspection at other locations, other remedial measures deemed necessary by an inspector to remove any risk the items pose of disseminating plant pests or noxious weeds, and any other restrictions of this chapter:

(i) Consolidated material derived from any strata or substrata of the earth. Examples include clay (laterites, bentonite, china clay, attapulgitte, tierrafino), talc, chalk, slate, iron ore, and gravel.

(ii) Sediment, mud, or rock from saltwater bodies of water.

(iii) Cosmetic mud and other commercial mud products.

(iv) Stones, rocks, and quarry products.

(c) *Conditions governing the interstate movement of soil—*(1) *General conditions.* Except for soil moved in accordance with paragraphs (c)(2) through (5) of this section, soil may be moved interstate within the United States without prior issuance of an interstate movement permit in accordance with § 330.201 or further restriction under this subpart. However, all soil moved interstate is subject to any movement restrictions and remedial measures specified for such movement referenced in part 301 of this chapter.

(2) *Conditions for the interstate movement within the continental United States of soil intended for the extraction of plant pests.* Soil may be moved in interstate commerce within the continental United States with the intent of extracting plant pests, only if an interstate movement permit has been issued for its movement in accordance with § 330.201, and if the soil will be moved directly to an APHIS-approved biocontainment facility in a secure manner that prevents its dissemination into the outside environment.

(3) *Conditions for the interstate movement within the continental United States of soil infested with plant pests and intended for disposal.* Soil may be moved in interstate commerce within the continental United States with the intent of disposing of plant pests, only if an interstate movement permit has been issued for its movement in accordance with § 330.201, and the soil will be moved directly to an APHIS-approved disposal facility in a secure manner

that prevents its dissemination into the outside environment.

(4) *Conditions for the interstate movement of soil samples from an area quarantined in accordance with part 301 of this chapter for chemical or compositional testing or analysis.* Soil samples may be moved for chemical or compositional testing or analysis from an area that is quarantined in accordance with part 301 of this chapter without prior issuance of an interstate movement permit in accordance with § 330.201 or further restriction under this chapter, provided that the soil is moved to a laboratory that has entered into and is operating under a compliance agreement with APHIS, is abiding by all terms and conditions of the compliance agreement, and is approved by APHIS to test and/or analyze such samples.

(5) *Additional conditions for interstate movement of soil to, from, or between Hawaii, the territories, and the continental United States.* In addition to all general conditions for interstate movement of soil, soil may be moved in interstate commerce to, from, or between Hawaii, the territories, and the continental United States only if an interstate movement permit has been issued for its movement in accordance with § 330.201. In addition, soil moved to, from, or between Hawaii, the territories, and the continental United States with the intent of extracting plant pests is subject to the conditions of paragraph (c)(2) of this section, while soil infested with plant pests and intended for disposal is subject to the conditions of paragraph (c)(3) of this section.

(d) *Conditions governing the transit of soil through the United States.* Soil may transit through the United States only if a transit permit has been issued for its movement in accordance with part 352 of this chapter.

(Approved by the Office of Management and Budget Under Control Number 0579-0054)

§ 330.204 Exceptions to permitting requirements for the importation or interstate movement of certain plant pests.

Pursuant to section 7711 of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the Administrator has determined that certain plant pests may be moved

interstate within the continental United States without restriction. The list of all such plant pests is on the PPQ Permits and Certifications website at <https://www.aphis.usda.gov/aphis/resources/permits>. Plant pests listed as being excepted from permitting requirements, unless otherwise indicated, may be moved interstate within the continental United States without further restriction under this subpart.

(a) *Categories.* In order to be included on the list, a plant pest must:

(1) Be from field populations or lab cultures derived from field populations of a taxon that is established throughout its entire geographical or ecological range within the continental United States; or

(2) Be commercially available and raised under the regulatory purview of other Federal agencies.

(b) *Petition process to add plant pests to the list—(1) Petition.* Any person may petition APHIS to have an additional plant pest added to the list of plant pests that may be imported into or moved in interstate commerce within the continental United States without restriction. To submit a petition, the person must provide, in writing, information supporting the placement of a particular pest in one of the categories listed in paragraph (a) of this section.

