DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 318, 319, 330, and 352

[Docket No. APHIS–2008–0076]

RIN 0579–AC98

Plant Pest Regulations; Update of Provisions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; withdrawal and reproposal.

SUMMARY: We are proposing to revise our regulations regarding the movement of plant pests. We are proposing criteria regarding the movement and environmental release of biological control organisms, and are proposing to establish regulations to allow the importation and movement in interstate commerce of certain types of plant pests without restriction by granting exceptions from permitting requirements for those pests. We are also proposing to revise our regulations regarding the movement of soil. This proposed rule replaces a previously published proposed rule, which we are withdrawing as part of this document. This proposal would clarify the factors that would be considered when assessing the risks associated with the movement of certain organisms and facilitate the movement of regulated organisms and articles in a manner that also protects U.S. agriculture.

DATES: We will consider all comments that we receive on or before March 20, 2017.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0076.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2008–0076, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0076* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Colin D. Stewart, Assistant Director; Pests, Pathogens, and Biocontrol Permits Branch, Plant Health Programs, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737–1236; (301) 851–2237.

SUPPLEMENTARY INFORMATION:

Background

Under the Plant Protection Act (7 U.S.C. 7712 *et seq.,* referred to below as the PPA or the Act), the Secretary of Agriculture has authority to carry out operations or measures to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests. Section 7711(a) of the Act provides that ''no person shall import, enter, export, or move in interstate commerce any plant pest, unless the importation, entry, exportation, or movement is authorized under general or specific permit and in accordance with such regulations as the Secretary may issue to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States.'' The Act gives the United States Department of Agriculture (USDA) the flexibility to respond appropriately to a wide range of needs and circumstances to protect American agriculture against plant pests. The Act defines a plant pest as ''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) A protozoan; (B) A nonhuman animal; (C) A parasitic plant; (D) A bacterium; (E) A fungus; (F) A virus or viroid; (G) An infectious agent or other pathogen; (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.''

In addition, section 412(a) of the Act provides that the Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of, among other things, any biological control organism if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States. The Act defines a biological control organism as ''any enemy, antagonist, or competitor used to control a plant pest or noxious weed.''

The purpose of the regulations in ''Subpart—Movement of Plant Pests'' (7 CFR 330.200 through 330.212) and ''Subpart—Movement of Soil, Stone, and Quarry Products'' (7 CFR 330.300 through 330.301) is to prevent the dissemination of plant pests into the United States, or interstate, by regulating the importation and interstate movement of plant pests, soil, stone, and quarry products.

These regulations were issued by the Animal and Plant Health Inspection Service (APHIS) under the authority provided by, among other statutes, the Department of Agriculture Organic Act of 1944, as amended (7 U.S.C. 147a), and the Federal Plant Pest Act, as amended (7 U.S.C. 150aa through 150jj), both of which were superseded and repealed by the PPA. Most of the provisions of the PPA regarding the importation and movement of plant pests were modeled on or directly derived from these two Acts; thus, the enactment of the PPA did not necessitate a major revision of the subpart. However, the PPA did contain provisions that clarified the authority in the earlier Acts regarding, among other things, our ability to regulate the importation and interstate movement of biological control organisms, as well as noxious weeds and associated articles.

Accordingly, on October 9, 2001 (66 FR 51340–51358, Docket No. 95–095–2), we published in the **Federal Register** a proposed rule which would have revised the plant pest regulations. Among other proposed provisions, it would have established a notification process that could be used as an alternative to the permitting system, provided for the environmental release of organisms for the biological control of weeds, and updated the text of the subpart to reflect the provisions of the PPA.

We solicited comments for 60 days ending December 10, 2001. We received 1,332 comments by that date. They were from State Departments of Agriculture, a State fish and wildlife agency, universities, plant societies, biocontrol organizations, USDA's Forest Service and Agricultural Research Service, the U.S. Environmental Protection Agency (EPA), zoological associations, the World Trade Organization, pharmaceutical groups and biological supply companies, wildlife protection and conservation groups, trade organizations, butterfly breeders and associations, elementary schools, and private citizens.

The majority of the comments that we received were from schools and students who requested that we continue to allow the environmental release of Monarch butterflies as part of a learning curriculum. Some of these commenters also requested that we continue to allow the environmental

release of Monarch butterflies for weddings and other ceremonies.[1]

We also received comments that addressed the proposed rule both generally and in regard to its specific provisions. Commenters often requested clarification regarding or suggested modification to several of the rule's provisions, but were, on the whole, generally supportive of the proposed rule. Accordingly, based on our evaluation of the comments that we received, we planned to issue a final rule.

However, the events of September 11, 2001, led to a further evaluation of our proposal to determine whether the proposed provisions had sufficient safeguards governing our permitting process. Specifically, we evaluated whether an aspect of our proposal, which would have authorized the importation of regulated organisms without prior issuance of a permit, provided that the party receiving the organisms had entered into a compliance agreement with APHIS, could serve as a potential venue for bioterrorism. We also temporarily suspended issuance of new plant pest permits.

In addition, on March 31, 2003, USDA's Office of the Inspector General (OIG) issued an audit of APHIS' permitting programs. Among other things, the audit examined APHIS' issuance of plant pest permits, and its administration of the permitting process. The audit suggested that we implement ePermits, a more thorough and technologically advanced permitting database than that used at the time, that we discontinue our practice at the time of issuing ''blanket'' permits to individuals or organizations to move plant pests and biological control organisms in favor of specific permits for each movement of a regulated organism, that we require more thorough documentation of an organism's intended use on each permit application, that we develop risk-based criteria for deciding whether or not to issue a permit for a particular movement, that we inspect the destinations listed on permit applications more regularly to evaluate their suitability for the organisms held onsite, and that we establish clear protocols, with an adequate degree of APHIS oversight, regarding the disposal of organisms once a permit expires. A 2007 followup OIG audit again encouraged us to fully implement ePermits, particularly at ports of entry into the United States.

Although APHIS has not substantively revised the regulations in the subpart since the promulgation of the PPA and the release of the OIG audits, these audit reports have informed Agency decisions regarding our regulation of the movement of plant pests, biological control organisms, and associated articles.

In this proposal, we are withdrawing our 2001 proposed rule and replacing it with an alternative proposal. This proposal retains several of the provisions of the 2001 proposal. For example, the conditions under which we would consider an organism a plant pest, and thus regulated by the subpart, remain similar to those of the 2001 proposal. However, this proposal also removes or modifies other provisions of the 2001 proposal. For example, we have removed provisions that would have authorized the movement of regulated organisms through a process consisting of compliance agreements and notification of movement.

Additionally, this proposal also incorporates new provisions that were not contained in the 2001 proposed rule but that would codify procedures that we have identified as best practices since that time but not yet added to the regulations.

The most significant changes in this new proposal are:

- We are proposing to establish criteria for the movement and environmental release of both biological control organisms of noxious weeds and those of plant pests; and
- We are proposing to remove ''Subpart—Movement of Soil, Stone, and Quarry Products'' and would instead regulate these articles in a subpart titled ''Subpart—Movement of Plant Pests, Biological Control Organisms, and Associated Articles.''

The full text of the proposed regulations appears in the rule portion of this document. Our discussion of the proposed provisions follows.

Definitions

In addition to our proposed revision of ''Subpart—Movement Plant Pests'' and removal of ''Subpart—Movement of Soil, Stone, and Quarry Products,'' we would also revise § 330.100, ''Definitions,'' of ''Subpart—General Provisions,'' to incorporate the applicable new definitions provided by the PPA and to update or eliminate some of the definitions currently provided in that section.

From the PPA, we would add definitions for the terms *article, biological control organism, enter (entry), export (exportation), import (importation), noxious weed, plant,* and *plant product;* and we would replace the current definitions of *move (moved and movement), permit, person, plant pest,* and *State* with the definitions provided for those terms in the PPA. However, regarding the definition of *permit,* although the PPA definition mentions the issuance of oral permits, our proposed definition does not. For the purposes of the plant pest regulations, oral permits would not provide a reliable means of verifying that a permittee was aware of the permit conditions at the time he or she was issued the permit, and would, we believe, adversely affect APHIS' ability to ensure appropriate compliance and enforcement of our regulatory requirements.

We would also add definitions for *Animal and Plant Health Inspection Service (APHIS), biocontainment facility, EPA, hand-carry, interstate movement, living, permittee, responsible individual, secure shipment, sterilization (sterile, sterilized), taxon (taxa), transit,* and *U.S. Customs and Border Protection (CBP).* We will first discuss what we mean by the term *taxon (taxa).* We will then discuss, in alphabetical order, the definitions of the other new terms that we are proposing to add to the regulations.

We would define *taxon (taxa)* as: ''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.'' This proposed definition is based on the International Plant Protection Convention's (IPPC's) Glossary of Phytosanitary Terms,[2] which uses taxon, at various points, in reference to family, species, and subspecies.

We would define the term *Animal and Plant Health Inspection Service (APHIS)* as: ''The Animal and Plant Health Inspection Service of the United States Department of Agriculture.''

We would define the term *biocontainment facility* as: ''A physical structure, or portion thereof,

[1] Under this proposed rule, which withdraws our 2001 proposal, we would authorize the issuance of permits for the environmental release of Monarch butterflies in accordance with current practices. Under these practices, permits issued to permittees who reside east of the Rocky Mountains would authorize the environmental release of Monarch butterflies east of the Rockies, while those issued for permittees who reside west of the Rocky Mountains would authorize the environmental release of Monarch butterflies west of the Rockies. This is because there are two distinct ecological ranges for Monarchs in the United States, with each terminating at the Rocky Mountains.

[2] International Standard for Phytosanitary Measures (ISPM) Number 5. To view this and other ISPMS, go to *https://www.ippc.int/en/core-activities/standards-setting/ispms/#publications.*

constructed and maintained in order to contain plant pests, biological control organisms, or associated articles.''

We would define the term *EPA* as: ''The Environmental Protection Agency of the United States.''

We would define the term *hand-carry* as: ''Importation of an organism that remains in one's personal possession and in close proximity to one's person.'' Our requirements governing the movement of plant pests by baggage, currently found in § 330.212, are commonly referred to as the ''hand-carry'' regulations; we are proposing to revise these requirements.

We would define the term *interstate movement* as: ''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.''

We would define the term *living* as: ''Viable or potentially viable.'' We are including ''potentially viable'' within our definition of *living* because most viruses and retroviruses of plants and plant products cannot grow or reproduce outside of a host cell; however, once inserted into the cell, they are capable of both growth and self-replication, and, over time, exhibit pathogenic effects. Because of this potential for both growth and self-replication, it is generally our policy to consider such viruses living plant pests, and to require a permit for their importation, interstate movement, transit, or continued curation.

We would define the term *permittee* as: ''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.''

