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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

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are revising our regulations regarding the movement of plant pests. We are also adding criteria to the regulations for the importation, interstate movement, and release of biological control organisms. This final rule also establishes regulations to allow the interstate movement of certain plant pests and biological control organisms without restriction by granting exceptions from permit requirements for those pests and organisms. Finally, we are revising our regulations regarding the importation and interstate movement of soil. This rule clarifies the points that we will consider when assessing the risks associated with the movement and release of certain organisms and facilitates the movement of regulated organisms and articles in a manner that protects U.S. agriculture.

DATES: Effective [Insert date 45 days after date of publication in the Federal Register].

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; [colin.stewart@usda.gov](mailto:colin.stewart@usda.gov); (301) 851-2237.

## SUPPLEMENTARY INFORMATION:

### Background

Under the Plant Protection Act (7 U.S.C. 7701 *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.<sup>1</sup> 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.

In addition, section 7712(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 B—Movement of Plant Pests” (7 CFR 330.200 through 330.212) and “Subpart C—Movement of Soil, Stone, and Quarry Products” (7 CFR 330.300 through 330.302) is to prevent the dissemination of plant pests into the United

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<sup>1</sup> 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.

States, or interstate, by regulating the importation and movement in interstate commerce of plant pests, soil, stone, and quarry products.

On January 19, 2017, we published in the *Federal Register* (82 FR 6980-7005, Docket No. APHIS-2008-0076) a proposal<sup>2</sup> to revise our regulations regarding the movement of plant pests to include criteria for the importation, movement in interstate commerce, and environmental release of biological control organisms, and 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 also proposed to revise our regulations regarding the importation and interstate movement of soil. We solicited comments concerning our proposal for 60 days ending March 20, 2017.

We extended the deadline for comments until April 19, 2017, in a document published in the *Federal Register* on February 13, 2017 (82 FR 10444, Docket No. APHIS-2008-0076). We received 62 comments by that date. The comments were from State departments of agriculture, nature centers, research laboratories, professional associations, universities, industry groups, manufacturers, law firms, and private citizens. The comments are discussed below by topic.

#### Definitions (§ 330.100)

We received comments regarding our proposed changes to § 330.100, “Definitions,” including requests to include additional terms to the section.

Two commenters asked about the purposes for which continued curation permits are issued.

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<sup>2</sup> To view the proposed rule, supporting documents, the comment extension notice, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0076>.

In proposed § 330.200(a)(3), we included requirements for such permits but did not provide a definition that explains their use. To address these commenters, we are adding a definition for *continued curation permit* to read as set out in the regulatory text below.

We proposed to add the term *import (importation)* to the list of definitions in § 330.100.

A commenter asked if our proposed definition of *import (importation)* means that the organism or article in question arrives in and originates from outside the United States.

The commenter is correct. We define *importation* to mean “to move into, or the act of movement into, the territorial limits of the United States.”

A commenter asked that we add the term “plant health” to § 330.100 and allow industry stakeholders to provide a definition for it.

We are making no changes in response to the commenter’s request. “Plant health” is not used in any specific or technical context in the proposed or current part 330 regulations and we consider the generally understood meaning of the term to be sufficient.

We proposed to add the term *responsible individual* to § 330.100 to mean the individual designated by the permittee to oversee and control the actions taken under a permit. We are requiring the assignment of a responsible individual to serve as the primary point of contact in order to improve communication between the Animal and Plant Health Inspection Service (APHIS) and the permittee. If the permittee is an individual, that individual can assign him or herself to the role should they so choose. We included as a condition that “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.”

Several commenters raised questions about our proposed definition of *responsible individual*. One commenter stated that our proposed definition of *responsible individual* does not allow for a designee to substitute for the responsible individual when that individual cannot be at or near the specified location for the duration of the permit due to illness or vacation. The commenter added that, if taken literally, the definition would likely result in nearly every permitted entity being in violation of permit requirements at some point. Similarly, another commenter stated that designating a responsible individual in a field release application is complicated by the fact that the applicant is often not the same person in charge of a field experiment station. The commenter added that a company may test microbial formulations at dozens of sites, making it impossible for one person to enforce permit compliance and be physically present during business hours at each location. The commenter requested that corporate permittees be allowed to designate more than one responsible individual on a permit.

As the commenters noted, many permit applications for regulated articles do involve multiple field sites under the shared responsibility of several persons. Under current policy, we allow application requests to include more than one responsible individual, and more than one site within a single State may be designated as the permit location. This approach has ensured that permit actions are undertaken safely while accommodating stakeholder needs for flexibility. Our intention in proposing the definition was to emphasize responsible oversight of actions taken under the permit without literally requiring an individual's presence during business hours at all locations specified on the permit. Accordingly, we are removing the requirement that the responsible individual 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. We continue to require that the responsible individual or individuals ensure compliance with permit conditions during all phases of the activities being performed.

We proposed to define *taxon (taxa)* to mean 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.

Two commenters asked for clarification of our proposed definition of *taxon (taxa)*, with one commenter suggesting that *taxon (taxa)* be defined by the biopesticide and biostimulant industries.

We defined *taxon* as any recognized grouping or rank within the biological nomenclature of organisms. This definition is consistent with the term as it is used in the International Plant Protection Convention (IPPC's) Glossary of Phytosanitary Terms.<sup>3</sup> Aligning our definition of *taxon* in this way makes it easier to communicate and trade with other IPPC signatory countries. We disagree with the commenter that industry stakeholders should develop a separate definition of *taxon*, as doing so could result in a less flexible definition and potential conflicts with the internationally recognized IPPC definition.

A commenter asked APHIS to add the term “yield enhancement” to § 330.100 and to define it as “the use of microorganisms whose function when applied to plants or the rhizosphere is to stimulate natural processes to benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and crop quality.”

While some organisms we propose to regulate may stimulate natural processes in plants, we have no plans to define “yield enhancement” as we make no reference in the regulations to the term or the processes listed by the commenter. The ability of organisms or products to

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<sup>3</sup> International Standards for Phytosanitary Measures, ISPM 5, “Glossary of Phytosanitary Terms (2015): [https://www.ippc.int/static/media/files/publication/en/2015/05/ISPM\\_05\\_En\\_2015-05-29\\_CPM-10.pdf](https://www.ippc.int/static/media/files/publication/en/2015/05/ISPM_05_En_2015-05-29_CPM-10.pdf).

enhance plant yields is not a criterion that APHIS uses when determining whether to regulate an organism as a plant pest or a biological control organism.

#### Scope and General Restrictions (§ 330.200)

We proposed revising the subpart “Movement of Plant Pests” to regulate not only plant pests but biological control organisms and associated articles such as soil and packaging material. In proposed § 330.200, we specified the types of plant pests and biological control organisms that APHIS would regulate. We also established restrictions on the importation and movement of biological control organisms and plant pests.

#### General Permit

In § 330.200(a), we proposed to include a general permit as one means by which we may authorize the movement of plant pests, biological control organisms, and associated articles that we regard to be of low risk in certain areas of the United States. We indicated that we have only issued specific permits, that is, permits issued to individual persons, for each movement of plant pests interstate. We noted, however, that section 7711 of the PPA gives APHIS the authority to issue general permits for the importation or interstate movement of plant pests. Such a permit would authorize organizations that frequently move certain low-risk plant pests and organisms interstate to do so without having to obtain an individual permit for each movement. The general permit for the plant pest or organism would be posted on the APHIS website with a list of permit requirements. Persons would not be required to sign a permit or record movements of the plant pest or organism.

Some commenters endorsed the issuance of general permits for the importation and interstate movement of low-risk pests, while others expressed concern about whether a general permit will ensure adequate accountability, enforceability, and risk management. One

commenter asked how a corporation or university would be able to apply the conditions of a general permit to every situation and added that assigning responsibility for a permit at an organizational rather than an individual level will dilute that responsibility.

We acknowledge the concerns raised by commenters regarding general permits and questions about accountability and will therefore continue issuing only specific permits in which one or more responsible individuals are identified in the permit and agree to abide by its requirements. However, for future needs we are retaining in the regulations the language we proposed for issuing general permits and reaffirming our authority under the PPA to issue such permits. We will continue to evaluate the uses and purposes of general permits, and whenever we begin issuing them we will announce in a *Federal Register* notice the existence, location, and content of each such permit we issue.

#### Types of Plant Pests Regulated

In proposed § 330.200(b), we specified the types of plant pests that we would regulate under the revised subpart. For the purposes of the subpart, we stated that we consider an organism to be a plant pest if the organism directly or indirectly injures, damages, or causes disease in a plant or plant product, or if the organism is not known to be a 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.

Several commenters commented on the criteria by which APHIS considers an organism to be a plant pest.

One commenter stated that it would be helpful if the criteria for plant pests could be limited to identifying only pests that cause direct, actual damage to beneficial plants rather than indirect damage. As an example of indirect damage, the commenter cited an organism that has a

negative impact on another organism that in turn has a beneficial impact on a desired crop or plant.

We identify those organisms that indirectly harm or cause disease to plants and plant products as plant pests because the consequences of indirect harm can be as disruptive and costly as direct harm, particularly if such organisms establish themselves in the environment or harm organisms having a beneficial impact on crops, to cite the commenter's example. Moreover, the PPA specifically states that causing "direct or indirect injury to plants or plant products" is one attribute of a plant pest.

Another commenter stated that a plant pest's effect on plants or plant products is either known or unknown and asked for clarification of proposed § 330.200(b).

If an organism poses an unknown risk to plants or plant products but is similar to a plant pest or pathogen known to directly or indirectly injure, cause damage to, or cause disease in a plant or plant product, we will regulate that organism pending positive identification and an evaluation of the organism's actual risk to plants and plant products.

One commenter recommended that, for organisms that are not known to be plant pests, APHIS should notify the applicant of the reason a permit was required and explain how the organism is similar to one that meets the definition of a plant pest, thereby giving the applicant information needed to address the agency's concern for future regulatory actions for the organism.

We do not consider the commenter's suggestion to be practicable for every permit application involving an organism not known to be a plant pest. However, if a permit applicant

has specific questions regarding why a permit is required for a particular organism, we recommend that the applicant contact APHIS.<sup>4</sup>

#### Types of Biological Control Organisms Regulated

In proposed § 330.200(c), we listed the biological control organisms we would regulate under the subpart. We stated that these organisms consist of invertebrate predators, competitors, herbivores, microbial parasites, and microbial pathogens used to control invertebrate plant pests, plant pathogens, and noxious weeds.

A commenter stated that there are approved weed biological control organisms that attack exotic invasive plants not currently listed as “noxious weeds” by a regulatory authority. For this reason, the commenter recommended that in proposed § 330.200(c) we use the term "exotic invasive plants" instead of "noxious weeds" when referring to exotic invasive plants not officially identified as “noxious.”

An exotic invasive plant can be considered a noxious weed and regulated as such without being listed as a Federal noxious weed as long as it meets the PPA’s definition of a noxious weed. Meeting this definition are new incursions of plants that, like listed noxious weeds, can directly or indirectly injure or cause damage to crops, livestock, poultry, other interests of agriculture, or the environment. While federally-recognized noxious weeds are covered under 7 CFR part 360, the use of invertebrate herbivores and microbial pathogens to control such weeds is covered under part 330.

A commenter stated that, for any imported biological control organism, host-specificity testing documentation and identification verification are essential for protecting the resources of the United States.

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<sup>4</sup> For questions about organism and soil permits, please call (301) 851-2357 or (866) 524-5421 (toll free), or e-mail Pest.Permits@usda.gov.

We agree with the commenter. We exercise considerable care to ensure host specificity before approving an organism for release into the environment. As necessary, we conduct host-specificity testing documentation and identification verification as part of evaluating a permit application. Persons with questions about applications and uses of organisms and host-specificity testing can contact the person listed above under the heading FOR FURTHER INFORMATION CONTACT.

#### EPA Oversight

In proposed § 330.200(d), we exempted from this subpart biological control organism products regulated by the Environmental Protection Agency (EPA). This oversight exemption applies only to EPA registered products, experimental use permits, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 18 emergency exemptions, the importation of pesticides being imported under a EPA Pesticide Notice of arrival, as well as the interstate movement of pesticides being moved in accordance with EPA's regulations in 40 CFR 152.30, If EPA does not regulate an organism under APHIS jurisdiction, APHIS would regulate it regardless of whether it is commercial (applied to more than 10 acres) or experimental.

A commenter stated that while the regulatory status of microbial pathogens regulated by EPA is clear, the proposed rule was ambiguous regarding organisms that have been formulated into plant growth-promoting products, also known as biostimulants. The commenter asked what the framework is for regulating plant growth-promoting microbial pathogens and organisms as commercial products excluded from registration under FIFRA.

Although APHIS is not authorized under the PPA to regulate products based on their biostimulant properties, the Act does allow APHIS to regulate and impose restrictions on a product in order to prevent the introduction or dissemination of plant pests within the United

States. APHIS will evaluate each product and its uses to assess their potential plant pest risks and determine whether restrictions are warranted based on plant pest risk. Manufacturers or producers of products that EPA determines not to require registration should not assume that they would not be subject to regulation by APHIS under part 330.

A commenter stated that the proposal to establish criteria for the movement and release of unregistered microbial pesticides needs to be clarified in the regulations, suggesting that the expanded ability to import biological control organisms should also include the following: Research samples containing organisms that were part of a fermentation process destined to become an EPA registered bio-pesticide, material no longer meeting EPA-established specifications (expired lots), partially formulated bio-pesticides, experimental formulations, culture strains, and quality control samples.

We will continue to observe EPA's jurisdiction over organisms subject to their regulations as described in § 330.200(d). Other organisms falling outside EPA's jurisdiction but within the scope of APHIS' authority under the PPA will be subject to the regulations under part 330 as appropriate.

A commenter stated that having EPA-registered microbial pesticides be exempt from current APHIS regulations is a positive benefit, but that there needs to be clear, documented guidance to allow for successful clearances at U.S. border facilities.

We noted in the proposed rule that biological control organisms that are pesticides and not registered with EPA, but that are transferred, sold, or distributed in accordance with EPA's regulations in 40 CFR 152.30, would not be regulated under this subpart for their importation or interstate movement. However, persons desiring to import shipments of biological control organisms that are subject to FIFRA will need to submit to EPA a Notice of Arrival by Pesticides

and Devices as required by U.S. Customs and Border Protection (CBP) regulations. APHIS is working closely with CBP and EPA to ensure that such guidance is available and sufficient for clearances at U.S. border facilities.