(i) Information that the plant pest belongs to a taxon that is established throughout its entire geographical or ecological range within the United States must include scientific literature, unpublished studies, or data regarding:

(A) The biology of the plant pest, including characteristics that allow it to be identified, known hosts, and virulence;

(B) The geographical or ecological range of the plant pest within the continental United States; and

(C) The areas of the continental United States within which the plant pest is established.

(ii) Information that the plant pest is commercially available and raised under the regulatory purview of another Federal agency must include a citation to the relevant law, regulation, or order under which the agency exercises such oversight.

(2) *APHIS review.* APHIS will review the information contained in the petition to determine whether it is complete. In order to consider the petition complete, APHIS may require additional information to determine whether the plant pest belongs to one of the categories listed in paragraph (a) of this section. When it is determined that the information is complete, APHIS will commence review of the petition.

(3) *Action on petitions to add pests.* (i) If, after review of the petition, APHIS determines there is insufficient evidence that the plant pest belongs to one of the categories listed in paragraph (a) of this section, APHIS will deny the petition, and notify the petitioner in writing regarding this denial.

(ii) If, after review of the petition, APHIS determines that the plant pest belongs to one of the categories in paragraph (a) of this section, APHIS will publish a notice in the FEDERAL REGISTER that announces the availability of the petition and any supporting documentation to the public, that states that APHIS intends to add the plant pest to the list of plant pests that may be imported into or moved in interstate commerce within the continental United States without restriction, and that requests public comment. If no comments are received on the notice, or if, based on the comments received, APHIS determines that its conclusions regarding the petition have not been affected, APHIS will publish in the FEDERAL REGISTER a subsequent notice stating that the plant pest has been added to the list.

(c) *Petition process to have plant pests removed from the list—*(1) *Petition.* Any person may petition to have a plant pest removed from the list of plant pests that may be imported into or moved interstate within the continental United States without restriction by writing to APHIS. The petition must contain independently verifiable information demonstrating that APHIS' initial determination that the plant pest belongs to one of the categories in paragraph (a) of the section should be changed, or that additional information is now available that would have caused us to change the initial decision.

(2) *APHIS review.* APHIS will review the information contained in the petition to determine whether it is complete. In order to consider the petition complete, APHIS may require additional information supporting the petitioner's claim. When it is determined that the information is complete, APHIS will commence review of the petition.

(3) *APHIS action on petitions to remove pests.* (i) If, after review of the petition, APHIS determines that there is insufficient evidence to suggest that its initial determination should be changed, APHIS will deny the petition, and notify the petitioner in writing regarding this denial.

(ii) If, after review of the petition, APHIS determines that there is a sufficient basis to suggest that its initial determination should be changed, APHIS will publish a notice in the FEDERAL REGISTER that announces the availability of the petition, and that requests public comment regarding removing the plant pest from the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction. If no comments are received on the notice, or if the comments received do not affect APHIS' conclusions regarding the petition, APHIS will publish a subsequent notice in the FEDERAL REGISTER stating that the plant pest has been removed from the list.

(d) *APHIS-initiated changes to the list.* (1) APHIS may propose to add a plant pest to or remove a pest from the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction, if it determines that there is sufficient evidence that the plant pest belongs to one of the categories listed in paragraph (a) of the section, or if evidence emerges that leads APHIS to reconsider its initial determination that the plant pest was or was not in one of the categories listed in paragraph (a) of this section. APHIS will publish a notice in the FEDERAL REGISTER announcing this proposed addition or removal, making available any supporting documentation that it prepares, and requesting public comment.

(2) If no comments are received on the notice or if the comments received do not affect the conclusions of the notice, APHIS will publish a subsequent notice in the FEDERAL REGISTER stating that the plant pest has been added to or removed from the list.

(Approved by the Office of Management and Budget Under Control Number 0579-0187)

§ 330.205 Hand-carry of plant pests, biological control organisms, and soil.