We would define the term *responsible individual* as: ''The individual who a permittee designates to oversee and control the actions taken 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 must be physically present during normal business hours at or near the location specified on the permit as the ultimate destination of the plant pest, biological control organism, or associated article, and must serve as a primary contact for communication with APHIS. The permittee may designate him or herself as the responsible individual. The responsible individual must be at least 18 years of age. In accordance with section 7734 of the PPA, the act, omission, or failure of any responsible individual will also be deemed the act, omission, or failure of a permittee.''

Historically, we have only issued permits for the movement of plant pests, biological control organisms, and associated articles to individuals. However, as provided for in the definition of *permittee,* we would allow corporate entities to obtain permits under the revised regulations. This change will allow for better tracking and communication regarding a permit or permit application, and will also make it clear that the corporation as a whole is responsible for the permit. In such instances, we believe that it is of paramount importance that the permittee specifies a person whom APHIS may contact regarding the actions authorized under the permit who has first-hand knowledge of these actions. The responsible individual would fulfill this role.

We anticipate that, if this rule is finalized, we would still issue a significant number of permits to individuals, rather than corporate entities. We expect that, for the majority of such permits, the permittee would wish to designate him or herself as the responsible individual; therefore, the definition of *responsible individual* would allow for such designation.

Finally, Section 7734 of the PPA provides that a person will be held liable for the acts, omissions, and failures of an agent acting for that person, as long as the agent is acting within the scope of his or her office. Responsible individuals would be agents of the permittee pursuant to this section of the PPA.

We would define the term *secure shipment* as: ''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.''

We would define the term *sterilization (sterile, sterilized)* as: ''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.''

Note that, for the purposes of this subpart, the term sterilization does not refer to techniques that neutralize an organism by rendering it incapable of sexual reproduction. We recognize that this alternate meaning of the term ''sterilization'' might be more common within the regulated community, but believe that it is clear from the manner in which we would use the term in the revised subpart that it would have a different meaning within these regulations.

We would define the term *transit* as: ''Movement from and to a foreign destination through the United States.'' This definition would replace a definition currently in the regulations, *through the United States,* which we define as: ''From and to places outside the United States.''

We would define the term *U.S. Customs and Border Protection (CBP)* as: ''U.S. Customs and Border Protection within the Department of Homeland Security.'' This definition would replace the now outdated definition of *Customs* in the current regulations.

In addition, we would substantively revise the definition of *soil.* We currently define *soil* as: ''The loose surface material of the earth in which plants grow, in most cases consisting of disintegrated rock with an admixture of organic material and soluble salts.'' We would redefine *soil* as: ''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.'' This definition aligns with the current scientific understanding of soil, and would resolve ambiguities in the current definition that could be construed to suggest that soil includes consolidated or sterile matter that does not present a risk of harboring plant pests or noxious weeds. (For purposes of the regulations, it does not.) We would also remove the definition of *earth,* ''the softer matter composing part of the surface of the globe, in distinction from the firm rock, and including the soil and subsoil, as well as finely divided rock and other soil formation materials down to the rock layer,'' from the regulations.

We would remove the definition of *Plant Protection Act.* The Act is cited in the authority citation for part 330, and we do not believe it is necessary to define it in the regulations.

We would make nonsubstantive editorial changes to the definitions of *administrative instructions, Administrator, Department, Deputy Administrator, inspector, means of conveyance, owner,* and *Plant Protection and Quarantine Programs.*

Finally, we would retain, without modification, the existing definitions of *garbage, regulated garbage,* and *shelf-stable.*

Titles of the Part and Subpart

Currently, the title of part 330, ''Federal Plant Pest Regulations; General; Plant Pests; Soil, Stone, and Quarry Products; Garbage,'' reflects the

titles of its four subparts. As mentioned above, we are proposing to revise the second subpart, currently titled ''Subpart—Movement of Plant Pests,'' to clarify that it regulates the movement not only of plant pests, but also of biological control organisms and associated articles, including soil. Since we would now regulate soil within that subpart, we would remove and reserve the third subpart, ''Subpart—Soil, Stone, and Quarry Products.''

For this reason, we would also update the title of the second subpart. As amended, it would now be titled ''Subpart—Movement of Plant Pests, Biological Control Organisms, and Associated Articles.''

As a result of these proposed revisions, we would also revise the title of the part. It would now be titled: ''Federal Plant Pest Regulations; General; Plant Pests, Biological Control Organisms, and Associated Articles; Garbage.''

Scope and General Restrictions (§ 330.200)

The proposed regulations would begin by establishing the scope of the revised subpart. Paragraph (a) would state that 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:

- Authorized under an import, interstate movement, or continued curation permit issued in accordance with proposed § 330.201;
- Authorized in accordance with other APHIS regulations in 7 CFR chapter III;
- Explicitly granted an exception or exemption in the revised subpart from permitting requirements.
- Authorized under a general permit issued by the Administrator.

By ''authorized in accordance with other APHIS regulations in 7 CFR chapter III,'' we mean that certain movements of plant pests or associated articles are regulated under other APHIS regulations in title 7. For example, the transit of a plant pest through the United States would require a permit issued in accordance with § 352.5 of the plant quarantine safeguard regulations in 7 CFR part 352, and the interstate movement of regulated associated articles of domestic quarantine pests (*e.g.,* host articles of pine shoot beetle or Asian citrus psyllid) normally require certificates or limited permits issued in accordance with their respective subparts in the domestic quarantine notice regulations of 7 CFR part 301.

We discuss the exemptions from permitting requirements that we are proposing to grant for certain categories of biological control organisms in the discussion under the heading ''*Biological control organisms (§ 330.202),*'' and the exceptions from permitting requirements that we are proposing to grant for certain plant pests in the discussion under the heading ''*Exceptions to permitting requirements for the importation or interstate movement of certain plant pests (§ 330.204).*''

Finally, to date, we have only issued specific permits, that is, permits issued to specific persons, for the interstate movement of plant pests. However, pursuant to section 7711 of the PPA, the Administrator may also issue general permits, that is, general authorizations, for the importation or interstate movement of plant pests.

In recent years, we have contemplated issuing a general, Web-based permit for the interstate movement of certain plant pests that we regard to be low-risk unless they are moved into certain areas of the United States, rather than specific permits for the movement of these pests. If we finalize proposed paragraph (a) of § 330.200 and decide to issue such a permit, we would announce the existence, location, and content of this general permit through a notice in the **Federal Register**.

Paragraph (b) of § 330.200 would specify the types of plant pests that we would regulate under the revised subpart. The paragraph would state that, for the purposes of the subpart, we would consider an organism to be a plant pest if the organism either directly or indirectly injures, causes damage to, or causes disease in a plant or plant product, or if the organism or part 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.

This paragraph, which is not found in the current regulations, is similar to the criteria for designating an organism a plant pest that were contained in our 2001 proposal. We have, however, made two changes to those criteria.

First, while our 2001 proposal would have designated certain organisms as plant pests if they directly or indirectly adversely affected plants, plant parts, or plant products, in this proposed rule, we would designate these organisms as plant pests if the organisms directly or indirectly injure, cause damage to, or cause disease in a plant or plant product. These latter criteria are based on the definition of *plant pest* found in the PPA, and have been our framework in recent years for determining whether an organism is a plant pest.

We would also expand the scope of our 2001 proposal so that we may consider organisms of an unknown risk to plants or plant products to be plant pests, provided that the organisms are similar to an organism known to directly or indirectly injure, cause damage to, or cause disease in a plant or plant product.

In our 2001 proposal, we did propose that organisms of an unknown risk to plants or plant products would require a permit, but we would have designated them regulated organisms rather than plant pests. We also stated that permitting conditions for such organisms would be aimed primarily at affording us an opportunity to identify and deal with the organisms with some initial degree of regulatory oversight, in order to prevent the dissemination of plant pests into or within the United States. We thus framed permitting requirements for such organisms as a necessary stopgap measure pending positive identification of the organism and an assessment of the organism's potential risk to plants and plant products.

However, since 2001, there have been numerous occasions when applicants have requested authorization to import organisms that cannot readily be identified to the species level for a significant portion of their lifespans, but that may be plant pests. For example, we have issued several plant pest permits for the importation of larval scarabs. Before becoming mature, all scarabs are morphologically similar to one another and exhibit similar feeding patterns, but are not plant pests. However, once mature, certain scarab species are plant pests. In order to take this potential for future effects on plants, plant parts, and plant products into consideration, in issuing a permit for any scarab grub, we have considered it to be a plant pest, and tailored permitting and containment requirements accordingly.

Paragraph (c) of § 330.200 would specify the types of biological control organisms that we would regulate under the revised subpart. Although the PPA defines a biological control organism as ''any enemy, antagonist, or competitor used to control a plant pest or noxious weed,'' practically speaking, we have only required permits for certain types

of biological control organisms since the PPA was promulgated.[3] These are:

- Invertebrate predators and parasites (parasitoids) used to control invertebrate plant pests,
- Invertebrate competitors used to control invertebrate plant pests,
- Invertebrate herbivores used to control noxious weeds,
- Microbial pathogens used to control invertebrate plant pests,
- Microbial pathogens used to control noxious weeds, and
- Microbial parasites used to control plant pathogens.

Regarding these types of biological control organisms, we recognize that biological control organisms used to control noxious weeds are also plant pests, insofar as they injure, cause damage to, or cause disease in plants. However, since this effect is desirable and ultimately beneficial to other plants, plant parts, and plant products, it has been our policy to draft permitting conditions for the movement and environmental release of these organisms in a manner that encourages these effects, unless we have reason to believe that the organisms may also have plant pest effects on non-target plants or plant products.

As noted in the previous paragraphs, there are some types of biological control organisms for which we have not historically issued permits. However, there may be times when there would be a risk-based need to regulate the importation or interstate movement of an organism that falls within the PPA's definition of a *biological control organism,* but does not fall into any of the types of organisms listed above. For example, if a microbial parasite that has not previously been evaluated is put forth for the control of pathogenic fungi, it would not fall within the above categories, but could be an organism we would wish to regulate out of concern of the possibility of effects on non-target plants, such as fungi without phytopathogenic properties. To this end, paragraph (c) would also provide that other types of biological control organisms could be regulated under the revised subpart, as determined by APHIS. This determination would typically be on a case-by-case basis, and would be based on a permit application for movement of an organism which did not belong to any of the above types, but for which the Administrator determined it necessary to exercise a degree of regulatory oversight in order to prevent the introduction of a plant pest into the United States or the dissemination of a plant pest within the United States.

Paragraph (d) would exempt biological control organism products that EPA has issued experimental use permits for or that EPA has registered as microbial pesticide products having outdoor uses from regulatory oversight under the revised subpart. Under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.,* FIFRA), EPA regulates certain biological control organisms (eukaryotic microorganisms, prokaryotic microorganisms, and viruses) as ''substances,'' and has established a registration process for their use as microbial pesticides. EPA issues experimental use permits (EUPs) to allow persons to release these organisms into the environment on a limited basis in order to obtain information necessary to apply to have the organisms registered as microbial pesticides. EPA also allows the transfer, sale, and/or distribution of unregistered pesticides under certain circumstances in accordance with its regulations in 40 CFR 152.30. Because registered or permitted products are already subject to extensive regulation by EPA, we have entered into a memorandum of understanding with EPA stating that we consider the products to be exempt from our regulatory oversight, and paragraph (d) would largely codify the policy in this memorandum. It would also address EPA's provision for the transfer, sale, and/or distribution of unregistered pesticides under certain circumstances, and allow for the importation and interstate movement of such unregistered pesticides without APHIS' oversight, because of EPA's oversight.

