

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 7 CFR Part 330

[Docket No. 95–095–2]

RIN 0579–AA80

### Plant Pest Regulations; Update of Current Provisions

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to revise our regulations regarding the movement of plant pests by adding risk-based criteria for determining the plant pest status of organisms, establishing a notification process that could be used as an alternative to the current permitting system, providing for the environmental release of organisms for the biological control of weeds, and updating the text of the subpart. These proposed changes would clarify the factors that would be considered when assessing the plant pest risks associated with certain organisms, facilitate the importation and interstate movement of regulated organisms, and address gaps in the current regulations.

**DATES:** We invite you to comment on this docket. We will consider all comments that we receive by December 10, 2001.

**ADDRESSES:** Please send your comment and three copies to: Docket No. 95–095–2, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Please state that your comment refers to Docket No. 95–095–2.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except

holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS rules, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Robert Flanders, Risk Assessment Branch Chief, or Ms. Deborah Knott, Permits Branch Chief, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; phone 301–734–5930 (Dr. Flanders) or 301–734–5055 (Ms. Knott).

#### SUPPLEMENTARY INFORMATION:

##### Background

Under the Plant Protection Act (Title IV of Pub. L. 106–224, referred to below as the Act), the Secretary of Agriculture has broad authority to carry out operations or measures to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests. Section 411(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 is in accordance with such regulations as the Secretary may issue to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States.” The Act gives the United States Department of Agriculture (USDA) the flexibility to respond appropriately to a wide range of needs and circumstances to protect American agriculture against plant pests. The Act defines a *plant pest* as “[A]ny living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: (A) A protozoan. (B) A nonhuman animal. (C) A parasitic plant. (D) A bacterium. (E) A fungus. (F) A virus or viroid. (G) An infectious agent or other pathogen. (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.”

In addition, § 412(a) of the Act provides that Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of, among other things, any

biological control organism if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States. The Act defines a biological control organism as “any enemy, antagonist, or competitor used to control a plant pest or noxious weed.”

The purpose of the regulations in “Subpart—Movement of Plant Pests” (7 CFR 330.200 through 330.212) is to prevent the dissemination of plant pests into the United States, or interstate, by regulating the importation and interstate movement of plant pests. These regulations were issued by the Animal and Plant Health Inspection Service (APHIS) under the authority provided by, among other statutes, the Department of Agriculture Organic Act of 1944, as amended (7 U.S.C. 147a), and the Federal Plant Pest Act, as amended (7 U.S.C. 150aa through 150jj), both of which were superseded and repealed by the Plant Protection Act. The provisions of the Plant Protection Act that have a direct bearing on the proposed regulations in this document were derived from existing laws, including the Department of Agriculture Organic Act and the Federal Plant Pest Act, with little or no modification. Thus, the provisions of this proposed rule do not differ significantly from what we would have proposed under the authority of those applicable provisions of law that were repealed by the Plant Protection Act.

#### Advance Notice of Proposed Rulemaking

On September 27, 1996 (61 FR 50767–50770, Docket No. 95–095–1), we published in the **Federal Register** an advance notice of proposed rulemaking (ANPR) to solicit public comment on several issues pertaining to our current regulations regarding the importation and interstate movement of plant pests. Specifically, we sought public comment on the criteria used to determine whether an organism is a plant pest; what types of direct and indirect injury or damage to plants and plant products should be regulated; how to facilitate the interstate movement and use of biological control organisms; and how to best evaluate the safety of proposed releases into the environment of organisms with plant pest

characteristics. In the ANPR, we stated that we would use the information we gathered as we considered the need for regulatory changes and weighed alternative methods of addressing plant pest risk as it pertains to the importation, interstate movement, and release into the environment of plant pests or potential plant pest organisms.

We solicited comments concerning the ANPR for 90 days ending December 26, 1996. We received 52 comments by that date, including 3 comments received at a public hearing held on November 7, 1996. They were from university researchers and students, Federal researchers, insect zoo owners and employees, insect dealers, State agricultural agencies, a crop science society, biological control practitioners, and associations representing biological control producers and researchers, phytopathologists, zoos, seed companies, organic farmers and suppliers, and repositories of biological specimens.

The discussion contained in the ANPR and the questions it posed were, for the most part, well received by the majority of commenters. We considered the suggestions and criticisms offered in the comments during the drafting of this proposed rule. One aspect of the ANPR that was not well received was the suggestion that voluntary standards be considered for facilitating the interstate movement and release into the environment of organisms used in the biological control of plant pests. None of the commenters who addressed this subject recommended that we pursue this idea, most stating that such standards would be unenforceable and ill-advised.

Many of the comments we received were from individuals or groups who are involved in biological control research or practice, so their comments were focused on the need for, and content of, regulations regarding the introduction of biological control organisms. We believe that it is important to make it clear that APHIS' regulation of biological control occurs in the larger context of the Agency's statutory authority, which requires us to focus on preventing the introduction and dissemination of plant pests. This means that the plant pest risk presented by an organism, rather than its intended use as a biological control agent, must be APHIS' primary consideration.

This does not mean, however, that our proposed regulations would have no bearing on the study or practice of biological control. Indeed, most biological control endeavors begin with the importation of nonindigenous species that may exhibit some potential

as biological control agents, and those importations frequently consist of field-collected organisms of unknown or unconfirmed taxonomy, which precludes an adequate pre-import pest risk assessment. In addition, those organisms may be accompanied by plant material, foreign soil, or other organisms, all of which may pose a plant pest risk. Given these factors, the initial handling of organisms with potential biological control applications would not differ substantively from the handling of organisms imported for other purposes. Further, this proposed rule contains provisions regarding the release into the environment of agents for the biological control of weeds. This document represents our effort to address issues of concern to the biological control community in the context of our clear authority to take measures to prevent the introduction and dissemination of plant pests. The proposed regulations are discussed below.

#### Definitions

In addition to our proposed revision of "Subpart—Movement of Plant Pests," we would also revise § 330.100, "Definitions," of "Subpart—General Provisions," to incorporate the applicable new definitions provided by the Plant Protection Act and to update or eliminate some of the definitions currently provided in that section. The revised section is set out in its entirety in the rule portion of this document.

From the Plant Protection Act, we would add definitions for the terms *article*, *biological control organism*, *enter (entry)*, *export (exportation)*, *import (importation)*, *noxious weed*, *plant*, *plant product*, and *State*; we would also replace the current definitions of *interstate*, *means of conveyance*, *move (moved and movement)*, *permit*, *plant pest*, and *United States* with the definitions provided for those terms in the Plant Protection Act. In addition, the revised section would include a definition of *APHIS*, as the Agency's acronym is used in our proposed revisions to "Subpart—Movement of Plant Pests."

The definitions currently provided in § 330.100 for the terms *administrative instructions*, *Department*, *earth*, *garbage*, *owner*, *person*, *regulated garbage*, *shelf-stable*, *soil*, and *through the United States* would remain the same. We would also retain, with minor, nonsubstantive editorial changes, that section's definitions of the terms *Administrator*, *continental United States*, *Customs*, *Deputy Administrator*, *inspector*, and *Plant Protection and Quarantine Programs*. The definitions

provided in § 330.100 for *Plant Quarantine Act* and *the Federal Plant Pest Act* would be removed, as those acts were repealed by the Plant Protection Act, and we would remove the definition provided for the term *territories or possessions* because territories or possessions are included within the Plant Protection Act's definition of the term *State*.

#### Titles of the Part and Subpart

The title of part 330, "Federal Plant Pest Regulations; General; Plant Pests; Soil, Stone, and Quarry Products; Garbage," reflects the titles of its four subparts. The subpart that is the subject of this proposed rule is titled "Subpart—Movement of Plant Pests" (§§ 330.200 through 330.212). As explained below in our discussion of proposed § 330.200 and elsewhere, the scope of the proposed regulations would not be limited to the movement of plant pests, so we are proposing to change the title of the subpart to "Subpart—Movement and Release of Organisms Under the Plant Protection Act" in order to more accurately reflect the content of the proposed regulations. This proposed change in the subpart's title would be reflected in the title of part 330, which we would change to "Federal Plant Pest Regulations: General; Organisms; Soil, Stone, and Quarry Products; Garbage."

#### What Organisms Are Regulated Under This Subpart? (§ 330.200)

The proposed regulations would begin by identifying the categories of organisms that would be subject to the regulations in "Subpart—Movement and Release of Organisms Under the Plant Protection Act." As noted in the previous paragraph, the scope of the proposed regulations would not be limited to organisms commonly regarded as plant pests, but would include biological control agents when certain risk factors were present. We would introduce the term "regulated organism" in order to describe the variety of both harmful and beneficial organisms that would be subject to the regulations.

As used in the proposed regulations, the term "regulated organism" would describe an organism that: (1) Meets the statutory definition of plant pest (i.e., it can directly or indirectly injure or cause disease or damage in plants, plant parts, or plant products) and (2) will be imported into the United States, moved interstate, or released into the environment. In addition, we would classify an organism that will be imported into the United States as a regulated organism if that organism was not adequately identified or if we had

reason to believe that the importation of the organism presents a plant pest risk due to the inclusion of plant pests, plant material, or soil in the container in which the organism is shipped. The risk criteria we would use to determine whether an organism should be designated as a regulated organism are discussed below. For the sake of clarity, we wish to emphasize that the proposed regulations would not cover genetically modified organisms, which are covered by our regulations in 7 CFR part 340.