Plant pests, biological control organisms, and soil may be hand-carried into the United States only in accordance with the provisions of this section.

(a) *Authorization to hand-carry*—(1) *Application for a permit; specification of “hand-carry” as proposed method of movement.* A person must apply for an import permit for the plant pest, biological control organism, or soil, in accordance with § 330.201, and specify hand-carry of the organism or article as the method of proposed movement.

(2) *Specification of individual who will hand-carry.* The application must also specify the individual or individuals who will hand-carry the plant pest, biological control organism, or soil into the United States. If APHIS authorizes this individual or these individuals to hand-carry, the authorization may not be transferred to nor actions under it performed by individuals other than those identified on the permit application.

(b) *Notification of intent to hand-carry.* After the permittee has obtained an import permit but no less than 20 days prior to movement, the permittee must provide APHIS through APHIS’ online portal for permit applications or by fax with the names of the designated hand carrier, or carriers, assigned to that movement. Additional conditions for hand-carry are available on the APHIS website.³

(c) *Denial, amendment, or cancellation of authorization to hand-carry.* APHIS may deny a request to hand-carry, or amend or cancel any hand-carry authorization at any time, if it deems such action necessary to prevent the introduction or dissemination of plant

pests or noxious weeds within the United States.

(d) *Appeal of denial, amendment, or cancellation.* Any person whose request to hand-carry has been denied, or whose authorization to hand-carry has been amended or canceled, may appeal the decision in writing to APHIS.

§ 330.206 Packaging requirements.

Shipments in which plant pests, biological control organisms, and associated articles are imported into, moved in interstate commerce, or transited through the United States must meet the general packaging requirements of this section, as well as all specific packaging requirements on the permit itself.

(a) *Packaging requirements.* All shipments must consist of an outer shipping container and at least two packages within the container. Both the container and inner packages must be securely sealed to prevent the dissemination of the enclosed plant pests, biological control organisms, or associated articles.

(1) *Outer shipping container.* The outer shipping container must be rigid, impenetrable and durable enough to remain closed and structurally intact in the event of dropping, lateral impact with other objects, and other shocks incidental to handling.

(2) *Inner packages.* The innermost package or packages within the shipping container must contain all of the organisms or articles that will be moved. As a safeguard, the innermost package must be placed within another, larger package. All packages within the shipping container must be constructed or safeguarded so that they will remain sealed and structurally intact throughout transit. The packages must be able to withstand changes in pressure, temperature, and other climatic conditions incidental to shipment.

(b) *Packing material.* Packing materials may be placed in the inner packages or shipping container for such purposes as cushioning, stabilizing,

³ https://www.aphis.usda.gov/plant_health/permits/organism/downloads/HandCarryPolicy.pdf.

water absorption or retention, nourishment or substrate for regulated articles, etc. Packing material for importation must be free of plant pests, noxious weeds, biological control organisms not listed on the permit or associated articles, and, as such, must be new, or must have been sterilized or disinfected prior to reuse. Packing material must be suited for the enclosed organism or article, as well as any medium in which the organism or article will be maintained.

(c) *Requirements following receipt of the shipment at the point of destination.*

(1) Packing material, including media and substrates, must be destroyed by incineration, be decontaminated using autoclaving or another approved method, or otherwise be disposed of in a manner specified in the permit itself.

(2) Shipping containers may be reused, provided that the container has not been contaminated with plant pests, noxious weeds, biological control organisms, or associated articles. Shipping containers that have been in contact with or otherwise contaminated with any of these items must be sufficiently sterilized or disinfected prior to reuse, or otherwise disposed of.

(d) *Costs.* Permittees who fail to meet the requirements of this section may be held responsible for all costs incident to inspection, rerouting, repackaging, subsequent movement, and any treatments.

§ 330.207 Cost and charges.

The inspection services of APHIS inspectors during regularly assigned hours of duty and at the usual places of duty will be furnished without cost. APHIS will not be responsible for any costs or charges incidental to inspections or compliance with the provisions of this subpart, other than for the inspection services of the inspector.