Permit Requirements (§ 330.201)

Section 330.201 would describe the types of permits that APHIS issues for plant pests, biological control organisms, and associated articles, the process for applying for a permit, and the manner in which APHIS acts on permit applications.

Paragraph (a) of § 330.201 would provide information regarding the types of permits that APHIS issues for plant pests, biological control organisms, and associated articles. It would state that we issue import permits, interstate movement permits, continued curation permits, and transit permits.

Paragraph (a)(1) would provide information regarding import permits. It would state that APHIS issues import permits to persons for secure shipment from outside the United States into the territorial limits of the United States; that, 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; and that, when import 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.[4]

Paragraph (a)(2) would provide information regarding interstate movement permits. It would state that interstate movement permits are issued to persons for secure shipment from any State into or through any other State; that, 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; and that, 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.

Both import and interstate movement permits may contain conditions regarding the manner in which an organism may be moved from the destination listed on the permit. Such conditions are necessary to ensure that the organism is moved in a manner that will prevent its escape and dissemination and to ensure that the new facility to which it will be moved is capable of providing the necessary level of containment.

On a related matter, applicants for import and interstate movement permits should be aware that States and localities may have laws and regulations that restrict the movement or release of plant pests, biological control organisms, and associated articles for various reasons (for example, impact on the environment of the State or locality). We encourage applicants to consult with these authorities prior to applying for a permit.

Paragraph (a)(3) would provide information regarding continued curation permits. It would state that 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

[3] It is worth noting that, prior to the PPA, we issued permits for the movement and release of invertebrate herbivores used to control noxious weeds and microbial pathogens used to control noxious weeds pursuant to authority in the Federal Plant Pest Act (FPPA). The FPPA was superseded and repealed by the PPA.

[4] Please note that other Federal agencies have separate regulatory authority related to the importation of secure shipments of plant pests, biological control organisms, and associated articles. For example, pursuant to their general regulatory authority, DHS requires formal entry for organisms and soil that are imported via hand-carry or express courier organizations.

movement permit following the expiration of the original permit. It would also state that, 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. It would further state that, when continued curation 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.

Paragraph (a)(4) would provide information regarding transit permits. It would state that transit permits are issued for secure shipments through the United States, and that such permits are issued in accordance with 7 CFR part 352. As we mentioned above, § 352.5 of that part contains permitting requirements for transit permits.

However, part 352 currently provides for the transit of plant pests, but does not provide for the transit of biological control organisms. Therefore, we would amend part 352 to include references to biological control organisms. (For this reason, we would also amend part 352 to add definitions for the terms *biological control organism* and *noxious weed,* and to revise the definitions for *Deputy Administrator, person, plant pest,* and *soil.* The revised definitions would be identical to the ones we are proposing for part 330.)

Currently, part 330 contains provisions for the issuance of several additional types of permits: Permits for plant pest movement associated with national defense projects, permits for means of conveyance, and courtesy permits for organisms that are not subject to APHIS regulation. However, we no longer issue a special type of permit specifically for national defense projects; if such a permit application arises, we issue the appropriate type of movement permit, and specify as a permit condition that the use of the organism is for a national defense project. Similarly, we do not issue permits specifically for means of conveyance; if we have reason to believe the means of conveyance may be an associated article, we regulate it as such and issue the appropriate movement permit.

Until 2009, we issued courtesy permits in order to facilitate the movement of organisms that were not regulated under 7 CFR part 330, but that were similar enough to a known plant pest or biological control organism that their movement might otherwise be impeded if they were not accompanied by some sort of documentation from APHIS during transit. However, courtesy permits historically generated much confusion in the public and especially in the research community. The application form for courtesy permits was identical to the application for other types of permits, and the courtesy permit itself looked like other permits. This periodically led to the misunderstanding by some researchers that courtesy permits were required for the movement of certain organisms that were, in actuality, not subject to APHIS regulation. For these reasons, in recent years, Plant Protection and Quarantine (PPQ) has discontinued its issuance of courtesy permits for organisms that are similar to plant pests or biological control organisms, and it would not be necessary to include courtesy permits in the revised subpart.

In a related matter, § 330.207 of the current regulations states that APHIS recognizes permits issued by other Federal Agencies for the movement of regulated organisms and will issue administrative instructions or engage in correspondence with a permittee to augment the provisions of these permits through further conditions, rather than issue a duplicative permit.

We do not consider it necessary to retain those provisions in the revised subpart. First, we seldom engage in correspondence with the permittee for permits issued by another Federal agency, such as EUPs issued by EPA. Rather, if we believe that the actions authorized under the permit may place plants or plant products at risk, we discuss the matter with the issuing agency itself. Correspondingly, it is rare that we receive permit applications from applicants who have submitted a prior application to another regulatory agency. Therefore, the provisions do not reflect current Agency practices, and we believe that it is generally presupposed by the regulated community that we will recognize permits issued by other regulatory agencies for the movement of plant pests, biological control organisms, and associated articles.

Finally, we have periodically received requests from individuals to issue permits certifying organisms and associated articles that are destined for export from the United States. We note that foreign countries, rather than APHIS, set the conditions under which they will allow the importation of plant pests, biological control organisms, and associated articles from the United States. To this end, we would include a footnote stating that persons 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.

That being said, for certain high-risk plant pests, interstate movement permits may place conditions on the interstate movement of the organism for export purposes. This is not included in the current regulations, but reflects recent Agency policy. Such conditions are necessary to safeguard the movement of the organism to the port of export.

Paragraph (b) of § 330.201 would provide that permit applications must be submitted by the applicant in writing or electronically through one of the methods specified at *http://www.aphis.usda.gov/plant_health/permits/index.shtml,* and must be submitted in advance of the action(s) proposed on the permit application. That Web page would specify that persons may apply for a permit via the Internet through APHIS' secure site for online permit applications, and would provide a link to that portal. It would also provide that a person may submit a permit application by faxing the application to APHIS, and would specify the appropriate fax number. Additionally, it would state that an application may be obtained by calling PPQ at the number provided. Finally, it would provide that a person may submit a permit application by mailing it to APHIS at the address provided. We note that because of the need for additional administrative processing, permit applications that are submitted via fax or by mail may not be reviewed as expeditiously as those submitted through APHIS' online portal. We encourage applicants to submit their applications electronically.

Paragraph (c) of § 330.201 would provide that a permit application must be complete before we will evaluate it in order to determine whether to issue the permit requested. Guidance regarding how to complete a permit application, including guidance specific to various information blocks on the application, would be available at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.* The guidance would also specify that, in order to facilitate timely issuance of a permit, an application should be submitted at least 90 days before the actions proposed on the permit application are scheduled to take place, with additional time allotted for complex or novel applications, or applications for high-risk plant pests.

Paragraph (d) of § 330.301 would describe the actions APHIS takes on receiving a permit application. The introductory text to the paragraph

would state that APHIS reviews the information on the application to determine whether it is complete. In order to consider an application complete, APHIS may request additional information that we determine 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, we commence review of the information provided.

Paragraph (d)(1) would describe the first part of APHIS' formal review, consultation with States, Tribes, and other individuals. We share a copy of the permit application, and the proposed permit conditions, with the appropriate State or Tribal regulatory officials, and may share them with other persons or groups to provide comment. For instance, we may share the permit application with persons or groups other than State or Tribal regulatory officials when we lack technical expertise to evaluate certain aspects of a permit application and need to solicit the opinion of individuals or groups with such expertise.

Paragraph (d)(2) would describe the second part of our review, our initial assessment of sites and facilities where the organism or article will be held or released that are listed on the permit application. Such sites and facilities may include private residences, biocontainment facilities, and field locations. Although we may not do an onsite inspection in some cases, all sites and facilities would be subject to inspection as part of the assessment. All facilities would have to 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. Finally, the applicant would have to provide all information requested by APHIS regarding this assessment, and to 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 would constitute grounds for denial of the permit application.

Paragraphs (d)(3) and (d)(4) would describe the two possible actions we would take upon concluding review of the permit application: Issuance or denial of the requested permit. Paragraph (d)(3) would discuss permit issuance. APHIS may issue a permit to an applicant if APHIS concludes that the actions allowed under the permit would be highly unlikely to result in the introduction or dissemination of a plant pest, biological control organism, or noxious weed within the United States in a manner that presents an unacceptable risk to plants and plant products.

We would specify that the actions allowed under the permit must be highly unlikely to result in the introduction or dissemination of a plant pest, biological control organism, or noxious weed within the United States in a manner that presents an unacceptable risk to plants and plant products because we would allow the environmental release of certain plant pests and biological control organisms under the revised subpart. The considerations that lead us to determine whether to authorize the environmental release of such organisms are discussed later in this document.

Paragraphs (d)(3)(i) through (d)(3)(iv) would describe the manner in which APHIS would issue a permit under the revised subpart. Prior to issuing the permit, APHIS would notify the applicant in writing or electronically of all proposed permit conditions. The applicant would have to agree in writing or electronically that he or she, and all his or her employees, agents, and/or officers, would comply with all permit conditions and all provisions of the regulations. If the organism or associated article will be contained in a private residence, the applicant would have to 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.

APHIS would issue the permit after it receives and reviews the applicant's agreement. The permit would be valid for no more than 3 years. During that period, the permittee would have to abide by all permitting conditions,[5] and use of the organism or article would have to conform to the intended use on the permit. Moreover, the use of organisms derived from a regulated parent organism during that period would have to conform to the intended use specified on the permit for the parent organism.

We would specify that the use of the organism or article under the permit must conform to the intended use on the permit, because, on occasion, laboratories have obtained a permit for the movement of a plant pest or biological control organism into biocontainment, and then used the organism for purposes that differed from those specified as the intended use on the permit. In such instances, APHIS was not afforded an opportunity to evaluate the uses and determine whether they present a risk to plants and plant products within the United States. There have also been instances when laboratories have claimed that subsequent generations derived from a parent organism during the time period specified on a permit are distinct organisms, and thus should not be subject to the conditions specified on the permit and may be used at the laboratory's discretion. Such unregulated use of subsequent generations or progeny could present a risk of dissemination of the pest. Hence, we would require that the use of organisms derived from a regulated parent organism must conform to the intended use specified on the permit application for the parent organism.

All activities carried out under the permit would have to cease on or before the expiration date of 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 the actions.