One commenter asked if APHIS would issue general permits through the process outlined in a Memorandum of Understanding (MOU) with EPA or provide details of the process through APHIS guidance documents.

APHIS has no plans to continue issuing permits for the importation of EPA-registered materials. These items will be imported under EPA's regulatory oversight.

In addition to the MOU between EPA and APHIS, a commenter asked if there would be ongoing coordination between the agencies for regulating new products.

We intend to continue coordinating with EPA with respect to coordinating regulation of new products not yet registered by EPA. APHIS typically confirms EPA product registrations containing specific strains and maintains its own permitting database to include these strains.

A commenter asked if the APHIS regulatory oversight exemption for EPA-regulated materials applies to registered Technical Grade Active Ingredient, End Product, Active Ingredients, and Experimental Use permit materials, as well as Section 18 requests.<sup>5</sup> The commenter added that according to the guidance available, no APHIS permit would be required for any of these products.

The commenter is incorrect. The exemption applies only to EPA registered products and experimental use permits or pesticides being imported under a EPA Pesticide Notice of Arrival

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<sup>5</sup> Permits issued under section 18 of FIFRA that allow State and Federal agencies to permit the unregistered use of a pesticide in a specific geographic area for a limited time if emergency pest conditions exist.

A commenter stated that in order to prevent “double regulating,” APHIS should enter into an MOU with the U.S. Fish and Wildlife Service (USFWS) as it has done with EPA. The commenter stated that USFWS exempts arthropods from their oversight that are “farm raised” per the definition in 50 CFR 14.4. The commenter added that many commercially produced biological control arthropods have been farm raised for decades and fall under the definition, nevertheless USFWS requires permits at several ports of entry for organisms already regulated by APHIS.

We acknowledge the commenter’s concern to prevent double regulating by APHIS and USFWS and will continue to work with affected entities and the USFWS to identify and address instances of this occurring.

The same commenter recommended that APHIS establish a policy concerning symbionts<sup>6</sup> of pests, noting that while symbionts can promote pest fitness, they can also exist in non-pest contexts, as when a symbiont has multiple hosts. The commenter suggested that we define “symbiont” accordingly, as microbial taxa will inevitably occur on a pest host as environmental contaminants. The commenter stated that if detection on a pest host defines a symbiont organism, all environmental taxa might fit the definition of “symbiont” because of ephemeral encounters by pest hosts moving within their normal environments.

We acknowledge the commenter’s concern but have no plans to provide a definition for “symbiont.” We do not use the term in the regulations, and establishing a regulatory policy for all invertebrate plant pests and biological control organisms under a single definition of the term would by necessity be overly broad. Symbiont relationships may be beneficial or detrimental to the organisms involved in combinations and environmental contexts too varied to document.

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<sup>6</sup> Generally defined as organisms that live in symbiosis with one another.

Moreover, the available information regarding symbionts of any particular organism is typically incomplete, with a knowledge base frequently needing to be updated and revised. For these reasons, APHIS will retain the authority under the regulations to regulate symbionts as necessary on a case-by-case basis.

A few commenters stated that we did not define what we mean by “similar” in proposed § 330.200(b), “Plant pests regulated by this Subpart,” with respect to similarities existing between plant pests having an unknown risk potential and those having a known risk potential. One such commenter suggested that a definition of “similar” be defined through guidance instead of including it in the regulations so that APHIS will have sufficient flexibility to define the term based on evolving science. Another commenter noted that regulating organisms based on similarities to other regulated organisms could result in unintended consequences and suggested that such issues may be mitigated in part by using tools such as molecular evaluation of organisms.

We did not include a definition of “similar” in the proposed regulations as it is an inherently relative term, and as a commenter noted, scientific methods and genetic comparison techniques are evolving rapidly and requiring APHIS to maintain a degree of regulatory flexibility. A broad definition of “similar” that attempts to cover every possible situation would require potentially arbitrary restrictions on the characteristics used to compare organisms. If an initial comparison of an organism reveals similarities with a known plant pest or pathogen, we will undertake a closer evaluation of the pest risk potential for that organism.

#### Permit Requirements (§ 330.201)

Under the proposed section “Permit requirements,” we listed the types of permits that would be required for the importation, movement in interstate commerce, and particular uses of

plant pests, biological control organisms, and associated articles. We also proposed requirements for permit applicants as well as procedures for evaluating and taking action on permit applications.

In proposed § 330.201(a), we listed the types of permits that APHIS would issue for plant pests, biological control organisms, and associated articles. We also listed permit application requirements and conditions under which APHIS would assess applications and issue, deny, suspend, revoke, and amend permits.

One commenter stated that instead of requiring persons to apply separately for permits for different plant pathogens, APHIS should develop a list of conditions under which qualified persons can transport pathogen cultures, infected plant material, and infected soil under a blanket permit for organisms that will not be released or organisms that are native to a State. The commenter added that having to obtain new permits for every sample can be restrictive with respect to sharing isolates.

The commenter appears to be describing the general permit that we included in the proposal under § 330.200(a). In the above discussion of § 330.200, we decided to defer issuing general permits but are retaining the provision for issuing such permits for future needs. However, we acknowledge the commenter's suggestion and note that other options are available. Applicants meeting the requirements in proposed § 330.201 may include more than one type of organism and its intended use in a permit application, especially within a discipline such as plant pathology, but we often ask that arthropods and plant pathogens appear on separate applications. This lessens confusion for permit reviewers, permittees, and State and Federal regulators. APHIS also maintains lists of plant pathogenic fungi, bacteria, and viruses recognized as widely prevalent within various States. Finally, we note that we are establishing a petition-based

process for listing certain biological control organisms and plant pests (in §§ 330.202 and 330.204, respectively) that may be moved interstate within the continental United States without restriction.

A commenter stated that the availability of a comprehensive list of pathogens that APHIS considers to be high-risk plant pests would alleviate the permit application process and reduce follow-up questions. The commenter added that such a list would help to ensure that sufficient evidence is provided to APHIS for scientific review.

We acknowledge the commenter's suggestion for improving the permit application process. However, we do not consider it practical to compile a comprehensive list of high-risk plant pests, as any criteria we might develop to identify such pests is subject to many situational variables that require case-by-case evaluation. We note that in 7 CFR 331.3 we maintain a list of high-risk biological agents and toxins that have the potential to pose a severe threat to plant health or plant products. Persons applying for a permit for what they believe may be a high-risk organism are encouraged to contact APHIS with any questions they have about preparing and submitting an application.

We proposed in § 330.201(a)(1) that when import permits are issued to a corporate entity, that entity will need to maintain an address or business office in the United States with a designated individual for service of process.

A commenter stated that APHIS should consider whether "designated individual for service of process" should use the term in the plural as a way to create more flexibility for the permittee.

"Service of process" is the act of serving notice of legal action against another party. The "designated individual" in proposed § 330.201(a)(1) is a person located in the United States who

receives notice of legal action on behalf of the corporate entity. As a corporate entity can designate more than one individual to act in this role, we will change the wording to read “one or more individuals.”

One commenter noted that many biological products companies conduct research activities in U.S. territories and requested that corporate permits be allowed to cover such activities in those areas.

U.S. territories, as well as the District of Columbia, fall within the definition of *State* under the PPA and part 330, so interstate movement permits for activities regulated under part 330 may be issued for movement from those areas.

#### Curation Permits

In proposed §330.201(a)(3), we set forth provisions regarding continued curation permits, which are issued in conjunction with either an import permit or interstate movement permit prior to the expiration date of the permit.

A commenter asked whether continued curation permits as proposed in § 330.201(a)(3) are also intended to cover research and diagnostic activities.

Continued curation permits are issued prior to the expiration date for an import or interstate movement permit in order for a permittee to continue research or other actions listed on the import or interstate movement permit. Before a continued curation permit can be issued, the required laboratory conditions for safeguarding organisms received or isolated for research under an import or interstate movement permit must be reevaluated.

Two other commenters asked that we clarify the difference between a continued curation permit and the renewal of an existing movement permit authorizing diagnostic or research activities.

Continued curation permits do not allow acquisition of additional organisms for research and other authorized activities and only address retention of existing organisms for authorized uses. Continued curation permits are intended for situations in which the permit applicant wishes to retain live regulated organisms but does not request permission for their continued or additional movement, which would require a separate permit. The renewal of a permit would allow for such movement, although it is not required that movement occur. Thus it is usually more desirable to renew a permit authorizing movement in case organisms need to be restored or additional organisms might need to be received.

#### Application Process and Permit Issuance

In proposed § 330.201(b), we provided that permit applications would have to be submitted by the applicant in writing or electronically via the internet.

A commenter requested that APHIS continue to modernize its information technology systems to enable multistate listings on a single permit application as allowed by APHIS for permits under its biotechnology regulations in 7 CFR part 340.

We acknowledge the commenter's request. APHIS is modernizing its information technology systems and is currently making only critical technical improvements. However, we will consider including this feature in future updates to the permit application page on the Plant Protection and Quarantine (PPQ) website.

Another commenter stated that it would be useful for applicants to track the progress of permit applications.

We note that a tracking feature exists in the current online electronic permitting system.<sup>7</sup>

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<sup>7</sup> To access an existing account or register for a new APHIS ePermits account, visit ePermits at <https://www.aphis.usda.gov/aphis/resources/permits>.

One commenter suggested that it might be helpful to have affected scientific societies and their members involved in designing the APHIS permitting process.

APHIS typically solicits comments and feedback from scientific societies and other stakeholders to continuously improve our permitting process. In addition, APHIS received considerable input from other Federal agencies, State regulatory officials, and industry prior to developing the proposed rule.

In the preamble discussion of proposed § 330.201(c), we noted 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. We intended this number of days to be a suggestion to help ensure that permit decisions are made prior to the applicant's proposed permit activity.

One commenter asked that we define "novel" within the scope of APHIS' legal authority under the PPA as it relates to plant pests, noxious weeds, and biocontrol organisms. The commenter stated that "novel" should be defined solely within the scope of APHIS' legal authority under the PPA and not in a general sense.

We disagree with the commenter that our use of the word "novel" is outside the scope of our authority under the PPA. The commenter is referring to our use of the word "novel" in the proposed rule when referring to permit applications, in which we state that additional time should be allotted for submitting "complex or novel applications, or applications for high-risk plant pests." Such applications typically include new or unusual processes, safeguards, designs, and methods of organism destruction. As APHIS' primary purpose under the PPA is to safeguard the United States against the introduction or infestation of plant pests, noxious weeds,

and biological control organisms, novel applications require additional evaluation to ensure that the intended activities do not harbor a new or unforeseen plant pest risk.

Another commenter stated that the proposed rule does not indicate whether the targeted 90 days for submission of a permit application pertains to permits for imports, interstate movements, field releases, or all of these, and asked for clarification.

The guidance regarding 90 days to allow for sufficient processing was suggested for all permit applications.

Two other commenters asked that we provide timelines for permit-related actions and decisions. One suggested that a consultation timeline of 30 days and a permitting timeline of 60 days is reasonable.

As we indicate on the PPQ Plant Health website,<sup>8</sup> permit applications can be processed in as little as 30 days after they are received, but the specific circumstances of many applications make it difficult to publish accurate timelines for evaluating and making decisions on them. These circumstances can include the need for a facility inspection, the need to obtain additional equipment or equipment certifications, or the need for additional information from the applicant. Persons inquiring about the status of a permit application can contact APHIS.<sup>9</sup>

As part of APHIS' action on permit applications, we noted in proposed § 330.201(d)(1) that we will share a copy of the application and the proposed permit conditions with the appropriate State or Tribal regulatory officials.

A commenter stated that APHIS should ensure that proper procedures are in place whenever sensitive permit application information is shared with States or Tribes. The commenter stated that many States and other entities do not have procedures in place to protect

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<sup>8</sup> The website address is: <https://www.aphis.usda.gov/planthealth/organism-soil-permits>.

<sup>9</sup> See footnote 4 for contact information.

sensitive information to the extent that Federal agencies such as APHIS do, adding that many of them are legally required to provide information in their possession through “Sunshine Acts” and similar public disclosure laws.

We acknowledge the commenter’s concern regarding the protection of sensitive and confidential information. Although APHIS may sometimes request confidential business information as part of the permit application process, as a matter of policy we do not share the sensitive or confidential business information included in applications with States or Tribes.

Another commenter asked if APHIS informs the permit applicant when an application is shared with other persons or groups for analysis, and if so, whether the applicant is informed of who those persons or groups are. The commenter also asked how APHIS handles any objections arising from sharing permit information with third parties.

APHIS typically does not inform permit applicants about details of the evaluation process, of which deliberations with outside experts is sometimes a part. However, if an applicant has questions or concerns about the status of an application and how it is evaluated, he or she can contact APHIS.<sup>10</sup>

We indicated in proposed § 330.201(d)(3)(ii) that permits would be valid for no more than 3 years. One commenter stated that a timeframe of 5 years for a permit to be valid would be more desirable.

We acknowledge the commenter’s view but are making no changes to the proposal. Evolving developments in science, technology, and policy necessitate a re-evaluation of permits every few years. Under a longer timeframe, the original conditions of permitted activity could become obsolete or be subject to new policy or regulatory changes.

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<sup>10</sup> See footnote 4.

One commenter said that the requirements for biocontrol agents as currently administered are burdensome. The commenter noted that the APHIS Level 2 user requirement is a significant hurdle to working with many organizations because they are required to obtain this level before they can apply for permits.

The commenter is referring to the requirement for obtaining a Level 2 user account from APHIS, which allows users to apply for permits electronically through the APHIS ePermits system. The ePermits system currently supports Level 2 users for all permit application types and Level 1 users for selected permit application types. Level 2 access differs from Level 1 in that it requires identity authentication either through correctly answering online identity verification questions or by presenting a Government-issued photo ID at a local U.S. Department of Agriculture (USDA) office.<sup>11</sup> APHIS considers the procedures for obtaining a Level 2 user account to be necessary to maintaining adequate security and we do not believe its requirements to be unduly burdensome.