**Subpart C—Movement of Soil, Stone, and Quarry Products
[Reserved]**

Subpart D—Garbage

SOURCE: 71 FR 49314, Aug. 23, 2006, unless otherwise noted. Redesignated at 84 FR 2429, Feb. 7, 2019.

§ 330.400 Regulation of certain garbage.

(a) *Certain interstate movements and imports—*(1) *Interstate movements of garbage from Hawaii and U.S. territories and possessions to other States.* Hawaii, Puerto Rico, American Samoa, the Commonwealth of the Northern Mariana Islands, the Federated States of Micronesia, Guam, the U.S. Virgin Islands, Republic of the Marshall Islands, and the Republic of Palau are hereby quarantined, and the movement of garbage therefrom to any other State is hereby prohibited except as provided in this subpart in order to prevent the introduction and spread of exotic plant pests and diseases.

(2) *Imports of garbage.* In order to protect against the introduction of exotic animal and plant pests and diseases, the importation of garbage from all foreign countries except Canada is prohibited except as provided in § 330.401(b).

(b) *Definitions—Agricultural waste.* By-products generated by the rearing of animals and the production and harvest of crops or trees. Animal waste, a large component of agricultural waste, includes waste (e.g., feed waste, bedding and litter, and feedlot and paddock runoff) from livestock, dairy, and other animal-related agricultural and farming practices.

Approved facility. A facility approved by the Administrator, Animal and Plant Health Inspection Service, upon his determination that it has equipment and uses procedures that are adequate to prevent the dissemination of plant pests and livestock or poultry diseases, and that it is certified by an appropriate Government official as currently complying with the applicable laws for environmental protection.

Approved sewage system. A sewage system approved by the Administrator, Animal and Plant Health Inspection Service, upon his determination that the system is designed and operated in such a way as to preclude the discharge of sewage effluents onto land surfaces or into lagoons or other stationary waters, and otherwise is adequate to prevent the dissemination of plant pests and livestock or poultry diseases, and that is certified by an appropriate

Government official as currently complying with the applicable laws for environmental protection.

Carrier. The principal operator of a means of conveyance.

Garbage. All waste material that is derived in whole or in part from fruits, vegetables, meats, or other plant or animal (including poultry) material, and other refuse of any character whatsoever that has been associated with any such material.

Incineration. To reduce garbage to ash by burning.

Interstate. From one State into or through any other State.

Sterilization. Cooking garbage at an internal temperature of 212 °F for 30 minutes.

Stores. The food, supplies, and other provisions carried for the day-to-day operation of a conveyance and the care and feeding of its operators.

Yard waste. Solid waste composed predominantly of grass clippings, leaves, twigs, branches, and other garden refuse.

§ 330.401 Garbage generated onboard a conveyance.

(a) *Applicability.* This section applies to garbage generated onboard any means of conveyance during international or interstate movements as provided in this section and includes food scraps, table refuse, galley refuse, food wrappers or packaging materials, and other waste material from stores, food preparation areas, passengers' or crews' quarters, dining rooms, or any other areas on the means of conveyance. This section also applies to meals and other food that were available for consumption by passengers and crew on an aircraft but were not consumed.

(1) Not all garbage generated onboard a means of conveyance is regulated for the purposes of this section. Garbage regulated for the purposes of this section is defined as "regulated garbage" in paragraphs (b) and (c) of this section.

(2) Garbage that is commingled with regulated garbage is also regulated garbage.

(b) *Garbage regulated because of movements outside the United States or Canada.* For purposes of this section, garbage on or removed from a means of

conveyance is regulated garbage, if, when the garbage is on or removed from the means of conveyance, the means of conveyance has been in any port outside the United States and Canada within the previous 2-year period. There are, however, two exceptions to this provision. These exceptions are as follows:

(1) *Exception 1: Aircraft.* Garbage on or removed from an aircraft is exempt from requirements under paragraph (d) of this section if the following conditions are met when the garbage is on or removed from the aircraft:

(i) The aircraft had previously been cleared of all garbage and of all meats and meat products, whatever the country of origin, except meats that are shelf-stable; all fresh and condensed milk and cream from countries designated in 9 CFR 94.1 as those in which foot-and-mouth disease exists; all fresh fruits and vegetables; and all eggs; and the items previously cleared from the aircraft as prescribed by this paragraph have been disposed of according to the procedures for disposing of regulated garbage, as specified in paragraphs (d)(2) and (d)(3) of this section.