It should be noted that the designation of any particular organism as a regulated organism would not result in an outright, open-ended prohibition on its importation or interstate movement. In almost every case, we believe that it would be possible to arrange adequate safeguards that would allow a regulated organism to be imported or moved interstate. Similarly, the designation of biological control agents of weeds as regulated organisms would not mean that we considered those organisms to present the same kinds of plant pest risks as, for example, a destructive fruit fly or pathogen. Rather, our proposed use of the term "regulated organism," and the restrictions that such a designation would entail, is intended to provide us with a means of identifying and dealing with organisms that, at least initially, appear to require some degree of regulatory oversight in order to prevent the dissemination of plant pests in the United States and damage to this country's environment and ecosystems. It is our intention in promulgating these proposed regulations to achieve those goals within the scope of our existing statutory authority.

Under proposed § 330.200, regulated organisms would be divided into three categories: (1) Plant pests, (2) biological control organisms for the control of noxious weeds, and (3) imported biological control organisms for the control of plant pests and other imported organisms.

The first category of regulated organisms, plant pests, would be addressed in paragraph (a) of proposed § 330.200. That paragraph would provide that the importation, interstate movement, and, under certain limited circumstances, release into the environment of any plant pest would be subject to the restrictions of proposed §§ 330.201, 330.202, and 330.203(a), which are explained later in this document. (It should be noted that not all plant pests would be eligible for release into the environment under the proposed regulations. An explanation of the circumstances under which a plant pest would be eligible for environmental

release can be found later in the document in the discussion of proposed § 330.203.)

As an organism must be capable of directly or indirectly injuring, causing damage to, or causing disease in a plant or plant product to be considered a plant pest, proposed § 330.200(a)(1) and (a)(2) would list the factors that we would consider when assessing the plant pest status of an organism.

Under the criteria of proposed paragraph (a)(1), an organism would be determined to directly injure or cause disease or damage in plants, plant parts, or plant products when the organism:

- Reduces the yields, vigor, or viability of living plants by feeding on, infecting, parasitizing, or contaminating plants or plant parts or by vectoring agents of plant diseases; or
- Reduces the quality or marketability of plant products such as stored grain, stored fruit, or lumber by feeding on, infecting, or contaminating the plant products.

In establishing these proposed criteria, we have attempted to incorporate a degree of flexibility that would allow us to take into account the fact that some organisms only incidentally feed on, develop on, or contaminate plants, plant parts, or plant products without causing an appreciable degree of damage. These proposed criteria would place an emphasis on organisms that present an identifiable risk, *i.e.* organisms that are capable of quantifiable reductions in the yields, vigor, or viability of living plants or the quality or marketability of plant products.

Proposed paragraph (a)(2) would contain the criteria that would be considered in determining whether an organism presented a risk of indirectly injuring or causing disease or damage in plants, plant parts, or plant products. Under this paragraph, we would consider the risk of indirect injury, disease, or damage to be present when an organism adversely affects another organism that was beneficial to plants, and those adverse effects cause losses in yields of crops or forage plants or a reduction in the viability or vigor of ornamental or native plants. As with the proposed criteria regarding direct effects, these criteria would give us the flexibility to take into account the fact that some organisms only incidentally attack or otherwise harm beneficial organisms and thus may present little actual risk.

Because the organisms that can be considered to provide the most benefit to plants are those organisms that either control plant pests or pollinate plants, proposed § 330.200(b) indicates the two

types of organisms with indirect plant pest effects that would be of primary concern are organisms that are:

- Pathogens, predators, or parasites (except autoparasitoids) of important natural enemies of plant pests or weeds; or
- Pathogens, predators, or parasites of important or commercially available pollinators such as honeybees, bumble bees, and alkali bees.

We have included the modifiers "important" and "commercially available" with regard to the natural enemies and pollinators that might be affected by a regulated organism to avoid lending undue weight to a regulated organism's effects on another organism that might play only a minor or occasional role in the pollination of plants or the suppression of plant pests or weeds. Our determination as to the "importance" of a natural enemy or a pollinator would be based on our review of available information in the scientific literature regarding the role of those organisms in suppressing plant pest or weed populations or in the pollination of crops and native plants. Our determination as to whether pollinators are "commercially available" would take into account factors such as the inclusion of particular species in catalogs or their use by commercial pollination services. We acknowledge that these working definitions of "important" and "commercially available" could be further refined to take into account additional factors that would increase their usefulness and clarity; therefore, we encourage the submission of any specific comments regarding these terms.

The second category of regulated organisms, biological control organisms for the control of noxious weeds, would be addressed in paragraph (b) of proposed § 330.200. Under proposed § 330.200(b), the importation, interstate movement, and release into the environment of any biological control organism for the control of noxious weeds would be subject to the restrictions of proposed §§ 330.201, 330.202(a) and (b), and 330.203(b). Like plant pests with the direct effects on plants described above, biological control agents of weeds are capable of reducing the vigor or viability of living plants; however, those direct effects are actually the desired outcome when the plant in question is a noxious weed. Therefore, the regulations would provide that biological control agents of weeds may be eligible for release into the environment under the regulations.

The third category of regulated organisms, imported biological control organisms for the control of plant pests

and other imported organisms, would be addressed in paragraph (c) of proposed § 330.200. Under proposed § 330.200(c)(1), an organism that was proposed for importation into the United States could be determined to present a risk of disseminating a plant pest when it was:

- A field-collected organism that, in natural conditions, is associated with plant pests and there is reason to believe that the plant pests could be shipped with the field-collected organisms; or
- A laboratory-reared organism that is provided with plant pests as host material during rearing or shipment; or
- An organism that will be shipped with plant material or soil; or
- An organism that has not been positively identified.

In the first three criteria listed above, the plant pest risk is based on the risk that the shipment of organisms is contaminated by plant pests, either on the organism itself or in the material included in the shipment. We believe that our proposed use of these three criteria in the regulations is consistent with the approach APHIS takes to the importation of other articles, such as fruits and vegetables. While an orange, for example, is not a plant pest, the circumstances surrounding its production or shipment (e.g., the presence of plant pests in the growing area) could lead APHIS to conclude that certain regulatory measures would be necessary to prevent that orange from introducing plant pests into the United States. We would use the proposed criteria in the same way to ensure that the importation of organisms from another country did not result in the introduction of plant pests into the United States. The final criterion listed above would be included due to the fact that we would be unable to make any sort of a determination regarding an organism's plant pest status in the absence of a positive identification of the organism.

After the organism had been imported into the United States, paragraph (c)(2) of proposed § 330.200 would provide for the organism to be moved interstate without any further restriction under the regulations if, while being held under the conditions assigned to its importation, the organism was positively identified (if such identification had not been made prior to importation), was determined to not be a plant pest (i.e., once identified, the organism was found to not meet any of the criteria of proposed § 330.200(a) or (b)), and was separated from any associated plant pests, plant material, soil, and other media. Satisfying these three requirements would address the

contamination and identity risk factors listed in proposed § 330.200(c)(1), thus making the subsequent movement of the organism possible without the risk of plant pest dissemination.

It should be noted that although the Environmental Protection Agency (EPA) has exempted certain biological control agents from the requirements of its regulations issued under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), other biological control agents (eukaryotic microorganisms, procaryotic microorganisms, and viruses) are still regulated by EPA as "substances" under FIFRA. Such substances, unless otherwise exempt, would therefore need to be registered under FIFRA prior to their sale or distribution. Moreover, where residues of any biological control agents remain in or on food or feed, a tolerance or exemption from the requirement of a tolerance would be necessary under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) before such food could legally be moved in interstate commerce. Therefore, while the provisions of proposed § 330.200(c)(2) may allow some regulated organisms to be moved without further restriction under APHIS' regulations after satisfying certain requirements, those organisms may still be subject to EPA's requirements under FIFRA and FFDCA.

#### **Movement of Regulated Organisms**

As described in the following sections, the regulations would provide for three ways to move a regulated organism:

- With a permit;
- Through post-movement notification if a compliance agreement is in place; and
- Without a permit (and without need of notification) if the regulated organism is on the list in proposed § 330.202(c)(1) of negligible-risk, indigenous plant pest species that could be moved interstate within the continental United States if moved from populations located within the continental United States.

Each of these three options is explained in greater detail below. In preparing this proposed rule, we also considered the possibility of including a fourth movement option that would be tailored specifically to low-risk organisms, i.e., those regulated organisms whose movement might not require the level of oversight and information processing that permitting and post-movement notification entail, but that for various reasons—most notably limited geographic distribution—would not qualify for

inclusion on the "no permit required" list.

While we believe that it might be possible to address the movement of these low-risk organisms through a pre-movement notification process that would not require the use of a compliance agreement, we identified two potential complicating factors with such an approach that led us to not include pre-movement notification in this proposed rule.