In proposed § 330.201(d)(3), we indicated that APHIS may issue a permit to an applicant if APHIS concludes that the actions indicated in the permit application are not likely to introduce or disseminate a plant pest, biological control organism, or noxious weed within the United States in a manner that exposes plants and plant products to unacceptable risk.

A commenter stated that a purely risk-based approach on deciding whether to issue permits does not consider benefits to U.S. agriculture. The commenter said that the presence of a “balancing condition” that considers both risks and benefits is most appropriate for agriculture, and that the absence of such biological control alternatives has resulted in the current standard of chemical control with its associated risks. Another commenter similarly expressed support for

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<sup>11</sup> See the website address in footnote 7 for more information about obtaining an ePermits account.

researchers who consider both the risks and the benefits of imported biocontrol agents. The commenter noted that Australia has long been a leader in the regulation of biocontrol agents and has included in its analyses both the risks and benefits of importing biological control organisms.

The primary mission of APHIS is to safeguard American agriculture and the environment by applying and enforcing adequate protections to prevent the introduction and spread of harmful organisms. Although we are aware that both risks and benefits can be inherent in any permitting decision, the PPA provides us with no directive to consider benefits when issuing import or movement permits. While the PPA indicates that APHIS should facilitate the use of biological controls,<sup>12</sup> no part of the Act directs us to consider benefits other than safeguards to reduce risk.

On a practical level, the environmental risk or benefit occurring from release of an organism is circumstantial and difficult to predict. Conducting a risk/benefit analysis requires making assumptions and analyzing hypothetical situations that may or may not occur. Moreover, once a released organism establishes itself in the environment, there may be no way to reverse the action if unexpected risks arise or expected benefits never materialize.

A commenter asked if APHIS evaluates risk differently for different activities when considering issuing a permit for the release of biological control organisms, such as greenhouse releases versus field releases, or for agricultural purposes versus recreational or celebratory events such as weddings. The commenter suggested that APHIS should consider relative risk when making release determinations.

We agree with the commenter. APHIS always evaluates movement or release risk of organisms relative to the individual species and its intended use.

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<sup>12</sup> See PPA, section 7701(2), *Findings*.

A commenter noted that in proposed paragraphs (d)(3) and (4) of § 330.201, we explain the processes for permit application issuance and denial but provide no details of the initial consultation. The commenter referred to an initial consultation process presented by APHIS-PPQ in September 2016 in which potential applicants consulted with APHIS to determine whether an organism required a permit and, if it did, to gain initial feedback on what data would need to be provided in an application. The commenter asked that we include the consultation process in the regulations to provide transparency and consistency for the entire permitting process.

We do not plan to establish a formal consultation process in the regulations, as the consultation process is specific to the circumstances of each application. However, we will continue to use an informal process of initial consultation for complex situations on a case-by-case basis.

Two commenters raised concerns about the Letters of No Jurisdiction (LONJ) that APHIS issues in response to permit applications for organisms or products that do not fall under APHIS regulatory authority. One commenter acknowledged that although LONJs are important for clearing imported samples through customs, the letters sometimes contain extraneous information that can be confusing to CBP agents. The commenter cited as an example a LONJ stating that a sample can only move from a certain country to a certain State even though APHIS has no jurisdiction over the sample. The commenter asked that we not include country, State, and address information in the LONJ and simply state that the organism is not regulated by APHIS and can be imported and moved without restriction. Another commenter similarly asked that APHIS revise the LONJ to state specifically that all actions taken with the organism or product, such as movement and release, are not under APHIS jurisdiction.

We acknowledge the commenters' concerns and will consider revising our LONJ templates accordingly. If APHIS issues a LONJ for an organism or product, it means that APHIS has no jurisdiction over its movement or release. However, we encourage persons to determine whether other Federal or State agencies have jurisdiction over actions relating to the organism or product.

A commenter requested that APHIS develop guidance to help permit applicants provide the appropriate information to show that an organism is not a plant pest. The commenter stated that if the applicant can provide such information, APHIS should issue a LONJ to the previous permit holder.

We are making no changes in response to the comment's request. Guidance regarding the determination of jurisdiction is intended to be specific to the taxonomic identity and biological properties of the organism listed in the permit application and is not retroactive to previous permit holders. APHIS will continue to work with applicants on a case-by-case basis.

A commenter asked that we not issue Letters of No Permit Required with an expiration date, as doing so results in additional administrative activities for APHIS and the applicant to obtain the same letter again following its expiration. The commenter acknowledged that APHIS has the authority to rescind this letter if circumstances change and the activities instead need to be conducted under a permit.

APHIS issues Letters of No Permit Required for organisms and products over which APHIS has legal authority but has determined that movement of the organism or product presents no appreciable risk. However, as a condition of granting an exception from permit requirements, the letter may base the exception narrowly on how the organisms are used, their geographical location, or other circumstances. Although most such letters issued by APHIS do

not include expiration dates, we reserve the right to include them when warranted to maintain the flexibility needed to minimize risks to plants and plant products.

One commenter stated that the proposed permitting requirements for movement or importation of organisms are not consistent with how APHIS administers the permitting process. According to the commenter, the APHIS website states that a PPQ 526 permit typically is not required for the interstate movement or release into the environment of domestically isolated microorganisms that are not plant pests and that are widely distributed in the continental United States. The commenter stated that, despite what the website says, APHIS currently requires permits for microorganisms that are not plant pests that are found and collected in multiple locations in the continental United States.

We regulate microorganisms if they are known plant pests, act as direct biological control organisms, or if their mode of action is unknown. We are therefore obligated to require permits for their interstate movement and importation regardless of how common they are in the environment. We will review our website content and clarify any requirements that may be unclear to readers.

In proposed § 330.201(d)(5), we included provisions for the withdrawal of a permit application. Applicants who wish to withdraw a permit application are required to provide this request in writing to APHIS, which in turn notifies the applicant regarding reception of the request and withdrawal of the application.

A commenter representing a State government wanted to know if withdrawals of applications by permit applicants could be posted on the APHIS ePermit website, or if States could otherwise be notified of the withdrawal. The commenter stated that knowledge of

application withdrawals helps the State maintain a better awareness of pest and biocontrol-related activities of familiar and new applicants.

Permit applications withdrawn by APHIS at the request of the applicant are recorded internally within the ePermit system. APHIS does not plan to modify the system to share additional information with States or stakeholders about applications that are not processed to a permit decision. If we consider a permit withdrawal to materially affect a State's agricultural or environmental welfare, we will share this information with the State accordingly.

#### Biological Control Organisms (§ 330.202)

In proposed § 330.202, we presented criteria for the importation, interstate movement, and release of biological control organisms. We noted that we regulate biological control organisms under authority of the PPA insofar as they have the potential to pose a plant pest or noxious weed risk.

In § 330.202(a), we proposed general conditions for the importation, interstate movement, and release of biological control organisms. We proposed that, except as provided in proposed § 330.202(b), no biological control organism regulated under the subpart may be imported, moved in interstate commerce, or released into the environment unless a permit has been issued in accordance with § 330.201 authorizing such importation, interstate movement, or release.

A commenter asked how APHIS will determine the pest risk to plants and plant products when considering issuing a permit for a biological control organism.

If APHIS determines the requested biological control organism is not established in the continental United States and will be a first-time release into the environment, we will undertake

a more comprehensive evaluation of the permit application. APHIS will conduct a scientific risk review of the proposed release of the particular organism.

#### Biological Control Organisms: Exceptions from Permitting

In the proposed rule, we established a notice-based process<sup>13</sup> by which persons could submit petitions for excepting certain biological control organisms from permitting requirements for importation, interstate movement, or environmental release. As part of this informal adjudication process, we will evaluate each petition we receive to determine whether the biological control organism is of a sufficiently low risk. If we determine there is sufficient evidence that the organism exists throughout its geographical or ecological range in the continental United States and that subsequent releases of the organism into the environment will present no additional plant pest risk, we will announce the availability of the petition in a notice published in the *Federal Register* and solicit public comment.

After we consider the comments we receive, we will announce our final decision on whether to except the organism from permitting requirements in a subsequent notice published in the *Federal Register*. The final notice constitutes final agency action, which is subject to being challenged in court under the Administrative Procedure Act.

We proposed the petition process for permit exceptions because we determined that certain low-risk biological control organisms have become established throughout their geographical or ecological range in the continental United States. The additional release of pure cultures derived from field populations of taxa of these organisms into the environment presents

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<sup>13</sup> We also proposed establishing in § 330.204 a parallel process for excepting certain plant pests from permitting requirements.

no additional plant pest risk (direct or indirect) to plants or plant products. We posted draft lists of these organisms for comment online.<sup>14</sup>

Referring to the list of organisms excepted from permitting requirements, a commenter asked APHIS to provide examples of items that would be in the list.

We posted examples of invertebrate organisms excepted from permit requirements for review and comment in an online list.<sup>15</sup> Products consisting of mixtures of biological control organisms may also be eligible for exceptions from permitting provided that all organisms included in the formulation appear on the list of exceptions.

With respect to a taxon's establishment throughout its geographical or ecological range, a commenter asked what the taxon is and does it have one strain or multiple strains.

As we noted in our proposed definition of the term, a taxon can be 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. A taxon can contain one strain or multiple strains.

A commenter asked if taxon identification will be based on whole genome sequencing.

APHIS will require identification using techniques appropriate for the taxon and the particular circumstances of the permit request.

The same commenter also asked whether a permit will be required to move an organism to a State outside its range if an organism is established throughout its geographic or ecological range within the United States.

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<sup>14</sup> See footnote 2 for the draft lists, which include “Invertebrate Organisms for the Biological Control of Weeds” and “Invertebrate Organisms for the Biological Control of Invertebrate Plant Pests.” These lists will be published and maintained on the PPQ Permits and Certifications website:

<https://www.aphis.usda.gov/aphis/resources/permits>.

<sup>15</sup> See footnote 2.

If an organism is on the list of biological control organisms excepted from permit requirements, that organism will not require a permit for interstate movement within the continental United States. Inclusion on the list indicates sufficient evidence that the species on the list cannot persist outside of its recorded range and that the species has already had ample opportunity to do so naturally.

The commenter also asked if APHIS will provide public access to the information that we use to determine a taxon's geographical or ecological distribution.

APHIS will provide access to the information referenced by the commenter. If a person petitions for a species to be added to the list of biological control organisms excepted from permit requirements, they do so with the understanding that we will make publicly available any information submitted by the petitioner with respect to determining the distribution of that species.

A commenter representing a State expressed concern that allowing certain biological control organisms to be moved interstate within the continental United States without further restriction does not take into account the organism's status in individual States and that any such list would need to be subject to review by individual States where agents will be used.

As we noted in proposed § 330.201(d)(1), APHIS will share a copy of the petition with the appropriate State or Tribal regulatory officials. APHIS does not approve the use or distribution of biological control organisms within the continental United States without first considering the organism's status in individual States. We also note that § 330.202(e) indicates that any organism may be removed from the list of organisms excepted from permitting requirements if information emerges that would have otherwise led APHIS to deny the petition to add an organism to the list.

In paragraph (b)(1) of § 330.202, we proposed that pure cultures of organisms excepted from permitting requirements may be imported into or moved interstate within the continental United States without further restriction under subpart B of part 330.

Citing pest risk concerns, several commenters recommended that all imported biological control organisms be excluded from the draft list of organisms excepted from permitting and that such imported organisms not be eligible for the proposed permit exception process. One commenter stated that biological control organisms could be imported from unverified sources and result in the inadvertent introduction of exotic parasitoids. The commenter added that the risk is high for weed biocontrol agents and plant pests because herbivores from a different geographic source than the originally introduced population often have different host ranges or are discovered to be a different species. Another stated that the proposed rule does not account for different or new foreign sources that would be added to the list of pests and organisms excepted from permit requirements, which may present varying levels of risk in terms of the reliability of sources to ensure correct identification, safe release practices, and freedom from contamination by harmful species.

While we have confidence in our proposed petition-based process for excepting organisms from permit requirements that pose a low risk to plants or plant products, we acknowledge that the importation of organisms from new sources and geographic locations could be a potential source of new unapproved exotic species or parasites and diseases of those species. An imported plant pest poses a potentially higher risk level than the same domestic species moved interstate because the former may be carrying unknown diseases or microbial pathogens from the foreign source. Therefore, we will continue at present to require permits for the importation of biological control organisms and plant pests in order to continue the appropriate

safeguards with respect to foreign sources. As we envision that stakeholders may wish in the future to import low risk species such as *Drosophila melanogaster*, we will retain the petition process for excepting biological control organisms and plant pests from permitting requirements in §§ 330.202 and 330.204, respectively. If we receive petitions for importing certain organisms or pests without a permit, we will review and consider making the petitions available for public comment. Any organisms and pests that APHIS lists as being able to be moved interstate without a permit will not be eligible to be imported without a permit unless APHIS expressly indicates otherwise.

One commenter objected to any regulation of the interstate movement of beneficial insects and mites because they are not plant pests. The commenter stated that the proposed regulatory changes would place beneficial insects and mites under the same movement restrictions applied to plant pests unless they are included in the list “Organisms for the Biological Control of Invertebrate Plant Pests.” The commenter stated that this list should be used to determine whether organisms can cross international boundaries unhindered but that no interstate movement of beneficial insects and mites should be regulated. The commenter also suggested that entire taxa containing no plant pests should be included in the proposed list of excepted organisms, as parasites and predators of plant pests except weed biocontrol agents should be “innocent until proven guilty.” The commenter cited as an example of such taxa the predatory mite family *Phytoseiidae*, which according to the commenter contains no species known to cause harm to plants.

We are making no changes with respect to our proposal to regulate beneficial invertebrates as biological control organisms. In response to previous documents published in the *Federal Register* in which we discussed codifying requirements for biological control

organisms, some commenters stated that APHIS should regulate biological control organisms only when their efficacy at controlling a target plant pest or noxious weed is in question. However, the risk exists that nonspecific and indiscriminant invertebrate parasites and predators intended for beneficial purposes can also attack non-target invertebrates that are themselves beneficial as pollinators or biocontrol organisms. The draft list we posted for public review and comment contains only those organisms for which there exists an established record of observed information and that meet the criteria for exception from permitting set forth in the regulations. We took this approach to the list to minimize the potential direct or indirect plant risk that adding entire taxa could pose absent an evaluation of the risk potential of these taxa. As authorized under the PPA, APHIS is required to evaluate the plant pest effects that organisms may pose to non-target plants and plant targets and regulate them until we are certain that such organisms can be safely released into the environment without further restriction.