Finally, at any point following issuance of a permit but prior to its expiration date, an inspector could 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. As with inspections associated with our initial assessment of sites or facilities prior to permit issuance, the permittee would have to allow all such assessments that we request during normal business hours. Failure to allow such assessments would constitute grounds for revocation of the permit.

Paragraph (d)(4) would set forth the conditions under which APHIS may deny an application for a permit. Currently, in § 330.204 of the regulations, APHIS will deny a permit application when such movement would involve a danger of dissemination of the pest. Danger of plant pest dissemination may be deemed to exist when any of the following five conditions occurs:

- No acceptable safeguards adequate to prevent plant pest dissemination can be arranged.
- The destructive potential of the plant pest to plants, and parts and products thereof, should it escape despite proposed safeguards, outweighs the probable benefits to be derived from

[5] Permitting conditions may reference the regulations and policies of other Federal agencies. For example, an import permit may provide conditions that a permittee must abide by in order for customs entry of his or her shipment to occur pursuant to CBP's regulations in title 19 of the CFR.

the proposed movement and use of the pest.

• The applicant, as a previous permittee, failed to maintain the safeguards or otherwise observe the conditions prescribed in a previous permit and failed to demonstrate his ability or intent to observe them in the future.

• The movement is adverse to the conduct of an eradication, suppression, control, or regulatory program of APHIS.

• The movement is objected to in writing by an appropriate official of a State, Territory, or possession, or the District of Columbia, on the ground it will involve a danger of dissemination of the plant pest into the State, Territory or possession, or District.

Although the current regulations set out criteria that will factor into APHIS' judgment of risk and may lead us to deny a permit application, certain of the considerations have been understood by regulated entities to be absolute, and may have dissuaded persons from submitting applications for which we would have likely issued a permit. For example, for several years, there was an erroneous but widespread interpretation that the last condition afforded States and territories the right to ''veto'' permit applications. From this perspective, the current criteria may appear too strict.

Conversely, the current regulations do not mention circumstances that may arise during the application process that would call into question that person's ability to comply effectively with permitting conditions, such as an applicant refusing to allow APHIS to inspect a biocontainment facility listed on the application, and would thus make it unlikely that we would issue him or her a permit.

Accordingly, we are proposing to revise the conditions under which the Administrator may deny a permit application. The revised conditions would be the following:

• 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.

This condition is intended to replace the current first condition, which does not appear to allow for environmental release of a plant pest or biological control organism, and the second condition, sometimes referred to as the ''balancing'' condition, which can be construed to suggest that APHIS will issue a permit for a high-risk movement or use of a regulated organism, provided that the benefits potentially derived from that movement or use may be equally great or greater. However, it is APHIS policy to base its decisions regarding permit issuance for the movement or use of plant pests, biological control organisms, and associated articles solely on an assessment of potential risk to plants and plant products associated with that movement or use.

We would retain the following two conditions drawn substantially from the current regulations:

• The actions proposed in the permit application would be adverse to the conduct of an APHIS eradication, suppression, control, or regulatory program.

• 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.

We would add the following conditions:

• The applicant does not agree to observe all of the proposed permit conditions that APHIS has determined are necessary to mitigate identified risks.

• 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.

• 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.

This last condition is intended to clarify the current third condition, which states that a permit application may be denied if the applicant, as a previous permittee, failed to maintain the safeguards or otherwise observe the conditions prescribed in a previous permit and failed to demonstrate his ability or intent to observe them in the future. Certain applicants have sought to interpret this current condition to suggest that actions taken under a previous permit cannot, on their own, serve as a basis for denying a future permit.

This interpretation is incorrect. In deciding to issue a permit, APHIS often relies on the previous actions of an applicant to render a judgment regarding the likelihood that the applicant can comply with the permitting conditions. As a result, this last condition would also provide a list of factors that could lead us to a determination that the applicant cannot comply with the permit conditions:

• 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.

• Issuing the permit would circumvent any order denying or revoking a previous permit issued by APHIS (for example, by issuing a permit to an immediate family member of a person with a lengthy record of non-compliance with previous permits issued.)

• The applicant has previously failed to comply with any APHIS regulation.

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

• 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.

• APHIS has determined that the applicant has made false or fraudulent statements or provided false or fraudulent records to APHIS.

• 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.

Proposed paragraph (d)(5) would discuss withdrawal of a permit application. Any permit application could be withdrawn; however, applicants who wish to withdraw a permit application would have to provide this request in writing to APHIS. APHIS would provide written notification to the applicant as promptly as circumstances allow regarding reception of the request and withdrawal of the application.

Proposed paragraph (d)(6) of § 330.201 would discuss cancellation of a permit. Any permit that has been issued could be canceled at the request of the permittee. If a permittee wishes a permit to be canceled, he or she would have to provide the request in writing to APHIS–PPQ. Whenever a permit is canceled, APHIS would notify the permittee in writing regarding such cancellation.

Paragraph (d)(7) would discuss revocation of a permit. APHIS could revoke a permit for any of the following reasons:

• After issuing the permit, APHIS obtains information that would have

otherwise provided grounds for us to deny the permit application.

- 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.
- 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.[6]

Paragraph (d)(8) would discuss amendment of permits. Amendments could occur at the request of the permittee, or may be initiated by APHIS. 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 would have to contact APHIS to request the amendment and may have to provide supporting information justifying the amendment.

APHIS would review the request, and may amend the permit if only minor changes are necessary. Requests for more substantive changes could require a new permit application.

Prior to issuance of an amended permit, depending on the nature of the amendments, the permittee may have to agree in writing that he or she, and his or her employees, agents, and/or officers, would comply with the amended permit and conditions.

With regard to amendments initiated by APHIS, we could 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. We would also be able to amend a permit at any time to ensure that the permit conditions are consistent with all of the requirements of the regulations; for example, if a subsequent rulemaking prohibits certain categories or types of organisms from being moved in certain means of conveyance, and the permit lacks these specific prohibitions.

As soon as circumstances allow, APHIS would 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 would 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 would be revoked.

Paragraph (d)(9) would discuss suspension of actions authorized under a permit. It would state that we may suspend authorization of actions authorized under a permit if we identify new factors that cause us to reevaluate the risk associated with those actions. In such instances, we would notify the permittee in writing of this suspension and the reasons for it. This notification would also state the actions for which we are suspending authorization. Depending on the results of our evaluation, we would subsequently contact the permittee to remove the suspension, amend the permit, or revoke the permit.

Paragraph (d)(10) would establish procedures in the event that a 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, wishes to appeal the decision.

Biological Control Organisms (§ 330.202)

The PPA defines a biological control organism as ''any enemy, antagonist, or competitor used to control a plant pest or noxious weed.''

The PPA finds that ''biological control is often a desirable, low-risk means of ridding crops and other plants of plant pests, and its use should be facilitated'' by APHIS and other agencies. In accordance with the PPA, APHIS authorizes the movement and environmental release of both biological control organisms through the issuance of permits.

Since the PPA was enacted, we have published several documents in the **Federal Register** that have discussed codifying our permitting processes for biological control organisms. On each occasion, individuals who support the use of biological control have requested that we consider such organisms to be distinct from plant pests, and to regulate them in a manner that facilitates, rather than restricts, their movement and environmental release. Certain of these commenters have stated that APHIS should regulate biological control organisms only when their efficacy in controlling their target plant pest or noxious weed is not adequately established.

We regulate biological control organisms pursuant to the PPA insofar as they may pose a plant pest risk. We consider it necessary to exercise a degree of regulatory oversight regarding the movement or environmental release of such biological control organisms, even when their efficacy is well established.

It is worth noting, in that regard, that biological control organisms are usually moved for eventual environmental release. This is alluded to in the PPA's definition of biological control organism, which specifies that an organism must be used, that is, actively employed to control a plant pest or noxious weed in order for it to be considered a biological control organism. Because biological control organisms are almost always intended for eventual release into the environment, it is not sufficient for us only to consider their use in controlling their target plant pest or noxious weed. We must also take into consideration the plant pest effects that the organism may pose to non-target plants or plant products.

If the organism is known to have non-target plant pest effects, it is consistent with APHIS' mission to prohibit or restrict its release. To the extent that we do not know these likely non-target plant pest effects, it is also prudent for us to place regulatory controls on its movement and release until these impacts and effects are better understood.

Paragraph (a) of proposed § 330.202 would provide, as a general condition for the importation, interstate movement, and environmental release of biological control organisms that are regulated under the proposed regulations, that no such biological control organism may be imported, moved interstate, or released into the environment unless a permit has been issued in accordance with proposed § 330.201 authorizing such importation, interstate movement, or environmental release, and the organism is moved or released in accordance with this permit and the proposed regulations.

Because applications for the movement of biological control organisms often request that we authorize the release of the organism into the environment, several regulations issued pursuant to the National Environmental Policy Act of 1969, as amended (NEPA, 42 U.S.C. 4321 *et seq.*) require certain procedural actions before APHIS may issue a permit: 40 CFR parts 1500–1508, which contains the regulations of the Council

[6] Pursuant to section 424 of the PPA, such failure, whether on the part of the permittee or on that of his or her employees, agents, or officers, may result in the assessment of civil or criminal penalties.

on Environmental Quality for implementing the procedural provisions of NEPA; 7 CFR part 1b, which contains USDA's NEPA implementing regulations; and 7 CFR part 372, which contains APHIS' implementing regulations. In accordance with these regulations under NEPA, before issuing a permit, APHIS must assess whether the actions proposed on the applications, either individually or cumulatively, are likely to have significant impacts on the human environment.

In order to make such an assessment, we often have to request additional information from applicants regarding the proposed release of the organism as part of our evaluation of the permit application. The end of paragraph (a) of § 330.202 would alert interested parties to this fact, and direct them to our portal on the Internet for further information regarding the types of information that may be requested and the manner in which this information will be evaluated.

The requirements in proposed paragraph (a) of § 330.202 would apply to the importation, interstate movement, and environmental release of most biological control organisms. However, we are aware that certain taxa of 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 a taxon of these organisms into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products. For such organisms, we do not consider there to be a sufficient basis in risk to require permits for their interstate movement or environmental release within the continental United States.

To reflect this, paragraph (b) of § 330.202 would state that 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 within the United States. The paragraph would direct persons to APHIS' online portal for permit applications for a list of all such organisms.

Paragraph (b)(1) of § 330.202 would provide that pure cultures of organisms on that list may be imported into or moved interstate within the continental United States without further restriction under the regulations, and paragraph (b)(2) of § 330.202 would provide that pure cultures of organisms on the list may be released into the environment of the continental United States without further restriction under the regulations.

We have made a draft list of such organisms available on *Regulations.gov* as a supporting document for this proposed rule (see **ADDRESSES** at the beginning of this proposed rule) and request public comment on the list. While we will consider comments received on the draft list to be distinct from those received on the proposed rule, the comments received on the draft list will inform our evaluation of the suitability of the exemptions from permitting requirements contained in proposed paragraph (b) of § 330.202.