First, it appears that it would be necessary to assemble a list of organisms eligible for movement through pre-movement notification, and we anticipate that it would be a time-consuming process to obtain consensus among the interested parties (e.g., public and private scientists, State and Federal regulators, etc.) as to the content of such a list. Further, the list would have to take into account the current distribution of each organism and identify the areas into which the organism could or could not be moved under pre-movement notification; this too would take some time to accomplish.

The second consideration is determining how much information should be required of the person making the pre-movement notification. For a pre-movement notification process to offer benefits to its users, it would be necessary for us to pare down the number of data elements to be addressed in the notification (as compared to the questions contained in a permit application) without diminishing the ability of a reviewer to adequately consider the issues raised by the proposed movement. We believe that the resolution of the issues surrounding the list discussed in the previous paragraph would go far toward allowing us to construct a practical and useful pre-movement notification process.

While these two factors led us to not pursue the idea of pre-movement notification in this proposed rule, we have not abandoned that idea or, more generally, the idea of streamlining the process for moving low-risk organisms. With that in mind, we encourage anyone with an interest in these issues to provide comments and suggestions regarding pre-movement notification or any other approaches to simplifying the process for moving low-risk regulated organisms.

#### **Requirements for the Importation of Regulated Organisms (§ 330.201)**

Proposed § 330.201 would explain the options available to persons who wished to import a regulated organism into the United States. An importation

could be accomplished through notification or under permit when APHIS determines that the importation could be accomplished in a manner that would prevent the dissemination of plant pests. All imported organisms would have to be labeled in accordance with § 330.211, which is discussed below.

The introductory text of proposed § 330.201 would also address the importation of preserved or dried biological specimens of plant pests. Such specimens could be imported without restriction under the proposed regulations, but would be subject to inspection upon arrival in the United States to confirm the nature of the material and its freedom from risk of plant pest dissemination. These proposed provisions are the same as those found in the final sentence of § 330.200 in the existing regulations, with one exception: In order to address the potential that some dried specimens of fungi that are plant pests could be the source of viable spores, we would specify that a specimen would have to be nonviable. Thus, any viable specimens of fungi that are plant pests would be subject to the restrictions of the proposed regulations.

Paragraph (a) of proposed § 330.201 would explain that if a person has entered into a compliance agreement with APHIS and the State where the regulated organisms will be received, the importation of regulated organisms could be carried out under the notification provisions of proposed § 330.204. The rationale for our proposed use of compliance agreements and notification, as well as the procedures that would apply to each, are explained later in this document in the discussion of proposed § 330.204.

Paragraph (b) of proposed § 330.201 would explain that persons who do not wish to enter into a compliance agreement may apply for a permit for the importation of a regulated organism in accordance with proposed § 330.205. APHIS would use the information provided in a permit application to identify the plant pest risks associated with the regulated organism and its importation, and to assign any additional conditions that APHIS determined were necessary to mitigate any identified risks. Explanations of the permit application and permit conditions can be found later in this document in the discussions of §§ 330.205 and 330.208, respectively.

### **Requirements for the Interstate Movement of Regulated Organisms (§ 330.202)**

Proposed § 330.202 would explain the options available to persons who wished to move a regulated organism from one State into or through another State. An interstate movement could be accomplished through notification or under permit or, under certain limited circumstances, without a permit, when APHIS determines that the interstate movement could be accomplished in a manner that would prevent the dissemination of plant pests within the United States.

Paragraph (a) of proposed § 330.202 would explain that if a person has entered into a compliance agreement with APHIS and the State where the regulated organisms will be received, the interstate movement of regulated organisms could be carried out under the notification provisions of proposed § 330.204. As noted in the previous section regarding importation, the rationale for our proposed use of compliance agreements and notification, as well as the procedures that would apply to each, are explained later in this document in the discussion of proposed § 330.204.

Paragraph (b) of proposed § 330.202 would explain that persons who do not wish to enter into a compliance agreement may apply for a permit for the interstate movement of a regulated organism in accordance with proposed § 330.205. As would be the case with applications for a permit to import regulated organisms, APHIS would use the information provided in an application for an interstate movement permit to identify the plant pest risks associated with the regulated organism and its movement and assign any additional conditions that APHIS determined were necessary to mitigate any identified risks. Again, explanations of the permit application and permit conditions can be found later in this document in the discussions of §§ 330.205 and 330.208, respectively.

Paragraph (c)(1) of proposed § 330.202 would contain a list of indigenous plant pest species that could be moved interstate within the continental United States without a permit if they were moved from populations located within the continental United States. In assembling the list, we identified organisms for inclusion based on their wide distribution and low plant pest risk; we do, however, welcome any comments on the adequacy of these criteria, whether we accurately applied the criteria in our selection of organisms, and whether there are

additional considerations that should be taken into account. The organisms contained in the list are indigenous bacteria, insects, and viruses that are distributed throughout the continental United States and that are known to commonly accompany plants or plant products moved in interstate commerce. The proposed list of organisms is set out in the regulatory text at the end of this document under § 330.202,

“Requirements for the interstate movement of regulated organisms.” Given the wide distribution of these organisms, we believe that their interstate movement within the continental United States is not likely to result in additional plant pest risks. The proposed list, which is provided for under § 411(c) of the Plant Protection Act, is offered as a means of simplifying the movement of these ubiquitous organisms; we do not consider the list to be comprehensive and fully acknowledge that there may be additional organisms that could be appropriately included on the list. Therefore, we welcome any comments on the composition of the list and any suggestions for additions, deletions, or modifications to its contents. In that vein, we have included provisions in proposed paragraph (c)(2) of § 330.202 for a person to petition APHIS for the addition of species to, or removal of species from, the list of organisms that could be moved within the continental United States without a permit. The petitioner would have to send APHIS detailed information regarding the organism’s distribution and its biological, economic, and environmental significance. If, after reviewing the petition, we determined that it would be appropriate to allow the suggested organism to be moved within the continental United States without a permit, we would publish a proposed rule in the **Federal Register** to amend the list. Any such proposed rule would be supported by analyses documenting our review and consideration of the plant pest risks and potential environmental effects associated with the organism proposed for inclusion on the list.

Just as § 411(c) of the Plant Protection Act provides for the exceptions to the permit requirements for plant pests discussed in the previous paragraph, § 412(g)(1) of that act provides that “[i]n the case of biological control organisms, the Secretary may publish, by regulation, a list of organisms whose movement in interstate commerce is not prohibited or restricted. Any listing may take into account distinctions between organisms such as indigenous,

nonindigenous, newly introduced, or commercially raised.” APHIS, with the cooperation of the other USDA agencies represented on the Department’s Biological Control Coordinating Council (BCCC), is considering what options might be available to further streamline or even eliminate the regulatory requirements that would apply to the movement and environmental release of certain biological control agents. We intend to consult with the other members of the BCCC regarding the criteria that might be used to identify the specific biological control agents that could be considered for expedited approval or exemption from regulatory restrictions; however, we would also like to take this opportunity to solicit suggestions from interested persons regarding the criteria that should be considered in assembling a list of biological control organisms whose movement in interstate commerce is not prohibited or restricted. A suggested starting point for this list is the identification of biological control organisms that have a documented history of release in the United States and no known negative effects on nontarget organisms and the environment. We recognize, though, that additional considerations will likely need to be taken into account in assembling the list, so we encourage the submission of comments and suggestions on this subject.

#### **Requirements for the Release Into the Environment of Regulated Organisms (§ 330.203)**

Although the Federal Plant Pest Act specifically addressed only the importation and interstate movement of plant pests, and not environmental release, the Plant Protection Act (§ 403) includes “to release into the environment” in its definition of “move and related terms.”

Paragraph (a) of proposed § 330.203 would address the environmental release of plant pests. In most cases, the factors that would lead to an organism being considered a plant pest also recommend against that organism being intentionally released into the environment. However, proposed § 330.203(a) would recognize that there are limited circumstances under which a plant pest might be released into the environment. Specifically, proposed § 330.203(a)(1) would provide that any of the plant pests listed in proposed § 330.202(c)(1)—*i.e.*, those ubiquitous, low-risk organisms that could be moved interstate without a permit under that proposed paragraph—may be released into the environment within the continental United States without a

permit if the organism was collected from a population located within the continental United States. As we stated with regard to the interstate movement of those listed organisms, we believe that the wide distribution of these organisms throughout the continental United States makes it unlikely that their environmental release will result in any appreciable additional plant pest risks. Again, we encourage the submission of comments regarding the criteria used in assembling the list and the composition of the list itself. The provisions of proposed § 330.203(a)(1) regarding the release of plant pests without a permit would apply only to those organisms listed in proposed § 330.202(c)(1).

We also recognize that there are circumstances under which the release of other plant pests might be a necessary element of a testing or research protocol. One example of such a situation would be the release of plant pests into a test plot as challenge organisms for a resistant plant variety under development. Therefore, proposed § 330.203(a)(2) would provide that a plant pest not listed in proposed § 330.202(c)(1) may be released into the environment only for research or testing purposes and only if the release is authorized by an APHIS permit and is conducted in accordance with any safeguards assigned as a condition of the permit.