(ii) After the garbage and stores referred to in paragraph (b)(1)(i) of this section were removed, the aircraft has not been in a non-Canadian foreign port.

(2) *Exception 2: Other conveyances.* Garbage on or removed in the United States from a means of conveyance other than an aircraft is exempt from requirements under paragraph (d) of this section if the following conditions are met when the garbage is on or removed from the means of conveyance:

(i) The means of conveyance is accompanied by a certificate from an inspector stating the following:

(A) That the means of conveyance had previously been cleared of all garbage and of all meats and meat products, whatever the country of origin, except meats that are shelf-stable; all fresh and condensed milk and cream from countries designated in 9 CFR 94.1 as those in which foot-and-mouth disease exists; all fresh fruits and vegetables; and all eggs; and the items previously cleared from the means of conveyance as prescribed by this paragraph have been disposed of according

to the procedures for disposing of regulated garbage, as specified in paragraphs (d)(2) and (d)(3) of this section.

(B) That the means of conveyance had then been cleaned and disinfected in the presence of the inspector; and

(ii) Since being cleaned and disinfected, the means of conveyance has not been in a non-Canadian foreign port.

(c) *Garbage regulated because of certain movements to or from Hawaii, territories, or possessions.* For purposes of this section, garbage on or removed from a means of conveyance is regulated garbage, if at the time the garbage is on or removed from the means of conveyance, the means of conveyance has moved during the previous 1-year period, either directly or indirectly, to the continental United States from any territory or possession or from Hawaii, to any territory or possession from any other territory or possession or from Hawaii, or to Hawaii from any territory or possession. There are, however, two exceptions to this provision. These exceptions are as follows:

(1) *Exception 1: Aircraft.* Garbage on or removed from an aircraft is exempt from requirements under paragraph (d) of this section if the following two conditions are met when the garbage is on or removed from the aircraft:

(i) The aircraft had been previously cleared of all garbage and all fresh fruits and vegetables, and the items previously cleared from the aircraft as prescribed by this paragraph have been disposed of according to the procedures for disposing of regulated garbage, as specified in paragraphs (d)(2) and (d)(3) of this section.

(ii) After the garbage and stores referred to in paragraph (c)(1)(i) of this section were removed, the aircraft has not moved to the continental United States from any territory or possession or from Hawaii; to any territory or possession from any other territory or possession or from Hawaii; or to Hawaii from any territory or possession.

(2) *Exception 2: Other conveyances.* Garbage on or removed from a means of conveyance other than an aircraft is exempt from requirements under paragraph (d) of this section if the following two conditions are met when

the garbage is on or removed from the means of conveyance:

(i) The means of conveyance is accompanied by a certificate from an inspector stating that the means of conveyance had been cleared of all garbage and all fresh fruits and vegetables; and the items previously cleared from the means of conveyance as prescribed by this paragraph have been disposed of according to the procedures for disposing of regulated garbage, as specified in paragraphs (d)(2) and (d)(3) of this section.

(ii) After being cleared of the garbage and stores referred to in paragraph (c)(2)(i) of this section, the means of conveyance has not moved to the continental United States from any territory or possession or from Hawaii; to any territory or possession from any other territory or possession or from Hawaii; or to Hawaii from any territory or possession.

(d) *Restrictions on regulated garbage.* (1) Regulated garbage may not be disposed of, placed on, or removed from a means of conveyance except in accordance with this section.

(2) Regulated garbage is subject to general surveillance for compliance with this section by inspectors and to disposal measures authorized by the Plant Protection Act and the Animal Health Protection Act to prevent the introduction and dissemination of pests and diseases of plants and livestock.