Proposed paragraph (c) of § 330.202 would establish a petition-based process by which biological control organisms would be added to the list of organisms granted exceptions from permitting requirements for their importation or interstate movement. Any person would be able to request that APHIS add a biological control organism to the list referred to in paragraph (b) of § 330.202 by submitting a petition to APHIS. We would specify that individuals should submit the petition via email to *Pests.permits@aphis.usda.gov,* or through any other means listed on APHIS' Web site at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.*

The petition would have to include the following information:

- 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.
- Results from a field study where data was collected from representative habitats occupied by the biological control organism. Studies would have to 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 would have to be cited.
- Any other data, including published scientific reports, that suggest that that subsequent releases of the organism into the environment of the continental United States would present no additional plant pest risk (direct or indirect) to plants or plant products.

APHIS would review the petition to determine whether it is complete. If the petition is complete, we would 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 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.

If we determine that there is sufficient evidence that 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 (direct or indirect) to plants or plant products, we would publish a notice in the **Federal Register** announcing the availability of the petition and requesting public comment on that document.

If no comments are received on the notice, or if the comments received do not lead us to reconsider our determination, we would publish a subsequent notice in the **Federal Register** describing the comments received and stating that the organism has been added to the list referred to in proposed paragraph (b) of § 330.202.

If the comments received lead us to reconsider our determination, we would publish a subsequent notice in the **Federal Register** describing the comments received and stating our reasons for determining not to add the organism to the list referred to in proposed paragraph (b).

Proposed paragraph (e) of § 330.202 would provide that any biological control organism may be removed from the list referred to in paragraph (b) of the section if information emerges that would have otherwise led us to deny the petition to add the organism to the list. Whenever an organism is removed from the list, APHIS would publish a notice in the **Federal Register** announcing that action and the basis for it.

Soil (§ 330.203)

The regulations governing the importation, interstate movement, and transit of soil and certain stone and quarry products under permit are currently found in ''Subpart—Movement of Soil, Stone, and Quarry

Products,'' §§ 330.300 through 330.302. We are proposing to remove and reserve that subpart and integrate the regulations for soil into the revised ''Subpart—Plant Pests, Biological Control Organisms, Soil, and Associated Articles'' as § 330.203. We are proposing to do so primarily in order to clarify that we regulate soil insofar as it is or may be an associated article. That is, we regulate soil insofar as it may harbor plant pests or noxious weeds: When a permit application for soil is submitted to APHIS, a soil specialist evaluates this likelihood of contamination with plant pests or noxious weeds and determines whether a permit should be issued.

As part of our revision to the soil regulations, we would also update the regulations in light of the current scientific understanding of soil and the spread of soil-borne pathogens within Canada.

Proposed paragraph (a) of § 330.203 would state that 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. It would also provide two conditions under which the movement of soil would not be subject to the permitting requirements of § 330.201: If the movement is regulated pursuant to other APHIS regulations in 7 CFR chapter III (*e.g.,* § 301.86–5 requires certificates for the interstate movement of soil from an area quarantined for pale cyst nematode), or if § 330.203 states that the movement does not require such a permit. This second condition would apply to the importation of most soil from Canada, and most interstate movement of soil.

Proposed paragraphs (b)(1) through (b)(3) of § 330.203 would provide conditions governing the importation of soil. First, in a similar manner to our conditions for the importation of most biological control organisms, we would require an import permit to be issued in accordance with § 330.201 for the importation of soil, and the soil to be imported under the conditions specified on the permit. We are requiring a permit so that we can evaluate the risks associated with any particular importation of soil and assign the appropriate mitigation measures.

Currently, soil may be imported from Canada without a permit, unless the soil is from Newfoundland or the Land District of Central Saanich on Vancouver Island in the Province of British Columbia; these two areas are known to be infested with pale cyst nematodes (PCN). We are proposing to amend the regulations so that soil from any area of Canada regulated by the Canadian Food Inspection Agency (CFIA), the national plant protection organization of Canada, for a soil-borne plant pest would require a permit. We are doing this because there have been recent detections of soil-borne plant pests of quarantine significance in Canada (such as PCN in Quebec and potato wart disease on Prince Edward's Island) that are not reflected in the current regulations.

We would also clarify that the proposed regulations do not pertain to soil used as a growing medium for plants for planting from Canada. Plants for planting that are intended to be imported into the United States and their growing media are regulated under 7 CFR part 319, ''Subpart—Plants for Planting.''

Plants for planting that can be inspected, treated, or handled to prevent them from spreading plant pests are designated in that subpart as restricted articles. Section 319.37–4 requires all restricted articles imported into the United States to be accompanied by a phytosanitary certificate of inspection, unless the section explicitly exempts the articles from this requirement. Paragraph (a)(1) of § 319.37–4 exempts greenhouse-grown plants from Canada imported in accordance with the provisions of a certification program administered by CFIA from this requirement; paragraph (c) of that section contains the provisions of CFIA's program.

Section 319.37–8 addresses the growing media in which a restricted article may be imported. Currently, paragraph (a) of the section prohibits the use of soil as a growing medium for plants for planting from all countries other than Canada. Paragraph (b) allows a restricted article from Canada to be imported in any medium, with the restriction that articles from Newfoundland or a certain portion of the Municipality of Central Saanich in the Province of British Columbia must be accompanied by a phytosanitary certificate containing an additional declaration that the plants were grown in a manner to prevent infestation with potato cyst nematode. We are proposing to revise paragraph (b) of § 319.37–8 so that articles from any area of Canada that is regulated by CFIA for a soil-borne plant pest would have to be accompanied by a phytosanitary certificate with an additional declaration that the plants were grown in a manner to prevent infestation with that soil-borne plant pest.

Proposed paragraphs (b)(2) through (b)(4) of § 330.203 would set forth additional conditions for certain types of importations of soil. Paragraph (b)(2) would provide additional conditions for the importation of soil via hand-carry. In addition to the requirements of proposed paragraph (b)(1), we would allow soil to be hand-carried into the United States only if the importation meets the conditions of § 330.205. That section, which is discussed later in this document, would contain our regulations governing the hand-carry of plant pests, biological control organisms, and soil.

Proposed paragraph (b)(3) would provide additional conditions for the importation of soil intended for the extraction of plant pests. Since this soil is imported precisely because it is known to contain plant pests, with very few exceptions, it is not rerouted for sterilization upon arrival in the United States. Therefore, to mitigate the risk that such soil could present a pathway for the introduction or dissemination of plant pests within the United States, we would require all such soil to be imported directly to an approved biocontainment facility.

On occasion, soil that presents a risk of harboring plant pests is imported into the United States for disposal; for example, this sometimes occurs when a natural disaster strikes an area quarantined for a soil-borne pathogen and emergency management personnel need to dispose of the resulting debris. Proposed paragraph (b)(4) would contain additional conditions for the importation of such soil. In addition to general conditions for the importation of soil, soil infested with plant pests and intended for disposal would have to be imported directly to an APHIS-approved disposal facility. Although all such facilities are subject to evaluation and approval by EPA, we would require independent APHIS approval of the facility because certain of these EPA-approved facilities are municipal landfills that may not provide adequate safeguards against plant pest dissemination.

Currently, § 330.301 restricts the importation into the United States of stone and quarry products from areas in Canada that are infested with gypsy moth. This section has at times led to confusion regarding the relationship between soil and stone and quarry products, as well as questions regarding the regulated status of articles, such as clay, that are similar to but fundamentally distinct from soil.

Proposed paragraph (b)(5) of § 330.203 would list certain articles that are not soil, and that, because of their composition or origin, present a negligible risk of serving as a medium for plant pests or noxious weeds, provided that they are free of organic material. The articles could be imported

into the United States without an import permit, unless the Administrator has issued an order stating that a particular article is an associated article. (Such orders would be maintained on PPQ's Web site, at *http://www.aphis.usda.gov/plant_health/permits/organism/soil/index.shtml*.) However, all such articles would be subject to inspection at the port of first arrival, subsequent reinspection at other locations, and 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 or prohibitions in 7 CFR chapter III. The articles would be:

- Consolidated material derived from any strata or substrata of the earth. Examples include clay (laterites, bentonite, china clay, attapulgite, tierrafino), talc, chalk, slate, iron ore, and gravel.
- Sediment, mud, or rock from saltwater bodies of water.
- Cosmetic mud and other commercial mud products.
- Stones, rocks, and quarry products.

These provisions do not mean that we would no longer restrict the movement of stone and quarry products from areas in Canada that are infested with gypsy moth. Instead, we would amend ''Subpart—Gypsy Moth Host Material from Canada,'' § 319.77–1 through § 319.77–5, to incorporate those restrictions. Section 319.77–2 of that subpart contains a list of articles designated regulated articles; we would amend that section by adding a new paragraph (i) that would designate stone and quarry products as regulated articles. Section 319.77–4 contains conditions for the importation of regulated articles; we would amend the section by adding a new paragraph (d) that would provide that stone and quarry products originating in a Canadian area known to be infested with gypsy moth may be imported into the United States only if they are destined for an infested area of the United States and will not be moved through any noninfested areas of the United States, and may be moved through the United States if they are moved only through infested areas. We consider this subpart a more appropriate location for the restrictions.

Proposed paragraph (c) of § 330.203 would provide general conditions governing the interstate movement of soil. Most soil could be moved interstate without prior issuance of an interstate movement permit in accordance with § 330.201, or further restriction under the regulations. However, all soil moved interstate within the United States would still be subject to any movement restrictions and remedial measures specified for such movement in 7 CFR part 301.

As we mentioned earlier in this document, part 301 contains our regulations that designate certain areas of the United States as quarantined areas for a particular plant pest, and that prohibit or restrict the movement in interstate commerce of certain host articles of that pest. The provisions currently in our regulations in § 330.302 mention certain sections of part 301 in which soil is considered a regulated article, such as our Japanese beetle and gypsy moth regulations, but omit others, such as our golden nematode and PCN regulations, and do not take into consideration the possibility that outbreaks of new plant pests within the United States may lead us to regulate the interstate movement of soil from areas quarantined for those or other pests.

Proposed paragraph (c)(2) would provide conditions for the interstate movement within the continental United States of soil intended for the extraction of plant pests. Again, since such soil is moved precisely because it is known to contain plant pests, it is, by definition, an associated article, and therefore would require an interstate movement permit issued in accordance with § 330.201 in order to be moved. Moreover, because of the intended use of the soil, in order to mitigate the risk of the dissemination of plant pests, the soil would have to be moved directly to an approved biocontainment facility, and in a secure manner that prevents its dissemination into the outside environment.

Proposed paragraph (c)(3) would contain additional conditions for the interstate movement within the continental United States of soil infested with plant pests and intended for disposal. We would require issuance of an interstate movement permit prior to movement, and would require that all such soil to be moved directly to an APHIS-approved disposal facility, and in a secure manner that prevents its dissemination into the outside environment.