Paragraph (b)(1) of proposed § 330.203 would begin by stating that an agent for the biological control of weeds could be released into the environment in the United States only if the release is authorized by an APHIS permit. The introductory text of proposed § 330.203(b)(1) would also provide that the issuance of a permit would be based on our determination that the host range of the biological control agent is limited to the target weed or an acceptably narrow range of closely related species and upon our determination that the benefits that could be expected to accrue from the release were not outweighed by any significant negative environmental or ecological consequences resulting from the release. Those conclusions would be based on the reviews described below in the discussion of proposed § 330.203(b)(2). The process leading up to the issuance of a permit would ensure that APHIS, in consultation with other Federal and State officials and the applicant, had the opportunity to review the plant pest, environmental, and ecological considerations associated with the proposed release.

Paragraph (b)(1)(i) of proposed § 330.203 would address applications

for a permit to release a biological control agent of weeds that is not indigenous to the United States and that has not previously been released under an APHIS permit. Because the release of such organisms would not have previously been reviewed and approved by APHIS, the applicant would have to address all the data elements contained in proposed §§ 330.205 and 330.206, which are explained later in this document.

Paragraph (b)(1)(ii) of proposed § 330.203 would address permits for the release into the environment of regulated organisms that are native to the United States or that have been introduced (*i.e.*, released into an ecosystem where it did not exist previously) into the United States and have become established (*i.e.*, have formed self-perpetuating populations in the ecosystem into which they were introduced). APHIS’ National Environmental Policy Act (NEPA) implementing procedures in 7 CFR part 372 provide for a categorical exclusion from the requirement for the preparation of an environmental assessment or environmental impact statement for the permitting of the release into a State’s environment of pure cultures of organisms that are either native or established introductions. Therefore, proposed § 330.203(b)(1)(ii) would provide that an applicant for a release permit would not have to address the data elements in proposed § 330.206(h), “Potential environmental impacts,” if the candidate agent was native to, or established in, the State in which it would be released, and would further provide that the environmental assessment required by proposed § 330.203(b)(2)(iv) would not have to be prepared. In addition, it may be that the native or established status of the organism would preclude the need for the applicant to address other specific elements contained in proposed § 330.206 and would allow us to shorten or waive the remaining reviews required under proposed § 330.203(b)(2). Proposed § 330.203(b)(1)(ii) would, therefore, recommend that an applicant for a permit for the environmental release of pure cultures of regulated organisms that are either native or established introductions should consult with APHIS prior to preparing a permit application. This consultation would give APHIS and the applicant an opportunity to review the issues surrounding the proposed release and identify those aspects of the permitting process that could be omitted.

Paragraph (b)(2) of proposed § 330.203 would explain the reviews that would have to be conducted before APHIS

would issue a permit for the release into the environment of an agent for the biological control of weeds.

First, APHIS would request that the interagency Technical Advisory Group for Biological Control Agents of Weeds (TAG) review the proposed release. TAG is an independent, voluntary committee that was first formed in 1957 to provide advice to researchers. In its current role, TAG members review petitions for biological control of weeds and provide an exchange of views, information, and advice to researchers and those in APHIS responsible for issuing permits for importation, testing, and field release of biological control agents of weeds. TAG's membership currently includes Federal representatives from five USDA agencies (APHIS, the Agricultural Research Service, the Forest Service, the Natural Resources Conservation Service, and the Cooperative State Research, Education, and Extension Service), five agencies of the U.S. Department of the Interior (the Bureau of Land Management, the Bureau of Reclamation, the U.S. Fish and Wildlife Service, the National Park Service, and the U.S. Geological Survey), the U.S. Environmental Protection Agency, and the U.S. Army Corps of Engineers, and State officials representing the National Plant Board and the Weed Science Society of America. The TAG review considers the safety of the agent being considered, the potential risks that might be involved in its release, and the long-term ecological consequences of a successful release.

Second, APHIS would review the plant pest risk issues raised by the proposed release. TAG's conclusions regarding the host range of the candidate agent would figure prominently in our determination of whether or not the organism posed a risk of appreciably injuring or causing disease or damage in plants other than the target weed.

Third, APHIS would consult with the U.S. Fish and Wildlife Service to consider the potential effects of the candidate biological control agent on threatened and endangered species.

Finally, APHIS would prepare an environmental assessment of the proposed release as required by NEPA. The environmental assessment would allow us to reach a finding of no significant impact or would lead us to conclude that it was necessary to prepare an environmental impact statement or to deny the permit.

In paragraph (b)(3) of proposed § 330.203, we would encourage prospective permit applicants to contact the Fish and Wildlife Service at as early a stage as possible i.e., upon

identification of the target weed in order to identify possible Endangered Species Act issues that might need to be considered with regard to any program for the control of the target weed. Similarly, we would encourage prospective applicants to contact APHIS for early consultation on complying with NEPA. Engaging in such early consultation prior to applying for a permit would help the applicant and the relevant agencies become familiar with the environmental and endangered species issues surrounding a planned weed control program and would help to avoid the delays that could occur in the event that unexpected issues arose during the permit application review process.

#### **Compliance Agreements and Notification for Importation and Interstate Movement (§ 330.204)**

Proposed § 330.204 would address the purpose of, and procedure for, entering into a compliance agreement, along with the notification process that may be used for the importation and interstate movement of regulated organisms by persons who are operating under a compliance agreement. An applicant could expect to receive a permit for importation or interstate movement anywhere from 15 to 60 days after submitting an application. Under the proposed notification system, a person or facility operating under a compliance agreement would simply have to notify APHIS within 3 days after receiving a shipment of regulated organisms. By providing a mechanism that would allow individuals or facilities to receive advance approval for the importation or interstate movement of specified types of regulated organisms, we anticipate that the proposed notification process would greatly facilitate the movement of regulated organisms. Persons who only occasionally have a need to request a permit for the importation or interstate movement of regulated organisms may find that the permitting process would continue to meet their needs. However, for those individuals or facilities that regularly receive organisms from foreign sources or other States, the time savings that could be realized by entering into a compliance agreement and using the notification process could be substantial.

Paragraph (a)(1) of proposed § 330.204 would explain the considerations discussed in the previous paragraph, i.e., that a person or facility that routinely receives regulated organisms under permit may wish to enter into a compliance agreement in order to facilitate the importation or interstate movement of those organisms. The

paragraph would explain that compliance agreements would be signed by the applicant, APHIS, and the State into which the organisms would be moved, and that entering into a compliance agreement would allow the organisms to be moved under the notification process described in paragraph (b) of proposed § 330.204 rather than under permit.

Paragraph (a)(2) of proposed § 330.204 would explain that a compliance agreement could be arranged by contacting a local office of APHIS Plant Protection and Quarantine (PPQ) or by contacting PPQ's central offices in Riverdale, MD. The terms of the compliance agreement would be prepared with the participation of all parties involved, and would be based on the plant pest risks presented by the specific types of regulated organisms that the applicant would be receiving, the intended use of those organisms, and any safeguarding issues such as the degree of physical and operational security needed to prevent the escape or dissemination of the regulated organisms. The compliance agreement would also spell out the specific requirements for the notification of APHIS when a shipment of regulated organisms was received, the disposition of host material and other media included in the shipment, the handling of regulated organisms while in the facility, and any recordkeeping requirements. Those elements are normally addressed through the assigning of permit conditions under the normal permit issuance process, but no similar opportunity for assigning conditions is practical under the notification process, so it would be necessary to address them in the compliance agreement.

Paragraph (a)(3) of proposed § 330.204 would provide that a person could terminate a compliance agreement at any time by informing APHIS, in writing, of their desire to do so. That paragraph would also provide that APHIS could cancel a compliance agreement if an inspector found that a person had failed to comply with the terms of the compliance agreement or with the regulations. A cancellation could be issued by APHIS either orally or in writing, with an oral cancellation being confirmed in writing as promptly as circumstances allowed. The written cancellation or confirmation would document the reasons for the cancellation. These cancellation provisions would be included to inform the person of the procedure for terminating a compliance agreement and to allow APHIS to terminate the agreement when it is determined that its



provisions, which would have been assigned to prevent the dissemination of plant pests, were not being observed.

Paragraph (b) of proposed § 330.204 would explain the notification process. Paragraph (b)(1) would reiterate who is eligible to use the notification process, i.e., persons who have entered into a compliance agreement with APHIS and their State, and paragraph (b)(2) would set out the requirements for notification. Specifically, APHIS would have to be notified within 3 business days after the regulated organisms were received in the facility, either by mail, fax, or electronic mail; APHIS would acknowledge the notification within 3 business days of its receipt. The notification to APHIS would have to include:

- The recipient's name, organization, and compliance agreement number.
- The date the regulated organisms were received.
- The scientific name(s) of the regulated organisms.
- The life stage(s) of the regulated organisms.
- The total number of regulated organisms received.
- The origin of the regulated organisms.

This information, when combined with the elements recorded in the compliance agreement, would provide APHIS with the same types of data concerning the regulated organisms and their movement as are provided through the standard permitting process provided for under the existing regulations and this proposed rule. While we believe that the amount of information that would be required is appropriate for the purposes of the proposed notification system, we welcome any comments regarding the number and scope of the proposed data elements, as well as any suggestions for alternative ways of implementing the notification process.