#### Pure Culture

A number of commenters asked us to define "pure culture." One commenter noted that many products containing biological control organisms are typically formulated with carrier or host material, such as insects as a food source for entomophagous mites, and asked if such formulations can be considered as pure cultures. Another commenter stated that the requirements for pure cultures need to be clearly defined to ensure they consist of only specified biological control organisms free of predators, parasites, and pathogens, and contain no host material such as exotic invasive plant propagules. Another commenter expressed concern about how identification or purity of organisms could be assured prior to release into the environment, particularly as the term "pure culture" does not appear to be defined in law or policy.

We acknowledge that defining the term “pure culture” will provide stakeholders with a clearer understanding of requirements under the regulations and what constitutes a “clean” package of organisms excepted from permitting requirements, especially for field collected sources for weed biocontrol. Accordingly, we will define the term *pure culture* as a single species of invertebrate originating only from an identified/described population and free of disease and parasites, cryptic species, soil and other biological material, except host material and substrate as APHIS deems appropriate. Examples of “identified/described population” are those originating from a specific laboratory colony or field collection from a specified geographic area, such as an entire country, or States or provinces of a country.

For the excepted biological control organisms listed on the PPQ Permits and Certifications website (referenced in § 330.202(b)), we will also include the sources for each species excepted from permit. For example, species of commercial entomophagous biological control organisms will require verification that they are from domestic laboratory colonies. Likewise, weed biological control organisms will need to be field collected from within the continental United States or derived from domestic colonies from those field sources.

Another commenter asked how “pure culture” will be defined if organisms are harvested from the established geographical or ecological range in the continental United States.

As we noted above, a pure culture consists of a single species of invertebrate originating only from an identified/described population and free of disease and parasites, cryptic species, soil and other biological material except host material and substrate. The source of the organism may originate from the species’ established geographical or ecological range within the continental United States.

Another commenter asked whether the term "pure culture" also includes "pure populations" in reference to invertebrates.

We cannot answer the commenter's question as we do not know what is meant by "pure populations" and how it differs from "pure culture."

A commenter stated that "pure culture" can mean a single species derived from a population in a defined geographical area, but added that the biological control industry also considers the term to mean the absence of contamination in commercial inbound shipments and compliance with "truth in labeling" laws that require a package's label to be identical to its content. The commenter stated that packages are randomly checked by USDA inspectors for permitted organisms and that clarification is needed on how to resolve purity issues in organisms excepted from permitting requirements.

As we noted above, we will continue at present to require permits for the importation of biological control organisms and plant pests but will retain the petition process we proposed for excepting biological control organisms and plant pests from permitting in §§ 330.202 and 330.204, respectively. If we receive petitions to allow the importation of certain organisms or pests without a permit, we will review them and submit them for public comment.

A commenter asked what additional documentation or certificates may be required to move organisms and products defined as pure cultures, and what provisions will be implemented to ensure clarity with inspectors when importing listed organisms.

Documents and certificates required to move organisms and products are typically listed on the permit. APHIS provides guidance to CBP so that inspectors are clear about importation requirements for biological control organisms and products.

A commenter recommended that to ensure all redistribution efforts for weed classical biological control organisms, APHIS should consider the Code of Best Practices for Classical Biological Control of Weeds.<sup>16</sup>

APHIS is familiar with the document cited by the commenter and agrees in principle with its best practices.

One commenter expressed concern that if all bacteria belonging to the same genus as a plant pathogen are regulated, students isolating antibiotic-producing *Streptomyces* bacteria in an introductory-level microbiology lab exercise could inadvertently fall under APHIS purview. The commenter stated that this could occur because students would not typically move beyond morphologically classifying their isolates as *Streptomyces* and this genus contains plant pathogens such as *Streptomyces scabies*.

If persons have questions about lab or other specific activities that may fall under APHIS' regulation of plant pathogens, they are encouraged to contact APHIS for clarification.<sup>17</sup>

The commenter also stated that it would be helpful to have access to a comprehensive list of microbial pathogens of concern to APHIS so that stakeholders can identify and deal with problematic taxa appropriately.

APHIS has regulatory authority over all plant pests and biological control organisms moved in interstate commerce and imported into the United States. While we do not keep such a comprehensive list, an extensive table of U.S. regulated plant pests is available on the APHIS-PPQ website.<sup>18</sup>

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<sup>16</sup> *Proceedings of the X International Symposium on Biological Control of Weeds* 435 4-14 July 1999, Montana State University, Bozeman, Montana, USA; Neal R. Spencer [ed.]. p. 435 (2000). ([http://bugwoodcloud.org/ibiocontrol/proceedings/pdf/10\\_435.pdf](http://bugwoodcloud.org/ibiocontrol/proceedings/pdf/10_435.pdf).)

<sup>17</sup> See footnote 4 for contact information.

<sup>18</sup> <https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/rppl/rppl-table>.

Proposed § 330.202(c) lists the steps by which APHIS accepts and evaluates petitions for adding biological control organisms to the lists of those organisms granted exceptions from permit requirements for their importation or interstate movement. We noted that we drafted two lists of biological control organisms (one list for control of invertebrate plant pests, one for control of weeds) for which we would grant exceptions from the permit requirements, and made the lists available for comment.<sup>19</sup> Persons could request that an organism be added to a list by submitting a petition to APHIS. A notice of the petition would be published in the *Federal Register* for public comment. We stated in proposed § 330.202(c) that such petitions must provide evidence that the organism is indigenous to the continental United States throughout its range, or self-replicating for a period of time sufficient to consider the organism to be established in its range in the continental United States. The petition would also have to provide results from a field study during which data was collected from representative habitats occupied by the organism and provide any data indicating that subsequent releases of the organism into the continental United States will present no additional plant pest risk.

A commenter stated that, because the proposed rule addresses the process for requesting that biological control organisms be added to the lists of organisms excepted from permit requirements, APHIS needs to make the current list readily available. Another commenter stated that a clear description of how to access the lists is needed, and two other commenters stated that a mechanism for updating the lists also needs to be added to the regulations.

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<sup>19</sup> See footnote 2.

We made draft lists of biological control organisms excepted from permitting available for review at the website address listed in footnote 2.<sup>20</sup> We noted in the proposed rule that while we will consider comments received on the draft lists to be distinct from those received on the proposed rule, the comments received on the draft lists will inform our evaluation of the suitability of the exceptions from permitting requirements contained in proposed § 330.202(b). Once the rule is finalized and a list of excepted organisms is established on the APHIS website, persons can submit petitions according to the provisions included in § 330.202(c).

One commenter supported a process for excepting certain biological control organisms from permit requirements, but expressed concern that publishing petition notices in the *Federal Register* and soliciting public comment may make the process sufficiently onerous as to effectively limit its use. Instead, the commenter suggested that we establish a Technical Advisory Group (TAG) to expedite the listing process for excepted biological control organisms.

APHIS is committed to ensuring transparency and public participation with respect to reviewing petitions for permit exceptions. For this reason, we intend to publish notices of petitions we receive in the *Federal Register* and request public comment on them. We may also use our Stakeholder Registry as another means of notifying the public of proposed actions and requesting comment. Although we maintain an active TAG, we disagree with the commenter and do not consider it to be as efficient or as transparent as the petition comment process. Under § 330.201(d)(1), APHIS will have the option of consulting with technical experts on petitions as the need arises.

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<sup>20</sup> Invertebrate Organisms for the Biological Control of Weeds; Invertebrate Organisms for the Biological Control of Invertebrate Plant Pests; and Native and Naturalized Plant Pests Permitted by Regulation (Individual Permits not Required) for Their Interstate Movement within the United States.

The same commenter opposed a blanket permit for interstate movement of select organisms that appears to include field-to-field collections and releases without screening such organisms for unwanted contaminants, but acknowledged that field-to-field movement can include beneficial predators such as coccinellids (lady beetles). The commenter stated that a blanket permit system may result in intentional or unintentional mislabeling of shipments leading to accidental introduction of a potentially serious pest.

The commenter seems to be referring to the general permit we discuss above, which authorizes organizations that frequently move certain low-risk plant pests and organisms interstate to do so without having to obtain a separate permit for each movement. As we noted, we have decided to defer issuing general permits until a later time. We also note that APHIS does not approve the interstate movement and release of any biological control organism without consideration of the organism's status in individual States, and to that end solicits State review. Moreover, the issue of contaminants is mitigated in two ways. The majority of biocontrol releases are at present coordinated by government-related programs or personnel, who have training and experience in moving clean shipments. Likewise, commercial entities are economically motivated to provide clean, quality shipments. State and local plant regulatory personnel also have the opportunity and authority to observe, report, and enforce regulations regarding the movement and release of non-exempt, contaminant organisms in any shipment.

One commenter stated that movement permits need to be specific to each State, noting that transporting biological control organisms that are effective in California may have consequences if the same agents are used in another State. The commenter cited the potential danger of walnut twig bark beetles on the West Coast spreading Thousand Cankers disease to the Eastern United States. The commenter added that while allowing permits for the transport of

biological control organisms may help problems such as this one, it should be the decision of States to allow movement of certain agents across their borders.

The species listed by APHIS for exception from permitting requirements are species that exist throughout their full ecological range in the United States and therefore, from a State-by-State view, are either already present in a given State or have been shown to be unable to live in that State as a self-reproducing population. All other petitions for biological control organisms would be subject to APHIS permits for interstate movement and made available for review and input from Tribal and State representatives as provided for in proposed § 330.201(d)(1).

One commenter observed that the regulatory status of entomopathogenic nematodes is not addressed specifically in the proposed rule.

Entomopathogenic nematodes meet the definition of *biological control organism* we proposed in § 330.100 and therefore we regulate them accordingly. However, we have included seven such species on the draft list of biological control organisms proposed to be excepted from permit, which we posted for public comment.

One commenter stated that in classical biological control, individual populations of a species have been identified as possible importation sources into the United States, but even these need to be quarantined for screening for contaminants. The commenter stated that the list of excepted organisms maintained online should be reviewed in light of the International Code of Best Practices for Biological Control.

We note above that in this final rule we are not at present allowing importation of biological control organisms without a permit but will consider the commenter's suggestion should we begin to do so.

One commenter noted that the need for export certification on biological control organisms is not addressed, and suggested that APHIS should issue permits certifying the condition of organisms and associated articles that are destined for export from the United States. Another commenter stated that the need for export certification on biological control organisms has been addressed in the North American Plant Protection Organization (NAPPO) Regional Standards for Phytosanitary Measures (RSPM) 26 and that the approved RSPM has been waiting for the current proposed rule for appropriate action.

APHIS acknowledges that the proposed regulations do not include provisions for certifying the export of regulated biological control organisms. The IPPC has, however, published a set of guidelines<sup>21</sup> that addresses the export of biological control organisms, and the NAPPO standard<sup>22</sup> addresses foreign export certification requirements for biological control organisms being moved from the United States to Canada or Mexico. As a signatory and participating member of these organizations, APHIS observes internationally agreed upon standards for the export of biological control organisms and products.

Another commenter stated that a generic permit or other indication of status is needed for organisms listed as being excepted from permit requirements and recommended that we explain how the list relates to the biological control species approved in RSPM 26 Appendix II.<sup>23</sup>

The proposed list of biocontrol organisms to be excepted from PPQ permit requirements includes all the species on the list of biological control organisms approved in RSPM 26, Appendix II.

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<sup>21</sup> ISPM 3, “Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms,” published 2016.

<sup>22</sup> RSPM-26 “Certification of commercial arthropod biological control agents moving into NAPPO member countries,” published 2015.

<sup>23</sup> See footnote 22.

One commenter stated that RSPM 12, “Guidelines for Petition for First Release of Non-indigenous Entomophagous Biological Control Agents,”<sup>24</sup> should be added to the rule with respect to the petitioning process for excepted organisms. The commenter added that the RSPM already outlines many of the proposed requirements.

We considered RSPM 12 guidelines when developing the proposed rule. However, RSPM 12 is a tri-national agreement, is intended only as a guideline, and is periodically revised. For these reasons, it would not be practical or necessary to add RSPM 12 guidelines to the regulations.

One commenter proposed that a tiered, science-based approach be adopted to determine permit requirements for microorganisms isolated within the continental United States. The commenter suggested using the following three categories: “No permit required,” if the microbe is identified by its complete genome sequence and contains no proven plant pathogenic sequences; “fast track,” if the microbe is a member of a taxon not known to be a crop pathogen; and “all other microorganisms.” The commenter added that guidelines to the identity of these sequences should be developed by the biopesticide industry and the research community.

We are making no changes in response to the commenter’s proposal. Our approach to determining the permit status and requirements for microorganisms is done on a case-by-case basis. Our requirements for a “no permit required” determination include origin and distribution information and intended use that we evaluate for each application. Due to the evolving science, we do not identify specific microbial identification techniques but we do use the best and most appropriate methodology available to identify organisms.

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<sup>24</sup> [https://www.nappo.org/files/1814/4065/2949/RSPM12\\_30-07-2015-e.pdf](https://www.nappo.org/files/1814/4065/2949/RSPM12_30-07-2015-e.pdf).

A commenter stated that plant growth and plant health enhancing consortia and biostimulants should be treated the same as biological products making pesticidal claims, since the potential safety hazards are the same for all these groups of novel microorganisms.

Under the PPA, APHIS has no authority to regulate products on the basis of their plant health or growth enhancing attributes, but only on the basis of pest risk potential.

One commenter suggested that a specific organism used to manufacture an EPA-registered biopesticide should not require a plant pest permit to move interstate as a pure culture or as part of a formulation. The commenter added that if a beneficial organism can be applied to crops as a registered biopesticide, a small-scale release from an experimental formulation in a field trial should not pose a risk to U.S. agriculture.

Typically, APHIS does not require a permit for the interstate movement of a product that is regulated by EPA. However, other isolates or non-registered uses may require a permit.

Two commenters addressed the topic of States regulating the movement of plant pests and biological control organisms. One commenter opposed allowing States to establish regulations for interstate movement of organisms that are more restrictive than those established by the Federal Government, while another stated that States have the option of independently establishing more restrictive regulations.