Proposed paragraph (c)(4) would contain additional conditions for the interstate movement of soil samples from an area quarantined in accordance with 7 CFR part 301 for chemical or compositional testing or analysis. Such soil could be moved without prior issuance of an interstate movement permit in accordance with § 330.201 or further restriction under 7 CFR chapter III, 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.

Proposed paragraph (c)(5) would contain additional conditions for the 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 could be moved interstate 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. This condition would apply to all soil moved to, from, or between Hawaii, the territories, and the continental United States. In addition to this provision, soil moved to, from, or between Hawaii, the territories, and the continental United States with the intent of extracting plant pests would still be subject to the conditions of proposed paragraph (c)(2) of the section, and would therefore have to be moved directly to an approved biocontainment facility. Similarly, soil infested with plant pests and intended for disposal would be subject to the conditions of proposed paragraph (c)(3) of the section, and would therefore have to be moved directly to an APHIS-approved disposal facility.

Proposed paragraph (d) would contain conditions regarding the transit of soil. Such movement would require a transit permit issued in accordance with 7 CFR part 352.

The regulations in § 330.300 currently exempt movements of soil governed by § 318.60 or § 319.69 from permitting requirements. Section 318.60 currently prohibits the movement of sand (other than clean ocean sand), soil, or earth around the roots of plants from Hawaii, Puerto Rico, or the Virgin Islands into or through any other State, Territory, or District of the United States, unless the movement is in either direction between Puerto Rico and the Virgin Islands, or the soil is intended for experimental or scientific use by USDA. We would amend § 318.60 to clarify that it pertains only to the movement of soil around the roots of plants, and that all other movement of soil from Hawaii, Puerto Rico, or the Virgin Islands, other than that soil around the roots of plants, is regulated under 7 CFR part 330. We consider this amendment necessary primarily so that we would not regulate the movement of such soil in two different subparts, and secondarily so that the section may not be used to circumvent the regulations in part 330.

''Subpart—Packing Materials,'' § 319.69 through § 319.69–5, contains

our regulations regarding plants and plant products used as packing materials for imported commodities. Section 319.69 prohibits the use of soil containing an appreciable mixture of vegetable matter from being used as packing material, except for soil authorized as safe for packing by other rules and regulations in the subpart. Section 319.69–1 specifies that soil containing an appreciable admixture of vegetable matter is covered by this prohibition because its decaying vegetation or plant remains carries a definite pest risk. Finally, § 319.69–5 states that the following soil may be used as packing material: Peat, peat moss, or osmunda fiber.

After reviewing this section in light of the current scientific understanding of soil, as reflected in our proposed revision to the definition of *soil* in § 330.100, we have determined that this section does not refer to soil, as it is currently understood, but to the organic decaying vegetative matter for which soil may serve as a medium, and of which peat, peat moss, and osmunda fiber are all examples. We have also determined that an instance may arise when the mitigation measures that we require in part 319 for the importation of a plant, plant part, or plant product may also address the risk associated with using organic decaying vegetative matter as a packing material for that commodity.

Therefore, we would amend the existing prohibition in § 319.69 on the use of soil as a packing material so that it instead prohibits the use of organic decaying vegetative matter as a packing material. We would remove § 319.69–1(b), which considers matter containing decaying vegetation or plant remains to be soil. We would establish an exemption for any organic decaying vegetative matter expressly authorized to be used as a packing material elsewhere in part 319. Finally, we would revise the heading of § 319.69–5 to make it clear that it does not pertain to the use of soil as a packing material, but organic decaying vegetative matter.

Exceptions to Permitting Requirements for the Importation or Interstate Movement of Certain Plant Pests (§ 330.204)

Section 7711 of the PPA provides that the Secretary of Agriculture may issue regulations to allow the importation and the movement in interstate commerce of plant pests without further restriction, if the Secretary finds that a permit for such movement is not necessary. The section further states that if the Secretary does issue such regulations, any person may petition him or her to add a plant pest or remove a plant pest from this list of pests. Finally, the section provides that if a petition is submitted, the Secretary will act on the petition and notify the petitioner of the action he or she will take on the petition.

Section 330.204 would establish such regulations and petition process. The introductory paragraph would state that, pursuant to section 7711 of the PPA, the Administrator has determined that certain plant pests may be imported into or may move in interstate commerce within the continental United States without restriction. The list of all such plant pests would be on the PPQ Web site.

Paragraph (a) of the section would describe the three categories of plant pests that comprise the list. In order to be included on the list, a plant pest would have to:

- 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
- Be sufficiently attenuated so that it no longer poses a risk to plants or plant products; or
- Be commercially available and raised under the regulatory purview of other Federal agencies.

In our 2001 proposed rule, paragraph (c) of § 330.202 would have established a ''no permit necessary'' list for certain indigenous plant pest species that were already distributed throughout the continental United States and are known to commonly accompany plants or plant products moved in commerce. The first category aligns with the criterion for that 2001 list. We would not require permits for plant pests from a field population or lab culture derived from a field population of a taxon that is established throughout its entire geographical or ecological range within the United States because such pests are ubiquitous within the continental United States.

The second category reflects the fact that *in vitro* attenuation of plant pests such as phytopathogenic fungi, while rare, does occur. When a pest becomes attenuated, there is no longer a sufficient basis for us to presume that the pest presents a risk of directly or indirectly injuring, causing damage to, or causing disease in plants or plant products; in other words, an attenuated pest *de facto* no longer falls within the scope of the definition of *plant pest* under the PPA.

(In order to avoid confusion and the possible unregulated movement of the virulent strains of the plant pest, the list would specify the strains of the plant pest that APHIS considers attenuated of their pathogenicity.)

The third category of plant pests is intended to avoid duplicative or conflicting regulatory oversight of certain plant pests. For example, although it is a plant pest, *Penicillium chrysogenum* is regulated by the Food and Drug Administration (FDA).

We have made a draft list of plant pests that may be imported or move in interstate commerce within the continental United States without restriction available on *Regulations.gov* as a supporting document for this proposed rule, and request public comment regarding that list. The list largely mirrors the list contained in the 2001 proposed rule, but also contains certain plant pests that belong to the second and third categories.

Paragraph (b) of § 330.204 would contain a petition process to add a plant pest to the list. Any person would be able to petition to have an additional plant pest added to the list. To submit a petition, the person would have to provide, in writing, information supporting the placement of a particular pest in one of the categories listed in paragraph (a) of § 330.204.

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

- The biology of the plant pest, including characteristics that allow it to be identified, known hosts, and virulence;
- The geographical or ecological range of the plant pest within the continental United States; and
- The areas of the continental United States within which the plant pest is established.

The first category of information is intended to provide us with basic information regarding the plant pest for which unrestricted movement is sought. The second and third categories would aid our determination regarding whether the plant pest is established throughout its ecological or geographical range within the continental United States.

Information that the plant pest has been attenuated of its pathogenicity would have to include experimental data, published references, or scientific information regarding such attenuation.

Information that the plant pest is commercially available and raised under the regulatory purview of another Federal agency would have to include a citation to the relevant law, regulation,

or order under which the agency exercises such oversight. For example, *Penicillium chrysogenum* is regulated by FDA under the Kefauver-Harris drug amendments of 1962.

APHIS would 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 § 330.204. When it is determined that the information is complete, we would commence review of the petition.

If, after review of the petition, we determine that there is insufficient evidence that the plant pest belongs to one of the three categories listed in paragraph (a) of § 330.204—for example, the plant pest is known to exist throughout its entire geographical range in the continental United States, but population densities in certain areas are not sufficient to consider it established throughout its range—we would deny the petition, and notify the petitioner in writing regarding this denial.

Conversely, if, after review of the petition, we determine that the plant pest belongs to one of the categories in paragraph (a), we would publish a notice in the **Federal Register** that announces the availability of the petition and any supporting documentation to the public, that states that we intend to add the plant pest to the list of plant pests that may be imported into or move 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, we determine that our conclusions regarding the petition have not been affected, we will publish in the **Federal Register** a subsequent notice stating that the plant pest has been added to the list.

Under paragraph (c) of § 330.204, any person could submit, in writing, a petition to have a plant pest removed from the list. The petition would have to contain independently verifiable information demonstrating that our 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.

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

If, after review of the petition, we determine that there is insufficient evidence to suggest that our initial determination should be changed, we would deny the petition, and notify the petitioner in writing regarding this denial.

If, after review of the petition, we determine that there is a sufficient basis to suggest that our initial determination should be changed, we would 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 our conclusions regarding the petition, we would publish in the **Federal Register** a subsequent notice stating that the plant pest has been removed from the list.

Paragraph (d) of § 330.204 would provide for APHIS-initiated changes to the list. It would provide that APHIS may propose to add a plant pest to or remove a pest from the list without a petition, if we determine 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 us to reconsider our initial determination that the plant pest was or was not in one of the categories listed in paragraph (a) of the section. We would publish a notice in the **Federal Register** announcing this proposed addition or removal, making available any supporting documentation that we prepare, and requesting public comment.

If no comments are received on the notice, or if the comments received do not affect our conclusions, we will publish a subsequent notice in the **Federal Register** stating that the plant pest has been added to or removed from the list.

Hand-Carry of Plant Pests, Biological Control Organisms, and Soil (§ 330.205)

Currently, we authorize the importation of plant pests in personal baggage (referred to as ''hand-carry'') under § 330.212 of the regulations. The regulations provide that the person importing the plant pest must show the permit authorizing the importation to an inspector at the port of arrival where the baggage will be inspected, that the conditions specified on the permit must be observed, that an inspector will oversee the movement of the plant pest, that the owner of the plant pest will be responsible for all costs incidental to forwarding the plant pest prior to clearance, and that an inspector may specify and supervise the application of safeguards to prevent the dissemination of the pest until it is forwarded.

The 2003 OIG audit referenced at the beginning of this document pointed out that the hand-carry process in place at the time did not provide guidance regarding what materials may be hand-carried or who may hand-carry, and that APHIS did not track hand-carried materials to ensure that they arrive at the point of destination listed on the permit. For these reasons, the audit strongly suggested that we issue regulations to prohibit hand-carry of regulated organisms into the United States, and to explicitly state that all organisms must be imported into the United States via a bonded commercial carrier.

However, certain plant pests and biological control organisms are highly perishable, and may remain viable only if they are imported into the United States directly and without rerouting. We have also found that it is often useful, from a safeguarding perspective, to authorize hand-carry in order to have an expert regarding the organism or article exercise direct and continuous oversight of its importation.

Therefore, we would include provisions for hand-carry in this proposed rule. These provisions, which would be contained in § 330.205, would reflect current Agency processes regarding hand-carry.

The introductory text of § 330.205 would state that plant pests, biological control organisms, and soil may be hand-carried into the United States only in accordance with the provisions of the section.

Proposed paragraph (a) of § 330.205 would discuss the first such provision, authorization to hand-carry. In order to obtain such authorization, a person would have to 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.