#### **Applying for a Permit (§ 330.205)**

Proposed § 330.205 would set out the information that would have to be provided by a person seeking a permit for the importation, interstate movement, or release into the environment of a regulated organism. The section would begin by stating that permit applicants must reside in the United States, as we believe that a permittee must be in a position to directly supervise the handling and use of any regulated organisms for which a permit was issued, and would state that the applicant must supply the information called for in paragraphs (a) through (w) of the section. The information that would have to be

provided is the same as currently required by PPQ Form 526, which is the form that is used as a permit application under the existing regulations. These requirements are set out in the regulatory text at the end of this document under § 330.205, "Applying for a permit." The information requested on the PPQ Form 526 pertains to the regulated organism for which a permit is being sought, its origin and destination, its intended use, the facility in which it would be held, and the port or ports of entry through which the regulated organism would be imported into the United States. A footnote to the introductory text of proposed § 330.205 provides the address to which the completed application must be sent and provides information as to how a person may obtain a PPQ Form 526.

#### **Additional Application Data for Permits for the Environmental Release of Biological Control Agents of Weeds (§ 330.206)**

Proposed § 330.206 would list the additional information (i.e., in addition to the information listed in proposed § 330.205) that would have to be addressed by an applicant seeking a permit for the release into the environment of an agent for the biological control of weeds. This additional information would be necessary for APHIS to fully evaluate the plant pest risk considerations associated with the proposed release and would aid in the development of the documentation needed to address the environmental and endangered species considerations discussed in proposed § 330.203(b)(2). Because, as noted in that section, the interagency Technical Advisory Group for Biological Control Agents of Weeds (TAG) would review the proposed release and its supporting documentation before APHIS would issue its final approval for the release, the information that would have to be provided under proposed § 330.206 is the same as the information called for in the TAG's "A Suggested Format for Field Release Petitions." Although the TAG's information requirements for release petitions are rather lengthy, we believe that reproducing those requirements in the regulations would in the end save applicants time by precluding the need to prepare two sets of documentation, i.e., one set to accompany their permit applications submitted under the proposed regulations and one set to satisfy the needs of the TAG reviewers. The information requested in the TAG petition includes both questions related to the target weed (identity, distribution, impacts, etc.) and questions regarding

the candidate biological control agent (identity, distribution, biology, host specificity, etc.) This two-fold approach is consistent with the approach recommended by the Food and Agriculture Organization (FAO) of the United Nations (UN) in its publication "Code of Conduct for the Import and Release of Exotic Biological Control Agents" (Secretariat of the International Plant Protection Convention, FAO, UN, Publication No. 3, Rome, 1996). In addition, the TAG information requirements contain elements that will allow APHIS to consider the potential environmental effects of the proposed release and prepare the environmental assessment documentation required by NEPA. The consideration of potential environmental effects is also consistent with the approach recommended in the FAO code of conduct. The information requirements for release petitions are set out in the regulatory text at the end of this document under § 330.206, "Additional application data for permits for the environmental release of biological control agents of weeds."

#### **APHIS Review of Permit Applications; Denial or Cancellation of Permits (§ 330.207)**

Paragraph (a) of proposed § 330.207 would address the inspection of the premises where a regulated organism would be held. These proposed provisions are essentially the same as the existing regulations in § 330.202(b), the difference being that proposed § 330.207(a) would include a description of the three general areas that would be considered when APHIS inspected a facility. The current regulations provide that APHIS may inspect the facility where the regulated organisms would be received and handled to determine whether the facility will be adequate to prevent plant pest dissemination; those provisions would also be part of proposed § 330.207(a). Because different regulated organisms will present differing degrees of risk, depending on factors such as their escape potential, biology, and the availability of a suitable habitat in the area surrounding the facility, we believe that it would be counterproductive to attempt to prepare a detailed list of prescriptive requirements for facilities i.e., a "one size fits all" design standard in the context of the proposed regulations. Rather, we have prepared a brief set of performance standards that we would consider to the degree to which they were appropriate to the plant pest risks presented by the particular regulated organism for which the applicant was seeking a permit. (We would, however, include a footnote



regarding the availability of guidelines that describe suggested physical and operational characteristics for facilities.) The performance standards that would be included in § 330.207(a) are:

- *Does the facility have entryways, windows, and other structures, including water, air, and waste handling systems, to contain the regulated organisms and prevent the entry of other organisms and unauthorized visitors?*

This standard would focus on whether the physical structure and features of the facility were sufficient to contain the regulated organism and prevent other organisms or unauthorized persons from gaining access to the regulated organisms, which could increase the risk of plant pest dissemination.

- *Does the facility have operational and procedural safeguards in place to prevent the escape of the regulated organisms and to prevent the entry of other organisms and unauthorized visitors?* This standard is similar to the first, although in this case the focus would be on the non-physical aspects that contribute to the biological security of the facility, i.e., the procedural and operational safeguards that are in place.

- *Does the facility have a means of inactivating or sterilizing regulated organisms and any host material, containers, or other material?* As explained below in the discussion of proposed § 330.208(a), the standard conditions that apply to all permits require the destruction or sterilization of the container in which the regulated organisms were shipped and any accompanying material following the receipt of the organisms, as well as the destruction of the regulated organisms themselves upon completion of their intended use or the expiration of the permit. This standard would ensure that the facility had the means to fulfill those standard permit conditions.

Paragraph (b) of proposed § 330.207 would address the denial of permit applications. The paragraph would provide that APHIS will deny an application for a permit to move or release a regulated organism when we determine that the movement or release would involve a danger of the dissemination of a plant pest. These proposed provisions are the same as those contained in § 330.204(a) of the current regulations, which state that the danger of plant pest dissemination could be deemed to exist under any one of the following circumstances:

- Existing safeguards against plant pest dissemination (e.g., the biosecurity offered by the facility in which the organisms would be held) are inadequate and no adequate safeguards can be arranged.

- The destructive potential of the regulated organism to plants, plant parts, or plant products, should it escape despite the proposed safeguards, outweighs the probable benefits that could be derived from the proposed movement and use of the regulated organism. It is likely that a permit would be denied on this basis in only a few extraordinary cases, such as when a particularly destructive pest was proposed for movement into an area that was ideally suited to sustaining populations of that pest.

- When the applicant, as a previous permittee, failed to maintain the safeguards or otherwise observe the conditions prescribed in a previous permit and has failed to demonstrate the ability or intent to observe them in the future. We must have at least a reasonable expectation that the permittee can and will observe the conditions of the permit; otherwise, the safeguards offered by those conditions would be rendered ineffective.

- The proposed movement of the regulated organism is adverse to the conduct of an eradication, suppression, control, or regulatory program of APHIS. It is likely that this basis for the denial of a permit would not be invoked in the absence of circumstances related to either of the first two bullets above, i.e., those regarding existing safeguards and the destructive potential of the organism.

Paragraph (c) of proposed § 330.207 would address the cancellation of permits that have already been issued. The paragraph would provide that APHIS could cancel a permit if, following its issuance, we received information of circumstances that would have led us to deny the application for that permit, i.e., those circumstances described in the previous paragraph. The paragraph would also provide that APHIS could cancel a permit if the permittee failed to maintain the safeguards or other conditions specified in the permit or in any applicable regulation. These provisions for the cancellation of permits, which are the same as those found in § 330.204(b) of the current regulations, are necessary to mitigate the risk of plant pest dissemination when APHIS determines that our issuance of the permit was based on inaccurate or invalid information or that the permittee is failing to observe the conditions that have been deemed necessary to prevent the dissemination of plant pests.

#### **Permit Conditions (§ 330.208)**

Proposed § 330.208 would explain the standard conditions that would apply to all permits and provide for the inclusion

of special permit conditions when circumstances warranted. This section would also address permits for the movement of regulated organisms through the United States (i.e., transit permits) and the length of time for which permits may be valid.

Specifically, paragraph (a) of proposed § 330.208 sets forth the standard conditions that would apply to all permits that are issued, and would provide that the permit may specify a particular port of entry for the regulated organism. These conditions, which are the same as those that now apply to permits issued under the current regulations, would be included in the regulations as a safeguarding measure to prevent the dissemination of plant pests into the United States or interstate. The standard conditions that would apply to all permits for importation and interstate movement call for:

- The sterilization or destruction of the shipping container and all packing material, media, substrate, and soil after the regulated organisms have been removed from the shipping container. This measure would ensure that the plant pest risks posed by the container and any other associated material is mitigated.

- The regulated organisms to be kept within the laboratory or other designated holding area of the receiving facility, with prior approval from APHIS being required for their removal. This would ensure that the regulated organisms remain in the facility that was approved to receive them or, if necessary, in a facility with comparable security. This measure is necessary because the security offered by the receiving facility would have been one of the factors on which APHIS based its decision to issue a permit.

- Allowing authorized APHIS and State regulatory officials to inspect, without prior notice and during reasonable hours, the conditions under which the regulated organisms are kept. Such inspections by APHIS or its State cooperators may be necessary to ensure that the regulated organisms are being kept under the conditions deemed necessary to mitigate the risk of plant pest dissemination.