(3) All regulated garbage must be contained in tight, covered, leak-proof receptacles during storage on board a means of conveyance while in the territorial waters, or while otherwise within the territory of the United States. All such receptacles shall be contained inside the guard rail if on a watercraft. Such regulated garbage shall not be unloaded from such means of conveyance in the United States unless such regulated garbage is removed in tight, covered, leak-proof receptacles under the direction of an inspector to an approved facility for incineration, sterilization, or grinding into an approved sewage system, under direct supervision by such an inspector, or such regulated garbage is removed for other handling in such manner and under such supervision as may, upon request

in specific cases, be approved by the Administrator as adequate to prevent the introduction and dissemination of plant pests and animal diseases and sufficient to ensure compliance with applicable laws for environmental protection. *Provided that*, a cruise ship may dispose of regulated garbage in landfills at Alaskan ports only, if and only if the cruise ship does not have prohibited or restricted meat or animal products on board at the time it enters Alaskan waters for the cruise season, and only if the cruise ship, except for incidental travel through international waters necessary to navigate safely between ports, remains in Canadian and U.S. waters off the west coast of North America, and calls only at continental U.S. and Canadian ports during the entire cruise season.

(i) Application for approval of a facility or sewage system may be made in writing by the authorized representative of any carrier or by the official having jurisdiction over the port or place of arrival of the means of conveyance to the Administrator, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. The application must be endorsed by the operator of the facility or sewage system.

(ii) Approval will be granted if the Administrator determines that the requirements set forth in this section are met. Approval may be denied or withdrawn at any time, if the Administrator determines that such requirements are not met, after notice of the proposed denial or withdrawal of the approval and the reasons therefor, and an opportunity to demonstrate or achieve compliance with such requirements, has been afforded to the operator of the facility or sewage system and to the applicant for approval. However, approval may also be withdrawn without such prior procedure in any case in which the public health, interest, or safety requires immediate action, and in such case, the operator of the facility or sewage system and the applicant for approval shall promptly thereafter be given notice of the withdrawal and the reasons therefor and an opportunity to show cause why the approval should be reinstated.

(e) The Plant Protection and Quarantine Programs and Veterinary Services, Animal, and Plant Health Inspection Service, will cooperate with other Federal, State, and local agencies responsible for enforcing other statutes and regulations governing disposal of the regulated garbage to the end that such disposal shall be adequate to prevent the dissemination of plant pests and livestock or poultry diseases and comply with applicable laws for environmental protection. The inspectors, in maintaining surveillance over regulated garbage movements and disposal, shall coordinate their activities with the activities of representatives of the Environmental Protection Agency and other Federal, State, and local agencies also having jurisdiction over such regulated garbage

§ 330.402 Garbage generated in Hawaii.

(a) *Applicability.* This section applies to garbage generated in households, commercial establishments, institutions, and businesses prior to interstate movement from Hawaii, and includes used paper, discarded cans and bottles, and food scraps. Such garbage includes, and is commonly known as, municipal solid waste.

(1) Industrial process wastes, mining wastes, sewage sludge, incinerator ash, or other wastes from Hawaii that the Administrator determines do not pose risks of introducing animal or plant pests or diseases into the continental United States are not regulated under this section.

(2) The interstate movement from Hawaii to the continental United States of agricultural wastes and yard waste (other than incidental amounts (less than 3 percent) that may be present in municipal solid waste despite reasonable efforts to maintain source separation) is prohibited.

(3) Garbage generated onboard any means of conveyance during interstate movement from Hawaii is regulated under § 330.401.

(b) *Restrictions on interstate movement of garbage.* The interstate movement of garbage generated in Hawaii to the continental United States is regulated as provided in this section.

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(1) The garbage must be processed, packaged, safeguarded, and disposed of using a methodology that the Administrator has determined is adequate to prevent the introduction or dissemination of plant pests into noninfested areas of the United States.

(2) The garbage must be moved under a compliance agreement in accordance with § 330.403. APHIS will only enter into a compliance agreement when the Administrator is satisfied that the Agency has first satisfied all its obligations under the National Environmental Policy Act and all applicable Federal and State statutes to fully assess the impacts associated with the movement of garbage under the compliance agreement.