Under the PPA, a State may not regulate the movement in interstate commerce of any biological control organism, plant pest, or noxious weed if the Secretary has issued a regulation or order to prevent its dissemination within the United States. There are two exceptions listed in the Act: A State may impose movement restrictions as long as they are consistent with and do not exceed the regulations or orders issued by the Secretary, and a State may impose movement restrictions that are in addition to Federal restrictions as long as the State demonstrates a clear

need to do so based on science and pest risk. As we noted in the proposed rule, 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), and we encourage applicants to consult with these authorities when applying for a permit.

One commenter stated that if the proposed regulations supersede permits that were specifically issued for national defense projects, means of conveyance, and organisms that are not subject to APHIS regulation (i.e., courtesy permits), then this information needs to be conveyed to regulatory personnel so that packages containing organisms can be transported without inspection delays during the period of transition to the new regulations.

The proposed regulations do not supersede or nullify the status of current, valid permits.

A few commenters questioned whether notice of the petition and public comment are necessary for excepting certain organisms from permit requirements, with one commenter adding that APHIS could simply respond to the petition by conducting the risk assessment and notifying the petitioner of the decision, and that organisms either added or removed from the list could be noted on the website.

APHIS embraces a transparent process and is committed to public involvement during the petition process.

In § 330.202, paragraph (c)(1) states that petitioners proposing additions to the lists of organisms excepted from permitting requirements must provide evidence indicating that the organism is indigenous to the continental United States.

A commenter requested that APHIS provide guidance and examples that would demonstrate that an organism is indigenous.

Guidance and examples for permit applicants are posted on the APHIS Regulated Organism and Soil Permits website.<sup>25</sup> Applicants may also contact APHIS using the information in footnote 4.

A commenter asked if the development of a new biocontrol product involving previously unreleased organisms requires completion of a PPQ 526 Form (Application for Permit to Move Live Plant Pests or Noxious Weeds) and an assessment of potential environmental effects.

Any new biological control organism or product that has not been released into the environment requires completion of a PPQ 526 permit application form and an environmental assessment.

#### Soil (§ 330.203)

As we noted in the proposed rule, we are integrating the soil regulations into the revised “Subpart B—Plant Pests, Biological Control Organisms, Soil, and Associated Articles.” We moved the regulation of soil into the revised subpart B in order to highlight the fact that soil, as an associated article, may harbor plant pests and noxious weeds that can be spread within the United States through importation or interstate movement. In proposed § 330.203(a), we established that, as an associated article, the importation or interstate movement of soil is subject to the permitting requirements in § 330.201 unless otherwise indicated in the regulations.

#### Soil and Associated Articles from Canada

We proposed to amend the regulations in § 330.203(b)(1) 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 noted that this change is in response to recent detections of soil-borne plant pests of quarantine significance in

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<sup>25</sup> <https://www.aphis.usda.gov/planthealth/organism-soil-permits>.

new areas of Canada. Previously, permits were required for soil imports from a few small areas of Canada. These areas, and areas with new detections of soil-borne plant pests, are now regulated by the CFIA, and the risk of inadvertently introducing plant pests into the United States is higher in soil imported from these areas.

Two commenters disagreed with this proposed change. One of these commenters asked us to identify the specific quarantined areas in Canada from which importation of soil into the United States is not allowed and requested that we define what information is required with shipments of soil from Canada. The commenter stated that doing so would provide a consistent process for applicants to demonstrate to inspection officials at ports of entry that the soil is not from an area regulated by the CFIA for soil-borne plant pests. Similarly, another commenter asked us to indicate the procedure for proving to U.S. inspectors that imported soil is not from a quarantined area in Canada. The commenter stated that there is nothing specified in the proposal on how to prove the soil from Canada is not from a quarantined area.

Persons wishing to import soil into the United States from any area of Canada not regulated by the CFIA for soil-borne plant pests are responsible for verifying to inspectors that the soil is from such a non-regulated area. CBP inspectors at U.S. ports of entry typically require documentation provided by the CFIA to verify soil origin. Inspectors can corroborate this documentation with other shipment documentation, such as a bill of lading, to verify the origin of each shipment. One option for persons for whom providing such documentation is not practicable is to apply for a permit to move such soil. APHIS will evaluate the request and, if no permit is necessary, issue a Letter of No Permit Required on the basis that the soil originates from an area not regulated by CFIA for a soil-borne plant pest.

In paragraphs (b)(2) through (4) of § 330.203, we proposed additional conditions for the importation of soil into the United States.

A commenter asked if each of the purposes listed in those paragraphs requires an import permit along with the other conditions described.

An import permit with specific conditions is required for importation of soil via hand-carry, importation of soil intended for the extraction of plant pests, and importation of soil contaminated with plant pests and intended for disposal.

Section 330.203(b)(3) provides additional conditions for the importation of soil intended for the extraction of plant pests. To mitigate the risk of introducing plant pests through the movement of such soil, we will require the soil to be imported directly to an approved biocontainment facility.

One commenter agreed with the conditions proposed in § 330.203(b)(3) but wanted to know if the biocontainment facility will be at the permittee's destination or at a central inspection center prior to transport to the permittee's final destination. The commenter asked that we specify in the regulations that the facility must be an APHIS-approved biocontainment facility.

We would require such soil to be imported directly to the permittee's APHIS-approved biocontainment facility. Maintaining a biocontainment facility and having APHIS approve it for the extraction of plant pests are prerequisites for this type of permit.

In § 330.203(b)(5), we proposed to establish import permit exemptions for a list of articles, including rocks, silt, clay, and other quarry products, that are not soil. If the article being imported is free of organic material, it will not require an import permit unless the Administrator has issued an order stating that a particular article is an associated article.

A commenter asked us to clarify how § 330.203(b)(5) would apply to the following materials: Products of non-soil stone or quarry products combined with plant nutritive or soil conditioning materials such as composts and manures; bone meal, feather meal, or blood meal; fish, shellfish, or kelp materials; peat, coconut coir, humates, spores or live mycorrhizae, as often used with potting mixes; animal and insect repellent compounds like biological oils or neem oils, or geranium extracts; animal derived or extract materials such as insect pheromones; synthetic chemicals such as pesticides or fertilizers, and recovered nutrients from sewage. The commenter added that many beneficial plant growth products that include these materials are being developed and marketed, and that preventing their interstate movement could significantly inhibit the benefits they provide to agriculture.

To the extent that any of the articles listed by the commenter contain organic material and are thus associated articles having the potential to contain pests or plants and plant parts that pose a risk to American agriculture and the environment, a permit would be required to import such products or to move them interstate. Permit applicants with questions about specific articles can contact APHIS using the information in footnote 4.

The commenter also asked about interstate movement of plant growth enhancers in relation to the permit exemptions in § 330.203(b)(5), which addresses the import of certain articles but makes no reference to interstate movement.

APHIS considers permit requests for importation or interstate movement of the materials listed on a case-by-case basis. To facilitate our evaluation and permit decision process, we typically ask prospective permittees wishing to import or move plant growth enhancers to answer questions located on the APHIS plant growth enhancer website.<sup>26</sup> We note that some animal

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<sup>26</sup> <https://www.aphis.usda.gov/planthealth/organism-soil-permits>.

material, including bone, blood, and feathers, are regulated under the jurisdiction of APHIS Veterinary Services or other Federal agencies.

The same commenter asked whether zeolite minerals, lignitic and humate minerals, various cation-exchange capacity-enhancing clay minerals, phosphate rock, limestone, dolomite, and green sands would be exempt and considered non-soils under this proposed rule.

Articles eligible for exemption in proposed § 330.203(b)(5) must be free of all organic materials and considered to be non-soil. The examples of exempted materials listed in paragraphs (b)(5)(i) through (iv) are not intended to be exhaustive. If the materials cited by the commenter are free of organic material and thus considered to be non-soil, such material will be exempted from permitting requirements.

The commenter also asked if sterilization, heat treating, or other methods of killing possible pathogens or organisms applied to the products cited would allow for them to be exempt from regulation for interstate movement.

If we determine that any of the materials indicated contain soil, then restrictions for the interstate movement of soil will apply. Even if the customer claims that sterilization, heat treatment, or other methods of killing possible pathogens or organisms has been performed on the material and its intended use is for release into the environment, APHIS must first evaluate the material to determine a regulatory action.

Finally, the commenter asked whether meeting the USDA organic standards for composts, minimum heating times, and temperature regimes allow for interstate movement without special permitting or regulation under the proposed regulations.

The National Organic Program is administered by the USDA Agricultural Marketing Service and develops national standards for organically produced agricultural products. Those standards do not address plant pest risks.

As we noted above, we proposed placing revised regulations for the importation and interstate movement of soil under new “Subpart B—Movement of Plant Pests, Biological Control Organisms, and Associated Articles,” and removing and reserving current “Subpart C—Movement of Soil, Stone, and Quarry Products.” As part of this change, we removed current § 330.301, which contains restrictions for the movement of stone and quarry products from areas in Canada infested with gypsy moth. We explained in the proposed rule that we would retain these conditions but move them to 7 CFR 319.77-4 of “Subpart R—Gypsy Moth Host Material from Canada,” as we consider that subpart to be a more appropriate location for regulating gypsy moth.

One commenter stated that open gravel pits and other disturbed areas can harbor noxious weeds due to ground disturbances. The commenter expressed concern that importation of stone and quarry products from Canada without proper decontamination for noxious weeds may increase the genetic diversity of the weed population in the United States.

Under the soil regulations in § 330.203(b)(5), we proposed to exempt from regulation the importation and interstate movement of stones, rocks, and other quarry products that are free of organic material. If a shipment of gravel or other stone is found to contain organic material, it will be considered to be an associated article and be subject to the regulations under § 330.203.

Another commenter asked us to revise proposed § 330.203(b)(5)(ii), which includes a permit exemption for sediment, mud, rock, and similar articles from saltwater bodies of water, to include an exemption for similar articles taken from freshwater bodies of water.

We already consider peat, cosmetic mud, and other mud products from freshwater estuaries or the earth's upper surface, if processed to a uniform consistency and free of plant parts and seeds, to be exempt from our regulations. Rocks and other non-soil articles are already exempt under § 330.203(b)(5). However, plant pests can thrive in freshwater bodies of water and therefore articles containing organic material from freshwater bodies of water must be evaluated by APHIS to determine their regulatory status.

In proposed § 330.203(c), we established regulations governing the interstate movement of soil, which includes general conditions for moving soil interstate within the United States and conditions for moving soil interstate for specific purposes. Except for soil moved in accordance with § 330.203(c)(2) through (5), soil may be moved interstate within the United States without a permit or a compliance agreement. We require, however, that all soil moved interstate is subject to any restrictions and remedial measures specified for such movement in our domestic quarantine regulations referenced in 7 CFR part 301.

We proposed in § 330.203(c)(2) that soil may be moved in interstate commerce within the continental United States with the intent of extracting plant pests only if an interstate movement permit has been issued in accordance with § 330.201 and the soil will be moved directly to a biocontainment facility approved by APHIS.

A commenter asked if proposed § 330.203(c)(2) would provide additional conditions for the importation of soil intended for the extraction of plant pests. To mitigate the risk that such soil could present a pathway for the introduction or dissemination of plant pests within the United States, the commenter stated that APHIS would need to require all such soil to be imported directly to an approved biocontainment facility.

As indicated in § 330.203(b)(3), importation of soil into the United States intended for the extraction of plant pests requires a permit and the soil must be moved directly to a biocontainment facility approved by APHIS. The shipment is subject to all conditions for movement specified on the permit, including safeguarding requirements.

Proposed § 330.203(c)(4) allows for the movement of soil samples from an area quarantined in accordance with part 301 without prior issuance of an interstate movement permit, provided that the soil is moved to a laboratory that has entered into and is operating under a compliance agreement with APHIS and is approved by APHIS to conduct chemical/physical tests and analyses of such samples.

One commenter asked if no permit is required for movement of soil under § 330.203(c)(4) will there be another document required to accompany the soil. The commenter also wanted to know if a permit application needs to be submitted for such movement.

Proposed § 330.203(c)(4) requires that the laboratory to which the sample is destined to be moved enter into a compliance agreement with APHIS. The movement can be made without prior issuance of an interstate movement permit.

One commenter stated that the regulations for interstate movement of restricted soil between approved laboratories should be expanded to include foreign soil samples that are otherwise subject to the same handling and disposal requirements. The commenter noted that currently it is necessary to get USDA approval on a case-by-case basis to move foreign samples between laboratories.

Imports of soil, unless otherwise exempted in the regulations, must be accompanied by an import permit and sent directly to an APHIS-approved biocontainment facility. If we authorize additional movements of imported soil, the movements must also be to an APHIS-approved

biocontainment facility with the same safeguarding and containment capacity as the original facility and must be moved under a permit as well. As we consider imported soil to present a higher risk to U.S. agriculture and the environment, we consider it necessary to track and approve all foreign soil movements and disposition on a case-by-case basis as part of our standard permit conditions.

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

In accordance with the PPA, we proposed in § 330.204 to establish regulations allowing the importation and movement in interstate commerce of plant pests without further restriction if we determine that no permit is required. Specifically, we proposed a notice-based petition process by which the public could petition to have pests either added to or removed from the list of plant pests excepted from permitting requirements for importation or interstate movement. As part of this informal adjudication process, we will evaluate the petition to determine whether the plant pest is of a sufficiently low risk. If, after review of the petition, we determine that the plant pest belongs to one of the categories in § 330.204(a) that make it eligible for listing, we will publish a notice in the *Federal Register* announcing the availability of the petition and our intention to add it to the list of plant pests that may be imported into or moved interstate within the continental United States without restriction. We will also solicit public comment on the notice and petition. If after we consider the comments 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 listed and excepted from permitting requirements. This subsequent notice constitutes final agency action, which is subject to being challenged in court under the Administrative Procedure Act.

Several commenters expressed concern that importation of plant pests excepted from permitting could result in new diseases and damage to beneficial plants and plant products within the United States, particularly plant pests imported from new sources and locations.