- All regulated organisms kept under the permit to be destroyed at the completion of the intended use, and not later than the expiration date of the permit, unless an extension is granted by APHIS before the expiration of the permit. This measure would ensure that any plant pest risk posed by the regulated organisms is eliminated upon the completion of the research project or other activity in which they were being used.

- APHIS to be informed immediately, but no later than 24 hours, after the escape of a regulated organism being detected. This measure reflects basic biosecurity considerations and would ensure that APHIS had the opportunity to take appropriate measures in a timely manner in response to the unintentional release or escape of the regulated organisms.

- Records to be maintained that identify the organisms being held in the facility under the permit, the person from whom they were received, the date the regulated organisms were received at the facility, and the disposition of the organisms. The records would have to be maintained for a period of 1 year following the final disposition of the organisms. During normal business hours, an APHIS inspector would have to be allowed to inspect and copy those records. This recordkeeping measure would be necessary to ensure that the facility operator and, if necessary, APHIS, could track and account for the regulated organisms moved into the facility from another State or country.

Paragraph (b) of proposed § 330.208 would provide that supplemental conditions may be included on the permit. The supplemental conditions, which would be specific to the biology of the organism, the types of activities involved with the movement, or the specific needs of a facility, would be included if APHIS determined that such additional conditions were necessary to mitigate the risk of plant pest dissemination.

Paragraph (c) of proposed § 330.208 would state that permits for the movement of organisms through the United States (i.e., permits for organisms that would transit the United States while moving from one foreign country to another foreign country) will include shipping instructions as to routing, labeling, and similar requirements. Those instructions, which would address any pest risk considerations associated with such a movement, would be included on the permit as supplemental conditions.

Paragraph (d) of proposed § 330.208 would state that the length of a permit's validity will be indicated on the permit, with 10 years being the maximum length of time for which a permit could be valid. We would consider the information supplied by the applicant—especially the information supplied regarding the intended use of the organisms—in order to determine the appropriate length of time for which a permit would be valid. Having the flexibility to assign differing lengths of validity to permits would allow us to take into account the differing needs of

various permit applicants and their projects.

#### **Appealing the Denial or Cancellation of Permits and Compliance Agreements (§ 330.209)**

Proposed § 330.209 would describe the process to be followed when appealing the denial or cancellation of permits and compliance agreements. The appeal process described in proposed § 330.209 is the same as the appeal process that is provided elsewhere in APHIS' regulations for other programs. The current regulations in § 330.204(c) provide only that a person may submit a written request for reconsideration and provide additional information to support the original application; proposed § 330.209 would provide for an expanded appeals process.

Under proposed § 330.209, a person whose permit application was denied or whose permit or compliance agreement was canceled would be promptly informed, in writing, of the reasons for the denial or cancellation. The person would then be able to appeal the denial or cancellation by writing to the Administrator of APHIS. In the written appeal, the person would have the opportunity to provide all of the facts and reasons that he or she was relying upon to show that the permit application was wrongfully denied or the permit or compliance agreement was wrongfully canceled. The Administrator would respond to the appeal as promptly as circumstances allowed, either granting or denying the appeal, and would provide an explanation, in writing, of the reasons for his or her decision. If there was a conflict as to any fact that had a material bearing on the appeal, the person appealing the denial or withdrawal would be entitled to request a hearing to resolve the conflict. During that hearing, the person would have the opportunity to present information supporting the issuance or reinstatement of his or her permit or the reinstatement of his or her compliance agreement. The rules of practice for the hearing, which would be held before a hearing officer, would be adopted by the Administrator.

#### **Packaging of Regulated Organisms (§ 330.210)**

The packaging provisions that are found in §§ 330.210 and 330.210a of the current regulations would be located in § 330.210 of the revised subpart. Like the current regulations, proposed § 330.210 would require that the regulated organisms be packed in a container or combination of containers that will prevent the escape of the

organism, and that the outer container be clearly marked to indicate its contents. Proposed § 330.210 would also restate the provisions of current §§ 330.210 and 330.210a regarding the use of approved packing materials and the need to obtain advance APHIS approval for the inclusion of host material, soil, etc., in a package of regulated organisms. This advance approval continues to be necessary to ensure that APHIS has an opportunity to consider any risks that might be presented by the inclusion of such material in a package of regulated organisms.

#### **Labeling of Regulated Organisms (§ 330.211)**

The labeling provisions that are found in § 330.211 of the current regulations would be located in § 330.211 of the revised subpart. The provisions of proposed § 330.211 would be the same as the existing regulations with one exception, i.e., we would no longer issue labels for the interstate movement of organisms. The purpose of placing the APHIS-issued labels on packages is to clearly indicate that APHIS has issued a permit or otherwise approved the movement of the organisms into the United States, thus preventing delays in the clearance of the organisms by APHIS or U.S. Customs Service inspectors. Because packages of organisms being shipped interstate are not subject to the same APHIS and Customs Service inspection as packages arriving in the United States from outside the country, we do not believe that it is necessary to require their labeling.

#### **Exportation of Organisms From the United States (§ 330.212)**

Proposed § 330.212 would contain information regarding the exportation of organisms from the United States. Although the current regulations in § 330.201(b) require a permit for the interstate movement of plant pests for export, we do not believe that it is necessary to include that requirement in the revised regulations. When we have issued such permits under the current regulations, the only condition of the permit has been that the organisms must be securely packaged in order to prevent their escape during movement to the port of export. We do not believe that a permit is necessary if it simply requires secure packaging; that information could be conveyed in the regulations, so we are proposing to include it in § 330.212. Specifically, § 330.212 would require that anyone shipping regulated organisms to places outside the United States must ensure that the organisms are packaged in

accordance with § 330.210, "Packaging and labeling of regulated organisms."

#### **Executive Order 12866 and Regulatory Flexibility Act**

This proposed rule has been reviewed under Executive Order 12866. The 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 proposed rule would revise the regulations regarding the movement of plant pests by adding risk-based criteria for determining the plant pest status of organisms, establishing a notification process that could be used as an alternative to the current permitting system, providing for the environmental release of organisms for the biological control of weeds, and updating the text of the subpart. These proposed changes are intended to clarify the factors that would be considered when assessing the plant pest risks associated with certain organisms, facilitate the importation and interstate movement of regulated organisms, and address gaps in the current regulations.

This proposed rule would be beneficial from an efficiency standpoint, primarily because it would allow individuals and entities to expedite the movement of regulated organisms. Under the proposed notification process, persons would be allowed—once they entered into a compliance agreement—to move regulated organisms without prior approval from APHIS. Currently, those persons can move regulated organisms of a different species only after applying for and obtaining a permit from APHIS, a process that generally takes about 30 days. An expedited process for moving regulated organisms could prove especially beneficial to those in the scientific and research communities, whose work could be aided or accelerated by the elimination of the time spent waiting for the issuance of a permit. Furthermore, as discussed below, the switch from the current permitting system to the proposed notification process could be accomplished with little or no additional burden on any of the affected parties, i.e., the individuals and entities who move regulated organisms, APHIS, and State agricultural agencies.

For the average affected entity, i.e., a research facility that applies for 20 permits and receives 100 shipments per year, the proposed notification process would pose about the same burden as the current permitting process. We estimate that it would take the average entity about 17 hours per year to

perform the administrative tasks needed to comply with the proposed notification process, assuming one compliance agreement covers all 100 shipments. The 17 hours is comprised of the time spent preparing the compliance agreement itself, as well as the time spent notifying APHIS of each shipment and the time spent preparing labels for each shipment. By comparison, we estimate that it would take the same entity about 18 hours per year to comply with the current permitting process. The 18 hours is comprised of the time spent preparing the 20 permit applications (PPQ Form 526), as well as the time spent preparing an annual summary report of shipments received. (Under the current permitting system, APHIS, not the regulated entity, prepares the shipping labels.) The inspection and documentation requirements would be the same under the current process and the proposed notification process. Persons who move regulated organisms are not charged a fee for obtaining a permit, and they would not be charged a fee for entering into a compliance agreement.

Currently, there are about 50 facilities in the United States that import regulated organisms or move regulated organisms interstate. Of that total, we estimate that about 35 facilities, or 70 percent, would choose to switch to the proposed notification process. The number of organisms moved by the remaining 15 facilities does not appear to be sufficiently high to warrant their interest in the proposed notification system. We estimate about 35 compliance agreements, 3,500 shipment notifications, and 700 fewer permit applications per year if the proposed rule is adopted. Permit applications would decline from 1,000 per year to 300 per year.

We do not believe that an entity's decision to switch from the current permitting system to the proposed notification process would have a significant impact on APHIS and the State agricultural agencies. For the average entity with one compliance agreement covering 100 shipments, we estimate that it would take APHIS and the affected State agency about 18 hours and 4 hours, respectively, per year to perform the administrative tasks needed to complete the compliance agreement and to process the subsequent notifications of individual shipments. By comparison, we estimate that it would take APHIS and the State agency about 18 hours and 3 hours, respectively, per year to perform their tasks under the current permitting process.

This proposed rule would add provisions for the issuance of permits for the release into the environment of biological control agents of weeds. We do not expect that the addition of this permit category would have much of an impact, as the interagency Technical Advisory Group has reviewed environmental release petitions for several years. The proposed provisions would simply serve to standardize the process in that regard.