The application would also have to specify the individual or individuals who would hand-carry the plant pest, biological control organism, or soil into the United States. If we authorize this individual or these individuals to hand-carry, this authorization could not be transferred to, nor actions under it performed by, individuals other than those identified on the permit application.

Under proposed paragraph (b) of § 330.205, the permittee would have to notify APHIS through our online portal for permit applications or by fax after the permittee has obtained an import permit but no less than 20 days prior to movement and provide the following information in order to receive a hand-carry authorization:

- A copy of the face page of the passport for the individual or individuals who will hand-carry the plant pest, biological control organism, or soil.
- A description of the means of conveyance in which the individual or individuals will travel, including flight number and airline name for air travel, or vehicle license number or other identifying number for other modes of transportation.
- Expected date and time of first arrival.
- Expected port of first arrival.
- Travel itinerary from port of first arrival to final destination.

We would require authorized identification, the description of the means of conveyance, and the expected date, time, and port of first arrival because, pursuant to the regulations in § 330.105, hand-carried organisms or soil, like all other imported articles, must be presented for inspection at the port of first arrival, and this information would help us ensure that the inspection takes place as expeditiously as possible. We would require the travel itinerary from the port of first arrival to the final destination in order to ensure that the individual does not intend to make prolonged stops en route that could result in breach of safeguarding and increase the risk of accidental dissemination of the organism or soil. The information also would help us respond promptly to accidental dissemination of the organism or soil en route to the final destination.

Under proposed paragraph (c) of § 330.205, the permittee or his or her designee would have to notify APHIS within 24 hours of arrival of the hand-carried plant pest, biological control organism, or soil at the biocontainment facility or other authorized point of destination. This notification would have to state that the plant pest, biological control organism, or soil has arrived at its destination and that the package in which it was hand-carried has remained sealed until arrival. Notification could be by fax or email, or via APHIS' permitting Web site.

Proposed paragraph (d) of § 330.205 would discuss denial, amendment, or cancellation of authorization to hand-carry. It would state that APHIS may deny a request to hand-carry, or amend or cancel any hand-carry authorization at any time, if we deem such action necessary to prevent the introduction or dissemination of plant pests or noxious weeds within the United States.

In a similar manner, proposed paragraph (e) of § 330.205 would state that any person whose request to hand-carry has been denied, or whose hand-carry authorization has been amended or canceled, would be able to appeal the decision in writing to APHIS.

Packaging Requirements (§ 330.206)

We are proposing to revise the packaging requirements for the movement of plant pests, currently found in § 330.210. The revised requirements would be contained in proposed § 330.206.

The introductory text of the section would state that shipments in which plant pests, biological control organisms, and associated articles are imported into, moved interstate, or transited through the United States must meet the general packaging requirements of the section, as well as all specific packaging requirements on the permit itself.

Proposed paragraph (a) would contain general packaging requirements. All shipments would have to consist of an outer shipping container and at least two packages within the container. Both the container and the inner packages would have to be securely sealed to prevent the dissemination of the enclosed plant pests, biological control organisms, or associated articles.

Paragraph (a)(1) would contain general requirements for the outer shipping container. The outer shipping container would have to be rigid, impenetrable, and durable enough to remain sealed and structurally intact in the event of dropping, lateral impact with other objects, and other shocks incidental to handling.

Paragraph (a)(2) would contain requirements for inner packages. The innermost package or packages within the shipping container would have to contain all of the organisms or articles that will be moved. As a safeguard, the innermost package would have to be placed within another, larger package, for example, bagged and sealed petri samples placed within a sealed cooler. All packages within the shipping container would have to be constructed or safeguarded so that they will remain sealed and structurally intact throughout transit. The packages would also have to be able to withstand changes in pressure, temperature, and other climatic conditions incidental to shipment.

Paragraph (b) would contain general requirements for packing material. It would specify that packing material must be free of plant pests, noxious weeds, or associated articles, and must be new, or must have been sterilized or disinfected prior to reuse. Packing material would also have to be suited for the enclosed organism or article, as well as any medium in which the organism or article will be maintained, and should not be capable of harboring or being a means of the dissemination of the organism or article.

We would provide guidance regarding suitable outer shipping containers, inner packages, and packaging on the PPQ Web site.

Paragraph (c) would provide that packing materials, including media and substrates, would have to 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. It would also provide that shipping containers could not be reused, except those that have been sterilized or disinfected prior to reuse.

Proposed paragraph (d) would state that permittees who fail to meet the requirements of the section may be held responsible for all costs incident to inspection, rerouting, repackaging, subsequent movement, and any treatments.

Cost and Charges (§ 330.207)

Proposed § 330.207 would state that the inspection services of APHIS inspectors during regularly assigned hours of duty and at the usual places of duty would be furnished without cost. It would also state that APHIS would 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.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This proposed rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order

13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides an initial regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the *Regulations.gov* Web site (see **ADDRESSES** above for instructions for accessing *Regulations.gov*).

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. However, we do not currently have all of the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

APHIS is proposing to revise its regulations regarding the importation, interstate movement, and environmental release of plant pests to incorporate provisions regarding biological control organisms (BCOs) and the movement of soils from which plant pests and BCOs are extracted. The proposed rule would revise and add definitions, streamline the permitting and compliance processes, and provide APHIS with increased flexibility in the regulation of plant pests. Parts 318, 319, and 352 of 7 CFR chapter III would also be updated to reflect the proposed changes in part 330.

A principal consequence of the proposed rule would be a streamlining of our permitting process and possible reduction in the number of permits issued under part 330, which numbered 6,538 in 2015. Approximately 33 percent of these permits (2,158) authorized the movement or environmental release of a plant pest or BCO that APHIS is proposing to exempt from permitting. While we do not expect the proposed rule would result in one-third fewer permits as one permit may list multiple BCOs or plant pests, we can say with confidence that the permitting burden would be reduced for applicants and that the permitting process could be expedited. We expect that affected entities would benefit from a 10 to 30 percent reduction in the overall time spent applying for and receiving permits under part 330. Assuming the time required to submit an application is 1 hour and assuming an average hourly wage of $45.50 per hour, then for the 6,538 permits issued in 2015, the time savings expected under the proposed rule would have totaled between 654 and 1,961 hours, which equates to a cost savings of between about $29,748 and $89,244.

The proposed rule would codify existing practices by allowing entities requesting permits to apply electronically rather than by using the mail only. Expanded use of online permit applications through APHIS' portal would result in time and cost savings as compared to applying by mail using paper applications.

Listing of exempted organisms on an APHIS–PPQ Web site, transparent procedures for petitioning for exceptions or exemptions to permitting, and provision for a notice-based process for adding and removing listed organisms would also combine to make an efficient, transparent, and user-responsive system that would facilitate the movement and environmental release of plant pests and BCOs.

Regulated entities would continue to incur time costs associated with providing information during the permitting application process, and with meeting somewhat more robust recordkeeping (maintaining records) requirements in certain instances such as with soil imports and risk based permits. The time required overall for permitting would be reduced, however, because of the newly excepted organisms.

The proposed revisions to 7 CFR part 330 would benefit entities, large and small, by increasing the efficiency of the permitting and compliance processes for plant pests, BCOs, and soils from which plant pests and BCOs are extracted, and by improving the general clarity and transparency of these regulations. The proposed rule also would facilitate the Agency's coordination with other Federal and State agencies in regulating the movement and environmental release of plant pests and BCOs. The majority of entities that would benefit from this rule are small entities, based on information obtained from the Economic Census.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the processes established by this proposed rule, we have prepared a draft environmental impact statement (EIS). The EIS was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The draft EIS is available on *Regulations.gov* for review and comment, and may be accessed via the Internet address provided above under the heading **ADDRESSES**. Copies may also be obtained by contacting the individual listed below the section titled **FOR FURTHER INFORMATION CONTACT**.

A notice of availability regarding the draft EIS will also be published by the Environmental Protection Agency in the **Federal Register**.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), some of the reporting, recordkeeping, and third party disclosure requirements included in this proposed rule are in the process of being reinstated under Office of Management and Budget (OMB) control number 0579–0054. The new reporting requirements included in this proposed rule have been submitted as a new information collection for approval to OMB.

Please send comments on the information collection request to OMB's Office of Information and Regulatory Affairs via email to *oira_submission@omb.eop.gov,* Attention: Desk Officer for APHIS. Please state that your comments refer to Docket No. APHIS–2008–0076. Please send a copy of your comments to USDA, using one of the methods described under **ADDRESSES** at the beginning of this document.

Under the PPA, the Secretary of Agriculture has authority to carry out operations or measures to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests. Section 7711(a) of the Act provides that ''no person shall import, enter, export, or move in interstate commerce any plant pest, unless the importation, entry, exportation, or movement is authorized under general or specific permit and in accordance with such regulations as the Secretary may issue to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States.'' The Act gives USDA the flexibility to respond appropriately to a wide range of needs and circumstances to protect American agriculture against plant pests.

In addition, section 412(a) of the Act provides that the Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of, among other things, any biological control organism if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States. The Act defines a biological control organism as ''any enemy, antagonist, or competitor used to control a plant pest or noxious weed.''

APHIS regulations implementing these aspects of the Plant Protection Act are contained (in part) in 7 CFR part 330.

APHIS is proposing to revise: (1) Regulations regarding the movement of plant pests; (2) criteria regarding the movement and environmental release of biological control organisms, and proposing to establish regulations to allow the importation and movement in interstate commerce of certain types of plant pests without restriction by granting exceptions from permitting requirements for those pests; and (3) regulations regarding the movement of soil. This proposal would clarify the factors that would be considered when assessing the risks associated with the movement of certain organisms and facilitate the movement of regulated organisms and articles in a manner that also protects U.S. agriculture.

This proposed rule replaces a previously published proposed rule, which APHIS is withdrawing as part of this document. This proposal would clarify the factors that would be considered when assessing the risks associated with the movement of certain organisms and facilitate the movement of regulated organisms and articles in a manner that also protects U.S. agriculture.

Implementing this rule will require respondents to complete a new petition process to remove permitting requirements for the interstate movement of certain plant pests or biological control organisms.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses).

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 160 hours per response.

Respondents: Importers and distributors of plants and plant products; importers, brokers, distributors, retailers, and exhibitors of biological control organisms and associated articles; and operators of biocontainment facilities.

Estimated Annual Number of Respondents: 6.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Annual Number of Responses: 6.

Estimated Total Annual Burden on Respondents: 960 hours (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

A copy of the information collection may be viewed on the *Regulations.gov* Web site or in our reading room. (A link to *Regulations.gov* and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) Copies can also be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483. APHIS will respond to any information collection request-related comments in the final rule. All comments will also become a matter of public record.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

Lists of Subjects

7 CFR Part 318

Cotton, Cottonseeds, Fruits, Guam, Hawaii, Plant diseases and pests, Puerto Rico, Quarantine, Transportation, Vegetables, Virgin Islands.