These comments raise concerns similar to those we received for § 330.202(b), in which we proposed allowing the exception from permitting for the importation and interstate movement of certain biological control organisms. We acknowledge that the importation of plant pests from new sources and locations could carry a risk for introducing new, unapproved plant pest species or parasites and diseases of those species. An imported plant pest poses a potentially higher risk level than the same domestic species of that pest moved interstate because the former may be carrying unknown diseases or microbial pathogens from the foreign source. Therefore, we will continue at present to require permits for the importation of plant pests. However, we will retain the petition process for excepting plant pests from permit requirements in § 330.204. If APHIS receives a petition for allowing the importation of low risk plant pests without a permit, we will review it. Based on our review, we will either deny the petition or submit it for public comment. Plant pests that APHIS lists as being able to be moved interstate without a permit will not be eligible to be imported without a permit unless APHIS expressly indicates otherwise.

#### Categories of Plant Pests Eligible for Exception from Permit Requirements

In § 330.204(a), we proposed three categories of plant pests that would be eligible for exception from permitting requirements: Pests from field populations or lab cultures derived from field populations of a taxon established throughout its entire geographical or ecological range within the continental United States; pests that are sufficiently attenuated so that they no

longer pose a risk to plants or plant products; and pests that are commercially available and raised under the regulatory purview of other Federal agencies.

We are making a change to § 330.204 with respect to excepting from permit requirements certain plant pests imported or moved interstate. In § 330.204(a)(2), we proposed excepting from permit requirements the category of plant pests that are sufficiently attenuated so that they no longer pose a risk to plants or plant products. We noted in the proposed rule that when a pest becomes attenuated, it loses its defining pest or biocontrol properties. For this reason, there is no longer a sufficient basis to presume that the pest presents a risk of injuring, damaging, 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. Accordingly, we will remove this category from the proposed regulations. In the case of an attenuated pest, we will issue a LONJ to a petitioner rather than a Letter of No Permit Required as the organism is no longer considered to be a plant pest and therefore is not under APHIS' jurisdiction.

A commenter stated that APHIS' guidance about permitting is inconsistent with how we administer the permitting process. The commenter noted that the APHIS website says a permit is typically not required for the interstate movement or release into the environment of domestically isolated microorganisms that are not plant pests and are widely prevalent in the continental United States. The commenter noted that, despite what the guidance says, APHIS currently requires permits for microorganisms that are not plant pests that are found and collected throughout the continental United States.

To address this inconsistency, the commenter requested that we define several terms, including "common," "prevalent," and "widespread," so that persons can determine whether they need a permit for activities involving plant pests and biological control organisms.

We are making no changes in response to the commenter's request as we do not believe that defining these terms is necessary to determining whether a permit is needed for interstate movement or release of a given organism. Persons with questions about whether an activity requires a permit under the regulations are encouraged to contact APHIS.<sup>27</sup>

A commenter representing the State of California noted that the State is opposed to and does not participate in the Widely Prevalent List program. The commenter noted that California is a large State with many microclimates that could support new invasive pests, that potential pathways for invasive species are numerous, and that the introduction of unwanted parasites and pathogens that can accompany such species would increase with a web-based permit system.

APHIS carefully evaluates the pest risk potential of organisms before considering them to be widely prevalent and will not allow any organisms posing a pest risk to be candidates for an exception to the permit requirements.

The same commenter stated his opposition to having the *Federal Register* be the only forum for contributing input regarding the list of plant pests excepted from permit requirements.

In addition to accepting public comments on notices, petitions, and proposed rules published in the *Federal Register*, we typically conduct stakeholder outreach and invite stakeholders to contact APHIS if they have questions or concerns.

A commenter asked whether the application process would exclude those species already on the approved species list for no permit.

The commenter is correct. Species on the list have been determined by APHIS to not require a permit.

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<sup>27</sup> See footnote 4 for contact information.

A commenter recommended that APHIS clarify that the exempted activities include release into the environment because the definition of *move* includes that action.

We agree with the commenter. Movement without restriction implies all uses, including release.

A commenter asked whether documentation supporting a petition to add or remove organisms from the list of those excepted from permitting requirements will also be made available for comment when the petition is published in the *Federal Register*.

When APHIS issues a notice of petition in the *Federal Register*, we will also make available for comment any documentation available that supports the petition.

A commenter asked whether the omission of “environmental release” from the heading of § 330.204(a) is intentional or accidental.

We did not consider it necessary to include the term “environmental release” in the heading “Exceptions to permitting requirements for the importation or interstate movement of certain plant pests” because the definition of *move* (*moved and movement*) we proposed in § 330.100 specifically includes releases into the environment.

The commenter also asked if the term "without restriction" in § 330.204(a) means that no permit of any kind is needed, and whether States are notified in such cases.

States will be notified of APHIS’ decision to not require permits for the importation or interstate movement of a given plant pest or organism. States, however, have the authority to require permits for the movement of these organisms into their boundaries. For example, while no Federal permit is required for the interstate movement of the Madagascar hissing cockroach, the State of Florida requires a permit to move the cockroaches to Florida from another State.

One commenter noted that APHIS maintains a list of plant pests in § 340.2 and stated that, because the authority for APHIS-PPQ and APHIS-Biotechnology Regulatory Services (BRS) to regulate plant pests comes from the PPA, PPQ and BRS should work together to ensure that the list in § 340.2 and the proposed list referenced in § 330.204 are consistent.

The list cited by the commenter in § 340.2(a) lists groups of organisms which are or contain plant pests for the purpose of determining what genetically produced or altered plant pests and products are regulated under the regulations in part 340. The list proposed for § 330.204 will include plant pests that may be moved interstate without a permit under the plant pest regulations in part 330. APHIS-PPQ and APHIS-BRS collaborate regularly to ensure that there are no inconsistencies between their respective lists.

Referring to native and naturalized plant pests, a commenter asked APHIS to clarify the meaning of "permitted by regulation."

The commenter is referring to the proposed list we made available for review, titled "USDA-APHIS-PPQ Native and Naturalized Plant Pests Permitted by Regulation (Individual Permits Not Required) For Their Interstate Movement within the United States."<sup>28</sup> This refers to the organisms proposed to be excepted from permit requirements under these regulations.

One commenter wanted to know the source of the proposed list we provided for review and what its intended use would be.

Draft lists were developed by APHIS and reviewed by the National Plant Board as well as by professional societies and Tribes. Many of the individual species are of a lower risk and commonly requested in applications processed by APHIS.

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<sup>28</sup> See footnote 2 for the location of the draft list.

The same commenter, citing the categories in paragraphs (a)(2) and (3) of § 330.200, asked which of these categories applies to the list of native and naturalized plant pests permitted by regulation.

Section 330.200(a)(3) refers to organisms under APHIS jurisdiction explicitly granted an exception from permitting requirements in this subpart. The term “permit by regulation” used by the commenter was not used in the proposed rule. However, we have used the term in the past in some APHIS documents and communications regarding these proposed regulations to denote the organisms that would be excepted from permitting requirements.

A commenter stated that APHIS should exempt dried herbarium specimens from permitting because they are dried by heating and then frozen. The commenter stated that no disease, pest, or invasive species has escaped from a herbarium specimen.

This rulemaking only covers articles that fall under the plant pest regulations, which includes herbarium specimens of parasitic plants not classified as Federal noxious weeds and specimens collected as plant disease samples. APHIS currently requires pest permits for the movement of these plants because of the potential for the presence of viable seeds in the case of parasitic plants, or of persistent resting stages (e.g., sclerotia, chlamydo spores) in the case of plant pathogens. As there is some risk associated with the importation and interstate movement of dried herbarium specimens, we acknowledge that the risk to U.S. agriculture and the environment from these specimens is low as long as risk protocols are observed.

A commenter noted that that tobacco mosaic virus (TMV) is on the proposed list of plant pests excepted from permitting requirements and suggested that tomato mosaic virus (ToMV) be added as well. The commenter stated that while differentiated by serological reaction and the amino acid sequences of the coat protein, these two Tobamoviruses are nearly identical in their

control by the tomato and pepper resistance genes, mechanical and seed transmission, and host range.

We disagree with the commenter. Although we acknowledge that TMV and ToMV are similar in morphology and serologically closely related, the sequence information of the genome is distinct enough to differentiate these viruses at a molecular level as different viral species according to the International Committee of Taxonomy of Viruses.<sup>29</sup>

Another commenter stated that the list of plant pests excepted from permitting requirements should contain all plant pests that are widely prevalent and thus present little additional plant pest risk due to movement.

Under the amended regulations, persons will be able to petition APHIS to add such plant pests to the list of plant pests excepted from permitting requirements.

The commenter also recommended that *Pantoea stewartii* (Stewart's wilt) be removed from the list of plant pests excepted from permitting requirements for interstate movement, as it has not been observed in the field for 8 years and testing for this pest costs the seed industry millions of dollars to allow import of seed to other countries.

We agree with the commenter and will remove this species from the list.

We are also changing the name *Agrobacterium tumefaciens* (crown gall) to *Rhizobium radiobacter* on the list of plant pests excepted from permitting requirements for interstate movement. We did this in order to update the name of the organism.

Finally, during Tribal consultation, a Tribe raised concerns about specific biological control organisms included on the draft list of organisms excepted from permitting requirements for interstate movement. Their concern was that the control organisms, which target species of

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<sup>29</sup> See [https://talk.ictvonline.org/ictv-reports/ictv\\_online\\_report/positive-sense-rna-viruses/w/virgaviridae/672/genus-tobamovirus](https://talk.ictvonline.org/ictv-reports/ictv_online_report/positive-sense-rna-viruses/w/virgaviridae/672/genus-tobamovirus).

St. John's wort, could be released without a permit on Tribal lands. As a result, we decided to continue to require permits for biological control organisms that target these species.

### Invertebrate Plant Pests

We received several comments requesting that certain animals be excepted from the permit requirements as plant pests.

#### Arthropods

Several commenters requested exceptions from permitting requirements for the importation and interstate movement of insects that cannot establish themselves in parts of the continental United States due to seasonal climate differences.

One commenter requested that we except certain ants from regulation as they are already established throughout the United States. The commenter added that several ant species cannot survive outside of heated buildings and are only found living with humans. Similarly, another commenter asked that we allow tropical species to move into the continental United States for use as pets because they cannot become established due to the cold seasonal climate in most of the country and are not threats to agriculture as many do not eat living plants. A few commenters asked that we relax restrictions on species that have been wiped out of an area or tropical species that cannot survive in our climate and that therefore pose no biological threat. Another commenter stated that foreign rhinoceros and stag beetles should be allowed to be imported without a permit because they cannot survive severe winters, acknowledging that warm States such as Florida should require continued monitoring. Another commenter asked that APHIS review, if not eliminate, restrictions upon certain beetle species that are common in zoos and the pet trade. As examples, the commenter cited *Dynastes*, *Megasoma*, and *Goliathus* species.

We do not intend to relax restrictions on the importation and interstate movement of arthropods with respect to seasonal climate differences. The biological threat of arthropod plant pests can be unseen, as unknown diseases and parasitoids may be transported significant distances through the movement and distribution of live specimens. We can, however, consider permit exceptions for arthropod stock that has been isolated and evaluated for disease and parasites. We note that this rulemaking establishes a petition process for persons wishing to add organisms to the list of plant pests that are excepted from permit requirements.

A commenter stated that the U.S. cricket pet food industry has been devastated by epizootic *Acheta domesticus* densovirus outbreaks, and that efforts to find an alternative, virus-resistant field cricket species have led to the widespread U.S. distribution of a previously unnamed *Gryllus* species despite Federal regulations to prevent such movement. The commenter expressed concern that this taxon is likely to become widely distributed throughout the United States and become an established agricultural pest, and claimed that the USDA has taken no action to prevent the movement and sales of *Gryllus*. The commenter asked that all cultures of *G. assimilis* and *G. locorojo* be eliminated from retail outlets in the United States.

We are evaluating our policies for the regulation of crickets and other arthropods used both as feeder insects and fish bait. We intend to address issues relating to the species noted by the commenter through policy statements and the permitting process rather than through rulemaking.

A commenter requested that APHIS use its authority under the PPA to regulate the interstate movement of bumble bee adults, nests, and used nest materials. The commenter also asked APHIS to promulgate rules prohibiting movement of bumble bee adults, nests, and used nest

materials outside of their native ranges and to allow such articles to be moved within their ranges only if the permit applicant shows that all such articles are certified to be free of disease.

APHIS has initiated a scientific review and is collecting data regarding the interstate movement of certain species of bumble bee adults, nests, and related articles outside of their native ranges. If we develop such regulations on the movement of bumble bees and related materials, we will promulgate those regulations in 7 CFR part 322, “Bees, Beekeeping Byproducts, and Beekeeping Equipment.”

A commenter stated that the permit process is onerous for acquiring zebra swallowtail butterflies and other native species that do not harm crops, and suggested that there are many species that are regulated for no good reason.

Zebra swallowtail butterflies are regulated for several reasons. The caterpillars feed on plants (in the genus *Asimina*) which makes them plant pests, placing them under the authority of the PPA. Butterflies are also important pollinators. Distributing zebra swallowtail butterflies significant distances could result in the dissemination of diseases or parasitoids to other lepidopteran species

A commenter stated that it should not be so difficult to obtain a permit to import dead insects because they cause no harm to the environment. The commenter added that just because *Ornithoptera alexandrae* is in need of protection does not mean that all members of the genus *Ornithoptera*, including dead specimens, should require permits for importation.

APHIS does not require import permits for dead insects unless they carry live plant pests or diseases in or on them. As indicated in part 322, we do have separate requirements for the importation of dead bees in the superfamily *Apoidea*. Dead insects and those overseen by the

Convention on International Trade in Endangered Species, in particular, are regulated by the USFWS.

Two commenters stated that some species of particular importance to the research community should be included on the proposed list of plant pests excepted from permitting requirements that we provided for review. The species cited by the commenters are: Corn earworm, *Helicoverpa zea*; tobacco budworm, *Heliothis virescens*; European corn borer, *Ostrinia nubilalis*, and codling moth, *Cydia pomonella*. Two commenters supported the inclusion of *Helicoverpa zea*, *Heliothis virescens*, *Ostrinia nubilalis*, and *Cydia pomonella* to the proposed list of insect species excepted from permit requirements.

APHIS will consider adding these species to the proposed list of organisms for which no permit is required if we receive the supporting information required as part of the petition process. Many more insect species were initially considered for the list and have been removed at the request of the National Association of State Departments of Agriculture and other groups.

Snails

We also received a number of comments requesting that we exempt certain snails from regulation as plant pests.