(3) All such garbage moved interstate from Hawaii to any of the continental United States must be moved in compliance with all applicable laws for environmental protection.

§ 330.403 Compliance agreement and cancellation.

(a) Any person engaged in the business of handling or disposing of garbage in accordance with this subpart must first enter into a compliance agreement with the Animal and Plant Health Inspection Service (APHIS). Compliance agreement forms (PPQ Form 519) are available without charge from local USDA/APHIS/Plant Protection and Quarantine offices, which are listed in telephone directories.

(b) A person who enters into a compliance agreement, and employees or agents of that person, must comply with the following conditions and any supplemental conditions which are listed in the compliance agreement, as deemed by the Administrator to be necessary to prevent the dissemination into or within the United States of plant pests and livestock or poultry diseases:

(1) Comply with all applicable provisions of this subpart;

(2) Allow inspectors access to all records maintained by the person regarding handling or disposal of garbage, and to all areas where handling or disposal of garbage occurs;

(3)(i) If the garbage is regulated under § 330.401, remove garbage from a

means of conveyance only in tight, covered, leak-proof receptacles;

(ii) If the garbage is regulated under § 330.402, transport garbage interstate in packaging approved by the Administrator;

(4) Move the garbage only to a facility approved by the Administrator; and

(5) At the approved facility, dispose of the garbage in a manner approved by the Administrator and described in the compliance agreement.

(c) Approval for a compliance agreement may be denied at any time if the Administrator determines that the applicant has not met or is unable to meet the requirements set forth in this subpart. Prior to denying any application for a compliance agreement, APHIS will provide notice to the applicant thereof, and will provide the applicant with an opportunity to demonstrate or achieve compliance with requirements.

(d) Any compliance agreement may be canceled, either orally or in writing, by an inspector whenever the inspector finds that the person who has entered into the compliance agreement has failed to comply with this subpart. If the cancellation is oral, the cancellation and the reasons for the cancellation will be confirmed in writing as promptly as circumstances allow. Any person whose compliance agreement has been canceled may appeal the decision, in writing, within 10 days after receiving written notification of the cancellation. The appeal must state all of the facts and reasons upon which the person relies to show that the compliance agreement was wrongfully canceled. As promptly as circumstances allow, the Administrator will grant or deny the appeal, in writing, stating the reasons for the decision. A hearing will be held to resolve any conflict as to any material fact. Rules of practice concerning a hearing will be adopted by the Administrator. This administrative remedy must be exhausted before a person can file suit in court challenging the cancellation of a compliance agreement.

(e) Where a compliance agreement is denied or canceled, the person who entered into or applied for the compliance agreement may be prohibited, at the discretion of the Administrator,

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from handling or disposing of regulated garbage.

(Approved by the Office of Management and Budget under control numbers 0579-0015, 0579-0054, and 0579-0292)

PART 331—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

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AUTHORITY: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.3.

SOURCE: 70 FR 13278, Mar. 18, 2005, unless otherwise noted.

§ 331.1 Definitions.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

Attorney General. The Attorney General of the United States or any person authorized to act for the Attorney General.

Biological agent. Any microorganism (including, but not limited to, bacteria, viruses, fungi, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(2) Deterioration of food, water, equipment, supplies, or material of any kind; or

(3) Deleterious alteration of the environment.

Centers for Disease Control and Prevention (CDC). The Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.

Diagnosis. The analysis of specimens for the purpose of identifying or confirming the presence or characteristics of a select agent or toxin, provided that such analysis is directly related to protecting the public health or safety, animal health or animal products, or plant health or plant products.

Entity. Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

HHS Secretary. The Secretary of the Department of Health and Human Services or his or her designee, unless otherwise specified.

HHS select agent and/or toxin. A biological agent or toxin listed in 42 CFR 73.3.

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

Information security. Protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide:

(1) *Integrity*, which means guarding against improper information modification or destruction, and includes ensuring information authenticity;

(2) *Confidentiality*, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(3) *Availability*, which means ensuring timely and reliable access to and use of information.

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