Also, this proposed rule would revise the regulations by adding risk-based criteria for determining the plant pest status of organisms. This revision should have no cost or workload impact, since it merely serves to formalize what is already being done in practice.

The Regulatory Flexibility Act requires that agencies consider the economic effects of their proposed regulatory changes on small entities (e.g., businesses, organizations, and governmental jurisdictions). The entities most likely to be affected by this proposed rule are research facilities that import and move regulated organisms interstate. These entities would likely benefit from the proposed notification system, as it would allow them to expedite the movement of regulated organisms. By using the proposed notification process, affected facilities would be able to move regulated organisms generally about 30 days sooner than they would under the current permitting process. Furthermore, the switch from the current permitting system to the proposed notification process could be accomplished with no additional burden on the affected facilities.

However, this proposed rule is not expected to affect a substantial number of entities, large or small. We estimate that only about 35 research facilities would choose to switch to the proposed notification process. The economic impact of the proposal is unknown, primarily because the impact of the expedited movement process on affected facilities is difficult to quantify in dollar terms.

The decision by research facilities to use the proposed notification process should not have a significant impact on APHIS and the State agencies, either in terms of increasing their current costs or adding to their current workload. APHIS and the State agencies could not be considered "small entities."

Under the U.S. Small Business Administration's (SBA) standards, firms primarily engaged in commercial physical and biological research (SIC 8731) are considered to be small if they have 500 or fewer employees. Even

though employment data is not available for each of the individuals and other entities that may be affected by this proposed rule, it is reasonable to assume that most are small by SBA standards. SBA data for 1993 shows that of the 3,783 U.S. firms in SIC 8731, 92 percent had fewer than 100 employees.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

#### Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

#### National Environmental Policy Act

We have determined that an environmental assessment is not necessary for these proposed regulations. The proposed regulations are procedural in nature and would not irrevocably commit the Agency to any decision concerning the movement or environmental release of any organisms. When considering an application for a permit to release an organism into the environment under the proposed regulations, an environmental assessment or environmental impact statement would be prepared as part of APHIS' decisionmaking process.

#### 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 proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 95-095-2. Please send a copy of your comments to: (1) Docket No. 95-095-2, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full

effect if OMB receives it within 30 days of publication of this proposed rule.

Under our current regulations, any person who wishes to import, move interstate, or release into the environment an organism subject to APHIS' jurisdiction under the Plant Protection Act must apply for, and be issued, a permit authorizing such a movement or release. In this document, we are proposing to amend our regulations to allow those persons the alternative of entering into compliance agreements with APHIS and the State into which regulated organisms would be moved in order to be eligible to use a notification procedure in lieu of a permit to more easily effect the movement of regulated organisms. We are also proposing to provide specific provisions for the issuance of permits for the release into the environment of agents for the biological control of weeds.

These proposed amendments would require the use of several information collection procedures, including permit applications, compliance agreements, notification, and environmental release petitions. We are asking OMB to approve our use of these information collections in connection with our efforts to ensure that the risks associated with the importation, interstate movement, and release into the environment of regulated organisms could be adequately reviewed and addressed.

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

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

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

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

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

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 0.33769 hours per response.

*Respondents:* Persons wishing to import regulated organisms into the United States, move regulated organisms interstate, or release agents for the biological control of weeds into the environment.

*Estimated annual number of respondents:* 2,500.

*Estimated annual number of responses per respondent:* 2.478.

*Estimated annual number of responses:* 6,195.

*Estimated total annual burden on respondents:* 2,092 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained by calling Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

#### List of Subjects in 7 CFR Part 330

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

Accordingly, we propose to amend 7 CFR part 330 as follows:

#### PART 330—FEDERAL PLANT PEST REGULATIONS; GENERAL; PLANT PESTS; SOIL, STONE, AND QUARRY PRODUCTS; GARBAGE

1. The authority citation for part 330 would continue to read as follows:

**Authority:** 7 U.S.C. 450, 2260, 7711, 7712, 7714, 7718, 7731, 7734, 7751, and 7754; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.3.

2. The title of part 330 would be amended by removing the words "PLANT PESTS;" and adding the word "ORGANISMS;" in their place.

3. In Subpart—General Provisions, § 330.100 would be revised to read as follows:

##### § 330.100 Definitions.

The following definitions apply for the purposes of this part:

##### *Administrative instructions.*

Published documents relating to the enforcement of the regulations in this part, issued under authority of such regulations by the Administrator.

*Administrator.* The Administrator of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or any employee of the U.S. Department of Agriculture delegated to act in his or her stead.

*APHIS.* The Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

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

*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.

*Customs.* The U.S. Customs Service of the U.S. Treasury Department, or, with reference to Guam, the Customs office of the Government of Guam.

*Department.* The U.S. 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.

*Earth.* The softer matter composing part of the surface of the globe, in distinction from the firm rock, and including the soil and subsoil, as well as finely divided rock and other soil formation materials down to the rock layer.

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

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

*Inspector.* A properly identified employee of the U.S. Department of Agriculture or other person authorized by the Department to enforce the provisions of the Plant Protection Act and related legislation, quarantines, and regulations.

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

*Means of conveyance.* Any personal property used for or intended for use for the movement of any other personal property.

*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 agent (including a carrier), having responsible custody of a plant pest, means of conveyance, product or article subject to the regulations in this part.

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

*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 a tree, a tissue culture, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a bulb, a root, and a seed.

*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 those articles. (For the purposes of the regulations in §§ 330.200 through 330.212 of this part, "plant pest" does not include any organism that has been genetically engineered as defined in § 340.1 of this chapter.)

*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 Act.* Title IV of Public Law 106-224, 114 Stat. 438, 7 U.S.C. 7701-7772, which was enacted June 20, 2000.

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

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

*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 loose surface material of the earth in which plants grow, in most

cases consisting of disintegrated rock with an admixture of organic material and soluble salts.

*State.* Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

*Through the United States.* From and to places outside the United States.

*United States.* All of the States.

4. Subpart—Movement of Plant Pests, §§ 330.200 through 330.212, including the title of the subpart, would be revised to read as follows:

#### **Subpart Movement and Release of Organisms Under the Plant Protection Act**

Sec.

- 330.200 What organisms are regulated under this subpart?
- 330.201 Requirements for the importation of regulated organisms.
- 330.202 Requirements for the interstate movement of regulated organisms.
- 330.203 Requirements for the release into the environment of regulated organisms.
- 330.204 Compliance agreements and notification for importation and interstate movement.
- 330.205 Applying for a permit.
- 330.206 Additional application data for permits for the environmental release of biological control organisms for the control of noxious weeds.
- 330.207 APHIS review of permit applications; denial or cancellation of permits.
- 330.208 Permit conditions.
- 330.209 Appealing the denial or cancellation of permits and compliance agreements.
- 330.210 Packaging of regulated organisms.
- 330.211 Labeling of regulated organisms.
- 330.212 Exportation of organisms from the United States.

#### **§ 330.200 What organisms are regulated under this subpart?**

(a) *Plant pests.* The importation, interstate movement, and release into the environment of any plant pest will be subject to the restrictions of §§ 330.201, 330.202, and 330.203(a). The following factors will be considered when assessing the plant pest status of an organism:

- (1) *Direct effects.* An organism directly injures or causes disease or damage in plants, plant parts, or plant products when it:
  - (i) Reduces the yields, vigor, or viability of living plants by feeding on, infecting, parasitizing, or contaminating plants or plant parts or by vectoring agents of plant diseases; or
  - (ii) Reduces the quality or marketability of plant products such as stored grain, stored fruit, or lumber by

feeding on, infecting, or contaminating the plant products.

(2) *Indirect effects.* An organism indirectly injures or causes disease or damage in plants, plant parts, or plant products when the organism causes losses in yields of crops or forage plants or reduces the viability or vigor of ornamental or native plants by adversely affecting organisms that are beneficial to plants. Of primary concern are organisms that are:

(i) Pathogens, predators, or parasites (except autoparasitoids) of important natural enemies of plant pests or weeds; or

(ii) Pathogens, predators, or parasites of important or commercially available pollinators such as honeybees, bumble bees, and alkali bees.

(b) *Biological control organisms for the control of noxious weeds.* The importation, interstate movement, and release into the environment of any biological control organism for the control of noxious weeds will be subject to the restrictions of §§ 330.201, 330.203(b), and 330.204.

(c) *Imported biological control organisms for the control of plant pests; other imported organisms.* (1) The importation of any organism, including any biological control organism for the control of plant pests, that meets any of the following criteria will be subject to the restrictions of § 330.201:

(i) It is a field-collected organism that, in natural conditions, is associated with plant pests and there is reason to believe that the plant pests could be shipped with the field-collected organisms; or

(ii) It is a laboratory-reared organism that is provided with plant pests as host material during rearing or shipment; or

(iii) The organism will be shipped with plant material or soil; or

(iv) The organism has not been positively identified.

(2) If an organism that meets any of the criteria of paragraph (c)(1) of this section is imported in accordance with this subpart, the organism may be moved interstate without any further restriction under this subpart if it is positively identified, determined not to be a plant pest, and is separated from any associated plant pests, plant material, soil, and other media.