One commenter stated that the Federal government overregulates the snail industry. The commenter acknowledged that certain States may need to regulate and monitor movement of *Helix aspersa* movement but disagreed that Federal regulation of the species is necessary. The commenter noted that the need to regulate *H. aspersa* in Minnesota or New York is not as great as it is in Florida, which has already banned the species.

We are making no changes in response to the commenter. The brown garden snail, *Cornu aspersum* (formerly *H. aspersa*, *Cantareus aspersus*, and *Cryptomphalus aspersus*) is a

serious plant pest causing significant damage in areas where it has escaped cultivation. It feeds on a wide range of plant hosts and can be readily transported in contaminated nursery stock. More than 13 States have imposed quarantines against the brown garden snail and several States have spent considerable time and resources to eradicate infestations. We consider it necessary to continue regulating this snail species to prevent new introductions and limit its further spread.

Another commenter stated that certain snail species should be allowed to be transported, raised, and processed for food because they are not a threat to people or the environment. The commenter asked APHIS to create rules allowing easier transport of captive gastropods for pets and to remove the ban on giant African land snails, while another commenter asked that non-plant pest snail species (detritophages and epiphytic growth feeders) be exempted from regulation.

Snail species that are not plant pests are not regulated by APHIS under the regulations in part 330. We will consider adding species to our list of plant pests excepted from permitting if we receive the supporting information required as part of the petition process. However, APHIS will continue to regulate species of snails that are plant pests and cause significant damage in areas where they have escaped cultivation.

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

In proposed § 330.205, we included provisions that allow for plant pests, biological control organisms, and soil to be hand-carried into the United States under permit.

A few commenters specifically voiced support for the continued issuance of permits for hand-carrying plant pests, organisms, and soil into the United States. One commenter disagreed with the 2003 Office of the Inspector General audit referenced in the proposed rule recommending that hand-carry of samples be prohibited and noted that APHIS currently

authorizes the importation of plant pests in personal baggage under § 330.212 of the regulations. The commenter agreed with APHIS that individual hand-carry is important from a safeguarding perspective, as this option allows a responsible individual to exercise direct and continuous oversight of an article's importation.

APHIS recognizes the importance of hand-carry and will continue to authorize hand-carry events.

In § 330.205(b), we proposed that hand-carry permittees be required to provide APHIS with a copy of the first page of the passport and other identifying information. In paragraph (c) of § 330.205, we requested that permittees notify APHIS about the dates and itinerary of the permitted movement.

A commenter noted that APHIS makes no mention as to whether the passport page copy is attached to their permit file, or how long APHIS keeps this passport information. The commenter recommended that there be more specific language to address how securely personal information from permit applications will be stored and disseminated.

We have reevaluated the application requirements we proposed for hand-carry permits and determined that making them available on the APHIS website would allow more flexibility to adjust the requirements as conditions warrant. As a result, we are revising § 330.205(b) to state that after the permittee has obtained an import permit but no less than 20 days prior to movement, the permittee must provide APHIS, through its online portal for permit applications or by fax, with the names of the designated hand carrier, or carriers, assigned to that movement. We will also note in paragraph (b) that additional conditions for hand-carry are available on the APHIS website. Other conditions for hand-carry that were contained in proposed paragraph (c) will also be moved to the APHIS website.

The commenter also asked what the expected expiration date of the import permit would be, adding that it is not clearly defined whether the permittee must apply each time they travel but continue with the same permit, or whether the permittee must apply online each time.

We consider each hand-carry trip to be a unique event. For this reason, we require that the person wishing to hand-carry regulated materials or organisms under a current permit to notify APHIS through our online portal of the intention for a hand-carry event.

#### Packaging Requirements (§ 330.206)

We proposed in § 330.206 to include general and specific packaging requirements for the importation, interstate movement, or transit of plant pests, biological control organisms, and associated articles into or through the United States.

Regarding shipping of commercial biological control organisms, a commenter stated that APHIS should cooperate with industry to establish a process for shippers to expedite importation and movement of commercial biological control organisms, and to develop an efficient system for clearing shipments of commercial biological control organisms with potentially affected governmental agencies and State departments of agriculture. The commenter also stated that APHIS should identify points of contact for resolving problems that often occur when importing and transshipping commercial biological control organisms.

APHIS regularly works with industry to improve the efficiency and timeliness for clearance of imported commercial biological control organisms, including designating certain ports where clearance is a priority and delays are minimal. We recognize, however, that these specific designated ports (which is not the same as “port of entry”) may not be convenient for all importers and situations. APHIS will continue to work with industry to seek additional solutions while maintaining the safeguards needed for importation of live organisms.

A commenter wanted to know why we did not refer to RSPM 39<sup>30</sup> as it relates to packaging.

We did not refer to the guidelines mentioned by the commenter because we consider the proposed requirements for packaging to be adequate. RSPM 39 provides packaging guidelines to facilitate the movement of invertebrate biological control organisms into NAPPO member countries. The provisions and recommendations of RSPM 39, as currently written, exceed the packaging requirements of § 330.206. Moreover, RSPM guidelines are subject to change independent of the status of the plant protection regulations of any member country.

The commenter also asked whether organisms attenuated and excepted from permitting are also exempt from packaging requirements, as they do not require a permit.

As we noted in the above discussion of § 330.204, attenuated organisms will no longer be considered as plant pests and therefore not included on the exception list.

In proposed § 330.206(a), we include packaging requirements for the outer shipping container and inner packages. These include the requirements that the outer shipping container must be rigid, impenetrable, and durable enough to remain closed and structurally intact, and that inner packages must be sealed.

A few commenters expressed concerns about the lack of flexibility in the proposed packaging requirements, particularly as they relate to the environmental needs of live organisms.

One commenter stated that some packaged cultures consume oxygen quickly and generate carbon dioxide, creating conditions that kill beneficial organisms if there are no air holes for oxygen exchange. As an example, the commenter cited the current use of strong cardboard boxes with 1 to 1.5-inch holes drilled in the sides for transporting commercial

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<sup>30</sup> <http://www.nappo.org/files/5714/3889/7020/RSPM39Rev-08-12-2014-e.pdf>.

packages of beneficial organisms, including predatory mites and lady beetles. The commenter emphasized that the packaging described in the proposed regulation would block all airflow vital for the survival of beneficial organisms. For interstate travel of organisms that are not plant pests, the commenter stated that containment in one layer of packaging plus an outer breathable layer that keeps the inner packages from impact should be sufficient. Another commenter recommended establishing a performance-based standard for packaging that would require the permittee to ship the organism or soil in a secure manner and suggested that APHIS provide guidance and examples on its website for meeting this standard.

We acknowledge the commenters' concerns about the packing regulations and organism viability during shipment. We note that the regulations allow for modifications as long as they are in keeping with the proposed requirement that the packaging should not be capable of harboring or being a means of dissemination of the organism or article. For example, the requirement in § 330.206(a) that inner packages must be "securely sealed" does not equate to "airtight" unless it is appropriate to the organisms being shipped. We agree that additional guidance can be helpful, and accordingly APHIS will continue to work with industry and other stakeholders to address their concerns.

In proposed paragraphs (b) and (c) of § 330.206, we required that packing material and shipping containers be new, sterilized, or disinfected prior to reuse, or otherwise destroyed or disposed of at the point of destination.

A commenter suggested that the provision prohibiting the reuse of shipping containers, except for those sterilized or disinfected prior to reuse, should not apply to most insect shipments. The commenter stated that it is costly and time consuming to disinfect cardboard clad foam shippers, and that using only new containers will generate additional waste. Another

commenter agreed that not all shipping containers warrant sterilization and suggested revising proposed § 330.206(c). As an illustration, the commenter cited the content of a shipment containing all life stages of live insects within multiple packages. The commenter stated that the removal of only the inner containment packaging, which holds the insects, should suffice as decontamination.

We agree with the commenters that shipping containers do not warrant sterilization or disinfection for reuse as long as the inner packaging sufficiently contains the organisms to prevent contamination of the outer shipping container. We are revising § 330.206(c) accordingly.

#### Costs and Charges (§ 330.207)

In proposed § 330.207, we stated that we would furnish inspection services without cost during regularly assigned hours of duty and usual places of duty. We also stated that APHIS would not be responsible for any costs or charges incidental to inspections or compliance with the provisions of this subpart other than the services of the inspector.

A commenter asked if APHIS imposes charges for inspections and compliance checks. Another commenter recommended that APHIS include guidelines for charges associated with conducting inspections and verifying compliance with the regulations.

As we note in § 330.207, APHIS does not impose charges for inspections and compliance checks carried out during regularly assigned hours and usual places of duty. As we furnish inspection services under these conditions without cost, we see no reason to include guidelines for charging for such services.

## Other Comments

Several persons submitted general comments that did not address specific provisions included in the proposal.

One commenter noted that in a separate proposal to revise the regulations to 7 CFR part 340, APHIS noted that a genetically engineered plant pest organism meeting a proposed exemption from the part 340 definition of *genetic engineering* would still be subject to part 330 because an exemption, by its nature, is not considered an “explicit authorization.” The commenter asked that we wait to promulgate any final rule under part 330 until we fully consider comments received under the separate part 340 proposed rulemaking.

On November 7, 2017, APHIS published a document<sup>31</sup> in the *Federal Register* announcing withdrawal of the proposal referred to by the commenter.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule with the changes discussed in this document.

Executive Orders 12866, 13563, 13771, and Regulatory Flexibility Act

This final 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.

This final rule is considered an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in the rule’s economic analysis.

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,

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<sup>31</sup> <https://www.federalregister.gov/documents/2017/11/07/2017-24202/importation-interstate-movement-and-environmental-release-of-certain-genetically-engineered>.

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 a final 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 on the Regulations.gov website (see footnote 2 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

This rule will amend regulations regarding the importation, interstate movement, and environmental release of plant pests to incorporate provisions regarding biological control organisms and the movement of soils from which plant pests and biological control organisms are extracted. The rule adds definitions, streamlines the permitting and compliance processes, and provides APHIS with increased flexibility in the regulation of plant pests. The regulations in 7 CFR parts 318, 319, and 352 will be updated to reflect the changes in part 330. The rule will codify an existing process for electronically requesting permits. Using the online permit process yields time and cost savings as compared to mailing paper applications.

The rule will also reduce the number of permits issued under part 330, which numbered 6,538 in fiscal year (FY) 2015. About one-third of these permits (2,158) were for the movement or environmental release of plant pests or biological control organisms for which this rule will authorize exemption from permitting requirements, based on plant health risks. Their exemption from permitting requirements will reduce the permitting burden for applicants. Because one permit may list multiple biological control organisms or plant pests, we expect, overall, a 10 to 30 percent reduction in the time spent acquiring permits under part 330. Based on the 6,538

permits issued in FY 2015, and assuming the time required to submit an application is one hour, the annual time savings attributable to the rule will total between 654 and 1,961 hours. Given an average hourly wage of \$44.50 per hour, the annual total cost savings will be between about \$29,100 and \$87,300.

In accordance with guidance on complying with Executive Order 13771, the primary estimate of annualized cost savings attributable to this rule is \$54,950 (including consideration of the cost of unscheduled assessments by APHIS of sites, facilities, and means of conveyance). This value is the mid-point estimate of cost savings annualized in perpetuity using a 7 percent discount rate.

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

Certain regulated entities will continue to incur time costs associated with providing information during the permitting application process as was experienced before this rule was proposed. The time required overall for permitting will be reduced, however, because of the exempted organisms and the online, streamlined permitting system.

These revisions to part 330 will benefit entities, large and small, by increasing the efficiency of the permitting and compliance processes and by improving the clarity and transparency of these regulations. The majority of entities that will benefit from this rule are small, based on information obtained from the U.S. Economic Census. These entities include: academic, government, and commercial researchers; diagnostic enterprises such as plant

pathogen diagnostic laboratories; biological supply enterprises that include suppliers of biology teaching kits and suppliers of butterflies for release at special occasions; biological control organism producers; educational display enterprises such as butterfly houses, zoos, and museums; discovery companies that evaluate living organisms for novel pharmaceuticals and pesticides; taxonomists and systematists; educators; and hobbyists (see full economic analysis). The rule will also facilitate the Agency's coordination with other Federal and State agencies in regulating the movement and environmental release of plant pests and biological control organisms.

In our final regulatory flexibility analysis, we have used the best data available to examine potential impacts of the rule to achieve desired policy goals. We have determined that the rule will result in net cost savings for affected entities, nearly all of which are small. We cannot certify that this rule will have no significant impacts on small entities, but have found no evidence that it would have such impacts. We did not receive information during the public comment period on the proposed rule that would alter this assessment. Given the expected net cost savings, we have not identified steps that would minimize these impacts.

#### Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

#### Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this

rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### Executive Order 13175

In accordance with Executive Order 13175, APHIS has consulted with Tribal Government officials. A Tribal summary impact statement has been prepared that includes a summary of Tribal officials' concerns and of how APHIS has attempted to address them. The Tribal summary impact statement may be viewed on the Regulations.gov website.<sup>32</sup>

#### National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the processes in this final rule, we have prepared a final environmental impact statement (EIS). The final EIS is based on a draft EIS, which we drafted after soliciting public comment through a notice in the *Federal Register* to help us delineate the scope of the issues and alternatives to be analyzed. The final EIS responds to public comments, analyzes each alternative and its environmental consequences, if any, and provides APHIS' preferred alternative. 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).

Copies of the final EIS are available on the Regulations.gov website (see footnote 2 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

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<sup>32</sup> See footnote 2.

## Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this final rule, which were filed under 0579-0187, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the *Federal Register* providing notice of what action we plan to take.

## 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 rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

## List of Subjects

### 7 CFR Part 318

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

### 7 CFR Part 319

Coffee, Cotton, Fruits, Honey, Imports, Plants for planting, Plant diseases and pests, Plants, Quarantine, Reporting and recordkeeping requirements, Rice, Sugar, Vegetables.

7 CFR Part 330

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

7 CFR Part 352

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

Accordingly, we are amending 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.

2. In § 318.60, paragraph (c) introductory text is revised to read as follows:

§ 318.60 Notice of quarantine.