7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

7 CFR Part 330

Customs duties and inspection, Imports, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

7 CFR Part 352

Customs duties and inspection, Imports, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we propose to amend 7 CFR parts 318, 319, 330, and 352 as follows:

PART 318—STATE OF HAWAII AND TERRITORIES QUARANTINE NOTICES

■ 1. The authority citation for part 318 continues to read as follows:

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

§ 318.60 [Amended]

■ 2. In § 318.60, paragraph (c) is amended by adding the words '': *And provided finally,* that the prohibitions in this paragraph do not apply to the movement of soil from Hawaii, Puerto Rico, and the Virgin Islands, other than that soil around the roots of plants; movement of soil that is not around the roots of plants is regulated under part 330 of this chapter'' after the words ''paragraphs (c)(1), (2), and (3) of this section''.

PART 319—FOREIGN QUARANTINE NOTICES

■ 3. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

■ 4. In § 319.37–8, paragraph (b)(2) is revised to read as follows:

§ 319.37–8 Growing media.

* * * * *

(b) * * *

(2) A restricted article from an area of Canada regulated by the national plant

protection organization of Canada for a soil-borne plant pest may only be imported in an approved growing medium if the phytosanitary certificate accompanying it contains an additional declaration that the plant was grown in a manner to prevent infestation by that soil-borne plant pest.

* * * * *

■ 5. Section 319.69 is amended as follows:

■ a. By revising paragraph (a)(8); and

■ b. By removing paragraph (b)(4).

The revision to read as follows:

§ 319.69 Notice of quarantine.

(a) * * *

(8) Organic decaying vegetative matter from all countries, unless the matter is expressly authorized to be used as a packing material in this part. Exceptions to the above prohibitions may be authorized in the case of specific materials which has been so prepared, manufactured, or processed that in the judgment of the inspector no pest risk is involved in their entry.

* * * * *

§ 319.69–1 [Amended]

■ 6. Section 319.69–1 is amended by removing paragraph (b), and redesignating paragraph (c) as paragraph (b).

■ 7. Section 319.69–5 is amended by revising the section heading to read as follows:

§ 319.69–5 Types of organic decaying vegetative matter authorized for packing.

* * * * *

■ 8. Section 319.77–2 is amended as follows:

■ a. In paragraph (g), by removing the word ''and'';

■ b. By revising paragraph (h); and

■ c. By adding paragraph (i).

The addition and revision to read as follows:

§ 319.77–2 Regulated articles.

* * * * *

(h) Mobile homes and their associated equipment; and

(i) Stone and quarry products.

■ 9. Section 319.77–4 is amended by adding paragraph (d) to read as follows:

§ 319.77–4 Conditions for the importation of regulated articles.

* * * * *

(d) *Stone and quarry products.* Stone and quarry products originating in a Canadian infested area may be imported into the United States only if they are destined for an infested area of the United States and will not be moved through any noninfested areas of the United States, and may be moved through the United States if they are moved only through infested areas.

* * * * *

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

■ 10. The authority citation for part 330 continues to read as follows:

Authority: 7 U.S.C. 450, 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.

■ 11. The heading of part 330 is revised to read as set forth above.

■ 12. Section 330.100 is revised to read as follows:

§ 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.

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.

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 CBP 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.

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

Responsible individual. The individual who a permittee designates to oversee and control the actions taken 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 must be physically present during normal business hours at or near the location specified on the permit as the ultimate destination of the plant pest, biological control organism, or associated article, and must serve as a primary contact for communication with APHIS. The permittee may designate him or herself as the responsible individual. The responsible individual must be at least 18 years of age. 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.

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

■ 13. Subpart—Movement of Plant Pests, §§ 330.200 through 330.212, is revised to read as follows:

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

Sec.

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

§ 330.200 Scope and general restrictions.

(a) 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 plant pests 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 or exemption in this subpart from permitting requirements; or

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

(b) *Plant pests regulated by this subpart.* For the purposes of this subpart, 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.

(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.* The preceding paragraph notwithstanding, biological control organism-containing products that are currently under an EPA outdoor experimental use permit or that are currently registered with EPA as a microbial pesticide product having outdoor uses 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 the Federal Insecticide Fungicide and Rodenticide Act 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.

§ 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 a designated individual 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 business office in the United States with a designated individual 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.

[1] Persons 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.

(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. 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, biocontainment facilities, and field locations where the organism or 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 allowed under the permit will be highly unlikely to result in the introduction or dissemination of a plant pest, biological control organism, or noxious weed within the United States in a manner that presents an unacceptable risk to plants and plant products. 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 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 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.

§ 330.202 Biological control organisms.

(a) *General conditions for importation, interstate movement, and environmental 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 interstate, or released into the

environment unless a permit has been issued in accordance with § 330.201 authorizing such importation, interstate movement, or environmental 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 1500–1508, 7 CFR part 1b, and 7 CFR part 372 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. A list of these organisms is maintained online, at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.*

(1) *Importation and interstate movement of listed organisms.* Pure cultures of organisms on the list may be imported into or moved interstate within the continental United States without further restriction under this subpart.

(2) *Environmental 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 or interstate movement.* 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@aphis.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.

(2) Results from a field study where data was 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.

(3) 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) 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.

§ 330.203 Soil.

(a) 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 paragraphs (b)(1) or (c)(1) of this section.

(b) *Conditions governing the importation of soil.*

(1) *Permit.* Except as provided in § 319.37–8(b)(2) of this chapter and except for soil imported from areas of Canada other than those areas of Canada regulated by the national plant protection organization of Canada for a soil-borne plant pest, soil may only be imported into the United States if an import permit has been issued for its importation in accordance with § 330.201, and the soil will be 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 a biocontainment facility approved by APHIS.

(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 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 that a particular article is an associated article. All such articles are, however, subject to inspection at the port of first arrival, 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, attapulgite, 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 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 interstate 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 the soil will be moved directly to a biocontainment facility approved by APHIS 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 interstate 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 interstate 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.

§ 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 imported into or may move in interstate commerce within the continental United States without restriction. The list of all such plant pests is listed on the Internet at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.*

(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 established throughout its entire geographical or ecological range within the continental United States; or

(2) Be sufficiently attenuated so that it no longer poses a risk to plants or plant products; or

(3) 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 move 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 has been attenuated of its pathogenicity must include experimental data, published references, or scientific information regarding such attenuation.

(iii) 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 three 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 move 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 move in interstate commerce 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 without a petition, 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 lists 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.

§ 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 notify APHIS through APHIS' online portal for permit applications or by fax and provide the following information in order to receive a hand-carry shipping authorization:

(1) A copy of the face page of the passport for the individual or individuals who will hand-carry the plant pest, biological control organism, or soil;

(2) A description of the means of conveyance in which the individual or individuals will travel, including flight number and airline name for air travel, or vehicle license number or other identifying number for other modes of transportation;

(3) Expected date and time of first arrival;

(4) Expected port of first arrival; and

(5) Travel itinerary from port of first arrival to final destination.

(c) *Notification of arrival at the facility or point of destination.* The permittee or his or her designee must notify APHIS within 24 hours of arrival of the hand-carried plant pest, biological control organism, or soil at the biocontainment facility or other authorized point of destination. This notification must state that the plant pest, biological control organism, or soil has arrived at its destination and that the package in which it was hand-carried has remained sealed until arrival. Notification must be by fax or email, or via the Internet at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.*

(d) *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.

(e) *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 interstate, 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 material must be free of plant pests, noxious weeds, or associated articles, and 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, and should not be capable of harboring or being a means of the dissemination of the organism or article.[2]

(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 not be reused, except those that have been sterilized or disinfected prior to reuse.

(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.

[2] Guidance regarding suitable outer shipping containers, inner packages, and packaging is provided at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.*

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

■ 14. Subpart—Movement of Soil, Stone, and Quarry Products, §§ 330.300 through 330.302, is removed and reserved.

PART 352—PLANT QUARANTINE SAFEGUARD REGULATIONS

■ 15. The authority citation continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

■ 16. In § 352.1, paragraph (b) is amended by adding, in alphabetical order, definitions for *biological control organism* and *noxious weed,* and by revising the definitions for *Deputy Administrator, person, plant pest,* and *soil* to read as follows:

§ 352.1 Definitions.

* * * * *

(b) * * *

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

* * * * *

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.

* * * * *

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.

* * * * *

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

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 above.

* * * * *

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.

* * * * *

§ 352.2 [Amended]

■ 17. In § 352.2, paragraph (a) introductory text, the first sentence is amended by removing the words ''plant pests, noxious weeds, soil,'' and adding the words ''plant pests, biological control organisms, noxious weeds, soil,'' in their place, and by removing the words ''contain plant pests or noxious weeds'' and adding the words ''contain plant pests, biological control organisms, or noxious weeds'' in their place.

§ 352.3 [Amended]

■ 18. In § 352.3, paragraph (a) is amended by adding the words ''biological control organisms,'' after the words ''plant pests,'' each time they occur.

§ 352.5 [Amended]

■ 19. Section 352.5 is amended by adding the words ''biological control organisms,'' after the words ''plant pests,'' each time they occur.

§ 352.6 [Amended]

■ 20. Section 352.6 is amended as follows:

■ a. By removing footnote 2;

■ b. In paragraph (b), by removing the words ''as specified by'' and adding the words ''in accordance with'' in their place; and

■ c. In paragraph (c), by removing the citation ''§ 330.300(b)'' and adding the citation ''§ 330.203'' in its place.

§ 352.9 [Amended]

■ 21. Section 352.9 is amended by adding the words ''biological control organisms,'' after the words ''plant pests,''.

§ 352.10 [Amended]

■ 22. Section 352.10 is amended as follows:

■ a. By redesignating footnote 3 as footnote 2;

■ b. By removing the words ''plant pest or noxious weed dissemination'' each time they occur and adding the words ''plant pest, noxious weed, or biological control organism dissemination'' in their place;

■ c. In paragraph (b)(1), by adding the words ''biological control organisms,'' after the words ''Prohibited or restricted plants, plant products, plant pests,'';

■ d. In paragraph (b)(2)(i), by adding the words ''or biological control organisms,'' after the words ''plant pests'';

■ e. In paragraph (b)(2)(ii), by adding the words ''biological control organisms,'' after the words ''plant pests,''; and
■ f. In paragraph (b)(2)(iv), by removing the words ''plant pest dispersal'' and adding the words ''plant pest or biological control organism dispersal'' in their place.

§ 352.11 [Amended]

■ 23. In § 352.11, paragraph (a)(1) is amended by adding the words ''biological control organisms,'' after the words ''plant pests,''.

§ 352.13 [Amended]

■ 24. Section 352.13 is amended by adding the words ''biological control organisms,'' after the words ''plant pests,''.

§ 352.30 [Amended]

■ 25. Section 352.30 is amended by redesignating footnotes 4 and 5 as footnotes 3 and 4, respectively.

Done in Washington, DC, this 6th day of January 2017.

David Howard,

Acting Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2017–00532 Filed 1–18–17; 8:45 am]

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