\* \* \* \* \*

(c) Sand (other than clean ocean sand), soil, or earth around the roots of plants must not be shipped, offered for shipment to a common carrier, received for transportation or transported by a common carrier, or carried, transported, moved, or allowed to be moved by any person from Hawaii, Puerto Rico, or the Virgin Islands of the United States into or through any other State, Territory, or District of the United States: *Provided*, That the prohibitions in this paragraph (c) 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: *Provided further*, That the prohibitions of this section shall not apply to the movement of such products in either direction between Puerto Rico and the Virgin Islands of the United States: *Provided further*, That such prohibitions shall not prohibit

the movement of such products by the United States Department of Agriculture for scientific or experimental purposes, nor prohibit the movement of sand, soil, or earth around the roots of plants which are carried, for ornamental purposes, on vessels into mainland ports of the United States and which are not intended to be landed thereat, when evidence is presented satisfactory to the inspector of the Plant Protection and Quarantine Programs of the Department of Agriculture that such sand, soil, or earth has been so processed or is of such nature that no pest risk is involved, or that the plants with sand, soil, or earth around them are maintained on board under such safeguards as will preclude pest escape: *And provided further*, That such prohibitions shall not prohibit the movement of plant cuttings or plants that have been—

\* \* \* \* \*

#### PART 319—FOREIGN QUARANTINE NOTICES

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

Authority: 7 U.S.C. 1633, 7701-7772, and 7781-7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

4. In § 319.37-10, paragraph (b) is revised to read as follows:

§ 319.37-10 Growing media.

\* \* \* \* \*

(b)(1) Plants for planting from Canada may be imported in any growing medium, except as restricted in the Plants for Planting Manual. Restrictions on growing media for specific types of plants for planting imported from Canada will be added, changed, or removed in accordance with §319.37-20.

(2) Plants for planting 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) introductory text;
- b. By revising paragraph (a)(8);
- c. By removing the undesignated paragraph after paragraph (a)(8); and
- d. By removing paragraph (b)(4).

The revisions read as follows:

§ 319.69 Notice of quarantine.

(a) The following plants and plant products, when used as packing materials, are prohibited entry into the United States from the countries and localities named in this paragraph (a), exceptions to the prohibitions may be authorized in the case of specific materials which have been so prepared, manufactured, or processed that in the judgment of the inspector no pest risk is involved in their entry:

\* \* \* \* \*

(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 prohibitions in paragraphs (a)(1) through (7) of this section 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 revised to read as follows:

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

The following types of organic decaying vegetative matter are authorized as safe for packing:

- (a) Peat;
- (b) Peat moss; and
- (c) Osmunda fiber.

8. Section 319.77-2 is amended as follows:

- a. In paragraph (e), by removing the word “and”;
- b. By revising paragraph (f); and
- c. By adding paragraph (g).

The revision and addition read as follows:

§ 319.77-2 Regulated articles.

\* \* \* \* \*

- (f) Mobile homes and their associated equipment; and
- (g) 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.

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

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. The term includes associated articles such as soil and packaging.

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

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

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

*Continued curation permit.* A permit issued prior to the expiration date for an import permit or interstate movement permit in order for a permittee to continue research or other actions listed on the import or interstate movement permit. Continued curation permits do not allow acquisition of additional organisms for research and other authorized activities and only address retention of existing organisms for authorized uses.

*Department.* The United States Department of Agriculture.

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

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

*EPA.* The Environmental Protection Agency of the United States.

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

*Garbage.* That material designated as "garbage" in § 330.400(b).

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

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

*Inspector.* Any individual authorized by the Administrator of APHIS or the Commissioner of U.S. Customs and Border Protection to enforce the regulations in this part.

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

*Living.* Viable or potentially viable.

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

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

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

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

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

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

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

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

*Plant pest.* Any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

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

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

*Pure culture.* A single species of invertebrate originating only from an identified/described population and free of disease and parasites, cryptic species, soil and other

biological material except host material and substrate as APHIS deems appropriate. Examples of identified/described population are those originating from a specific laboratory colony or field collection from a specified geographic area, such as an entire country or States or provinces of a country.

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

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

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

*Shelf-stable.* The condition achieved in a product, by application of heat, alone or in combination with other ingredients and/or other treatments, of being rendered free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50 °F or 10 °C).

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

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

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

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

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

*United States.* All of the States and territories.

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

§ 330.105 [Amended]

13. In § 330.105, paragraph (a) is amended by removing the citation “§ 330.300” both times it appears and adding the words “this part” in its place.

14. Subpart B is revised to read as follows:

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

330.200 Scope and general restrictions.

330.201 Permit requirements.

330.202 Biological control organisms.

330.203 Soil.

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

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

330.206 Packaging requirements.

330.207 Costs and charges.

Subpart B—Movement of Plant Pests, Biological Control Organisms, and Associated Articles  
§ 330.200 Scope and general restrictions.

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

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

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

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

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

(b) *Plant pests regulated by this subpart.* For the purposes of this subpart, 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.* Paragraph (c) of this section notwithstanding, biological control organism-containing products that are currently under an EPA experimental use permit, a Federal Insecticide Fungicide and Rodenticide Act (FIFRA) section 18 emergency exemption, or that are currently registered with EPA as a microbial pesticide product, are not regulated under this subpart. Additionally, biological control organisms that are pesticides that are not registered with EPA, but are being transferred, sold, or distributed in accordance with EPA's regulations in 40 CFR 152.30, are not regulated under this subpart for their interstate movement or importation. However, an importer desiring to import a

shipment of biological control organisms subject to FIFRA must submit to the EPA Administrator a Notice of Arrival of Pesticides and Devices as required by CBP regulations at 19 CFR 12.112. The Administrator will provide notification to the importer indicating the disposition to be made of shipment upon its entry into the customs territory of the United States.

§ 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.<sup>1</sup>

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

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

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<sup>1</sup> 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.

(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 one or more designated individuals for service of process.

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

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

(c) *Completing a permit application.* A permit application must be complete before APHIS will evaluate it in order to determine whether to issue the permit requested. To facilitate timely processing, applications should be submitted as far in advance as possible of the date of the proposed permit activity. Guidance regarding how to complete a permit application, including guidance specific to the various information blocks on the application, is available at [http://www.aphis.usda.gov/plant\\_health/permits/index.shtml](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<sup>2</sup> or associated article will be held or released. As part of this assessment, all sites and facilities are subject to inspection. All facilities must be determined by APHIS to be constructed and maintained in a manner that prevents the dissemination or dispersal of plant pests, biological control organisms, or associated articles from the facility. The applicant must provide all information requested by APHIS regarding this assessment, and must allow all inspections requested by APHIS during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, excluding holidays). Failure to do so constitutes grounds for denial of the permit application.

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

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<sup>2</sup> Includes biological control organisms and plant pests.

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

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

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

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

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

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

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

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

(iv) The applicant does not agree to observe all of the proposed permit conditions that APHIS has determined are necessary to mitigate identified risks; or

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

(vi) APHIS determines that the applicant has not followed prior permit conditions, or has not adequately demonstrated that they can meet the requirements for the current application.

Factors that may contribute to such a determination include, but are not limited to:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) *Amendment initiated by APHIS.* APHIS may amend any permit and its conditions at any time, upon determining that the amendment is needed to address newly identified considerations concerning the risks presented by the organism or the activities being conducted under the permit. APHIS may also amend a permit at any time to ensure that the permit conditions are consistent with all of the requirements of this part. As soon as circumstances

allow, APHIS will notify the permittee of the amendment to the permit and the reason(s) for it. Depending on the nature of the amendment, the permittee may have to agree in writing or electronically that he or she, and his or her employees, agents, and/or officers, will comply with the permit and conditions as amended before APHIS will issue the amended permit. If APHIS requests such an agreement, and the permittee does not agree in writing that he or she, and his or her employees, agents, and/or officers, will comply with the amended permit and conditions, the existing permit will be revoked.

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

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

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

§ 330.202 Biological control organisms.

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

[http://www.aphis.usda.gov/plant\\_health/permits/index.shtml](http://www.aphis.usda.gov/plant_health/permits/index.shtml).

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

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

(2) *Release of listed organisms.* Pure cultures of organisms on the list may be released into the environment of the continental United States without further restriction under this subpart.

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

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

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

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

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

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

(d) *APHIS review of petitions--(1) Evaluation.* APHIS will review the petition to determine whether it is complete. If APHIS determines that the petition is complete, it will conduct an evaluation of the petition to determine whether there is sufficient evidence that the organism exists throughout its geographical or ecological range in the continental United States and that subsequent releases of pure cultures of field populations of the organism into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products.

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

(3) *Notice of determination.* (i) If no comments are received, or if the comments received do not lead APHIS to reconsider its determination, APHIS will publish in the *Federal Register* a

subsequent notice describing the comments received and stating that the organism has been added to the list referred to in paragraph (b) of this section.

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

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

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

§ 330.203 Soil.

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

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

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

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

accordance with § 330.201 and if the soil is imported under the conditions specified on the permit.

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

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

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

(5) *Exemptions.* The articles listed in this paragraph (b) are not soil, provided that they are free of organic material. Therefore, they may be imported into the United States without an import permit issued in accordance with § 330.201, unless the Administrator has issued an order stating otherwise. All such articles are, however, subject to inspection at the port of first 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 referenced in part 301 of this chapter.

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

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

(4) *Conditions for the interstate movement of soil samples from an area quarantined in accordance with part 301 of this chapter for chemical or compositional testing or analysis.* Soil

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) *Specification of individual who will hand-carry.* The application must also specify the individual or individuals who will hand-carry the plant pest, biological control organism, or soil into the United States. If APHIS authorizes this individual or these individuals to hand-

carry, the authorization may not be transferred to nor actions under it performed by individuals other than those identified on the permit application.

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

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

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

#### § 330.206 Packaging requirements.

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

(a) *Packaging requirements.* All shipments must consist of an outer shipping container and at least two packages within the container. Both the container and inner packages must be

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<sup>3</sup> [https://www.aphis.usda.gov/plant\\_health/permits/organism/downloads/HandCarryPolicy.pdf](https://www.aphis.usda.gov/plant_health/permits/organism/downloads/HandCarryPolicy.pdf).

securely sealed to prevent the dissemination of the enclosed plant pests, biological control organisms, or associated articles.

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

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

(b) *Packing material.* Packing materials may be placed in the inner packages or shipping container for such purposes as cushioning, stabilizing, water absorption or retention, nourishment or substrate for regulated articles, etc. Packing material for importation must be free of plant pests, noxious weeds, biological control organisms not listed on the permit or associated articles, and, as such, must be new, or must have been sterilized or disinfected prior to reuse. Packing material must be suited for the enclosed organism or article, as well as any medium in which the organism or article will be maintained.

(c) *Requirements following receipt of the shipment at the point of destination.* (1) Packing material, including media and substrates, must be destroyed by incineration, be decontaminated using autoclaving or another approved method, or otherwise be disposed of in a manner specified in the permit itself.

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

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

§ 330.207 Cost and charges.

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

Subpart C [Removed and Reserved]

15. Subpart C, consisting of §§ 330.300 through 330.302, is removed and reserved.

PART 352—PLANT QUARANTINE SAFEGUARD REGULATIONS

16. The authority citation for part 352 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.

17. In § 352.1, paragraph (b) is amended as follows:

- a. By adding, in alphabetical order, a definition for *Biological control organism*;
- b. By revising the definition for *Deputy Administrator*;
- c. By adding, in alphabetical order, a definition for *Noxious weed*; and

d. By revising the definitions for *Person*, *Plant pest*, and *Soil*.

The additions and revisions 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 plant pests listed in this definition.

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*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]

18. 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 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]

19. Section 352.3 is amended as follows:

a. In paragraphs (a) and (b), by adding the words “biological control organisms,” after the words “plant pests,” each time they appear; and

b. In paragraph (d), by removing the words “plant pest or noxious weed dissemination” and adding the words “plant pest, noxious weed, or biological control organism dissemination” in their place.

§ 352.5 [Amended]

20. Section 352.5 is amended by adding the words “biological control organisms,” after the words “plant pests,” each time they appear.

§ 352.6 [Amended]

21. Section 352.6 is amended as follows:

a. In paragraph (b), by removing footnote 2 and removing the words “as specified by” and adding the words “in accordance with” in their place; and

b. In paragraph (c), by removing the reference to footnote 2 and removing the citation “§ 330.300(b)” and adding the citation “§ 330.203” in its place.

c. In paragraph (e), by removing the words “plant pest or noxious weed dissemination” both times they appear and adding the words “plant pest, noxious weed, or biological control organism dissemination” in their place.

§ 352.9 [Amended]

22. Section 352.9 is amended by adding the words “biological control organisms,” after the words “plant pests,”.

§ 352.10 [Amended]

23. Section 352.10 is amended as follows:

a. By redesignating footnote 3 as footnote 2;

b. In paragraph (b)(1), by removing the words “plant pest or noxious weed dissemination” each time they appear and adding the words “plant pest, noxious weed, or biological control organism dissemination” in their place and adding the words “biological control organisms,” after the words “Prohibited or restricted plants, plant products, plant pests,”;

c. In paragraph (b)(2) introductory text, by removing the words “plant pest or noxious weed dissemination” both times they appear and adding the words “plant pest, noxious weed, or biological control organism dissemination” in their place;

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,”;

f. In paragraph (b)(2)(iii), by removing the words “plant pest or noxious weed dissemination” and adding the words “plant pest, noxious weed, or biological control organism dissemination” in their place;

g. 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; and

h. In paragraph (c)(1), by removing the words “plant pest or noxious weed dissemination” and adding the words “plant pest, noxious weed, or biological control organism dissemination” in their place.

#### § 352.11 [Amended]

24. In § 352.11, paragraph (a)(1) is amended by removing the words “plant pests, noxious weeds, and soil” and adding the words “plant pests, biological control organisms, noxious weeds, soil, or other products or articles” in their place.

#### § 352.13 [Amended]

25. Section 352.13 is amended by removing the words “plant pests, noxious weeds, and soil” and adding the words “plant pests, biological control organisms, noxious weeds, soil, or other products or articles” in their place and removing the word “parts” and adding the word “part” in its place.

#### § 352.15 [Amended]

26. Section 352.15 is amended by removing the words “plant pest or noxious weed dissemination” and adding the words “plant pest, noxious weed, or biological control organism dissemination” in their place.

§ 352.30 [Amended]

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

Done in Washington, DC, this 17th day of June 2019 .

Lorren E.S. Walker

Acting Under Secretary for Marketing and Regulatory Programs.

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