#### **§ 330.201 Requirements for the importation of regulated organisms.**

You may import an organism regulated under this subpart into the United States if APHIS determines that the importation can be accomplished in a manner that will prevent the dissemination of plant pests that are new to or not widely distributed in the United States. An importation may be

accomplished through notification (see paragraph (a) of this section) or under permit (see paragraph (b) of this section). All imported regulated organisms must be labeled in accordance with § 330.211. Nonviable biological specimens of plant pests, in preservative or dried, may be imported without further restriction under this subpart, but will be subject to inspection upon arrival in the United States to confirm the nature of the material and its freedom from risk of plant pest dissemination.

(a) *Through notification.* If you have entered into a compliance agreement with APHIS and the State where the regulated organisms will be received, you may import regulated organisms without a permit, provided that you notify APHIS upon receipt of the regulated organisms. The provisions of this subpart regarding compliance agreements and the requirements for notification are found in § 330.204.

(b) *Under permit.* If you wish to import regulated organisms without entering into a compliance agreement with APHIS and your State, you may apply for a permit to import a regulated organism. APHIS uses the information you provide in a permit application to identify the plant pest risks associated with the regulated organism and its importation. A permit issued for the importation of a regulated organisms may include requirements that APHIS determines are necessary to mitigate the identified risks. Instructions for applying for a permit are found in § 330.205.

#### **§ 330.202 Requirements for the interstate movement of regulated organisms.**

You may move an organism regulated under this subpart from one State into or through another State if APHIS determines that the interstate movement can be accomplished in a manner that will prevent the dissemination of plant pests that are new to or not widely distributed in the United States. An interstate movement may be accomplished through notification or under permit or, under certain limited circumstances, without a permit:

(a) *Through notification.* If you have entered into a compliance agreement with APHIS and the State where the regulated organisms will be received, you may move regulated organisms interstate without a permit, provided that you notify APHIS upon receipt of the regulated organisms. The provisions of this subpart regarding compliance agreements and the requirements for notification are found in § 330.204.

(b) *Under permit.* If you wish to move regulated organisms interstate without

entering into a compliance agreement with APHIS and your State, you may apply for a permit for the interstate movement of a regulated organism. APHIS uses the information you provide in a permit application to identify the plant pest risks associated with the regulated organism and its interstate movement. A permit issued for the interstate movement of a regulated organism may include requirements that APHIS determines are necessary to mitigate the identified risks. Instructions for applying for a permit are found in § 330.205.

(c) *No permit necessary.* (1) Certain indigenous plant pest species are distributed throughout the continental United States and are known to commonly accompany plants or plant products moved in interstate commerce. Given the wide distribution of these organisms, we have determined that their interstate movement within the continental United States is not likely to result in additional plant pest risks. Therefore, the following organisms may be moved within the continental United States without a permit if they are moved from populations located within the continental United States:

#### **Bacteria**

*Agrobacterium radiobacter*  
*Agrobacterium tumefaciens*  
*Bacillus subtilis*  
*Bradyrhizobium* spp.  
*Erwinia amylovora*  
*Erwinia carotovora* subsp. *atroseptica*  
*Erwinia carotovora* subsp. *betavascularum*  
*Erwinia carotovora* subsp. *carotovora*  
*Erwinia chrysanthemi*  
*Pseudomonas syringae* pv. *glycinea*  
*Pseudomonas syringae* pv.  
*morsprunorum*  
*Pseudomonas syringae* pv. *phaseolicola*  
*Pseudomonas syringae* pv. *syringae*  
*Pseudomonas syringae* pv. *tomato*  
*Rhizobium* spp.  
*Xanthomonas campestris* pv. *glycines*  
*Xanthomonas campestris* pv. *phaseoli*  
*Xanthomonas campestris* pv. *vesicatoria*

#### **Insects**

*Acanthoscelides obtectus*  
*Acheta domesticus*  
*Actias luna*  
*Antheraea polyphemus*  
*Blatella germanica*  
*Blatella vaga*  
*Bombyx mori*  
*Brachystola magna*  
*Callosobruchus maculatus*  
*Citheronia regalis*  
*Eacles imperialis*  
*Ephestia kuehniella*  
*Gromphadorhina portentosa*

*Hyalophora cecropia*  
*Hyalophora euryalus*  
*Hyles lineata*  
*Manduca sexta*  
*Manduca quinquemaculata*  
*Microcentrum retinerve*  
*Microcentrum rhombifolium*  
*Periplaneta americana*  
*Sitophilus granarius*  
*Sitophilus oryzae*  
*Sitotroga cerealella*  
*Tenebrio molitor*  
*Tenebrio obscurus*  
*Trialeurodes vaporariorum*  
*Trilobium castaneum*  
*Trilobium confusum*  
*Vanessa atalanta*  
*Vanessa cardui*  
*Vanessa virginiensis*  
*Zoophobas morio*

#### Viruses

Tobacco Mosaic Virus

(2) You may petition APHIS to add species to, or remove species from, the list of organisms that may be moved within the continental United States without a permit. The petition must include detailed information as to the organism's distribution and its biological, economic, and environmental significance and must be submitted to Permits and Risk Assessment, PPQ, Vanessa virginiensis APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236.

#### § 330.203 Requirements for the release into the environment of regulated organisms.

(a) Environmental release of plant pests. The release into the environment of plant pests is prohibited except under the following circumstances:

(1) A plant pest that is listed in § 330.202(c)(1) may be released into the environment within the continental United States without a permit if the organism was collected from a population located within the continental United States.

(2) A plant pest that is not listed in § 330.202(c)(1) may be released into the environment in the United States only for research or testing purposes and only if the release is authorized by an APHIS permit and is conducted in accordance with any safeguards assigned as a condition of the permit. Instructions for applying for a permit are found in § 330.205.

(b) *Environmental release of organisms for the biological control of weeds.* (1) A biological control organism for the control of noxious weeds may be released into the environment in the United States only if the release is authorized by an APHIS permit. APHIS will issue a permit based on its

determination that the host range of the biological control organism is limited to the target weed or an acceptably narrow range of closely related species, and upon our determination that the benefits that could be expected to accrue from the release were not outweighed by any significant negative environmental or ecological consequences resulting from the release.

(i) *Unprecedented releases of nonindigenous organisms for the biological control of weeds.* If the organism you wish to release into the environment for the biological control of a weed is a nonindigenous organism that has not previously been released under an APHIS permit, you must address all the data elements contained in §§ 330.205 and 330.206.

(ii) *Releases of organisms that are native to the United States or that are established introductions.* APHIS' National Environmental Policy Act Implementing Procedures in part 372 of this chapter provide for a categorical exclusion from the requirement for the preparation of an environmental assessment for the permitting of the release into a State's environment of pure cultures of organisms that are either native or established introductions. Therefore, if you are applying for a permit to release an agent for the biological control of weeds and that agent is native to, or established in, the State into which it will be released, it will not be necessary for you to address the data elements contained in § 330.206(h), "Potential environmental impacts," and the review required under paragraph (b)(2)(iv) of this section will be waived. In addition, the native or established status of the organism may preclude the need for you to address other specific elements contained in § 330.206 and the reviews required under paragraph (b)(2)(i) through (b)(2)(iii) of this section may be abbreviated or waived. Therefore, we recommend that you consult with APHIS prior to preparing an application for a permit for the environmental release of biological control agents of weeds that are either native or established introductions.

(2) *Levels of review.* A petition for a permit to release an agent for the biological control of weeds will be reviewed at four levels before a permit may be issued:

(i) APHIS will request that the interagency Technical Advisory Group for Biological Control Agents of Weeds (TAG) review the proposed release. TAG review will consider the safety of the agent, the potential risks that might be involved in its release, and the long-

term ecological consequences of a successful release.

(ii) APHIS will review the plant pest risk issues raised by the proposed release.

(iii) APHIS will consult with the U.S. Fish and Wildlife Service in order to consider the potential effects of the agent on threatened and endangered species.

(iv) APHIS will prepare an environmental assessment of the proposed release, if required.

(3) *Early consultation.* With regard to the reviews described in paragraphs (b)(2)(iii) and (b)(2)(iv) of this section, we encourage you to contact the U.S. Fish and Wildlife Service as early a stage as possible—i.e., upon identification of the target weed—in order to identify possible Endangered Species Act issues that might need to be considered with regard to any program for the control of the target weed. Similarly, we encourage you to contact APHIS for early guidance on complying with the National Environmental Policy Act. Engaging in such early consultation prior to applying for a permit will help you and the relevant agencies become familiar with the environmental and endangered species issues surrounding a planned weed control program and may help to avoid the delays that could occur should unexpected issues arise during the review of your permit application.

#### § 330.204 Compliance agreements and notification for importation and interstate movement.

(a) *Compliance agreements.* (1) If you routinely receive regulated organisms under permit, you may wish to enter into a compliance agreement in order to facilitate the importation or interstate movement of those organisms. Entering into a compliance agreement, which will be signed by you, APHIS, and the State into which the regulated organisms are moved, will allow the organisms to be moved under the notification process described in paragraph (b) of this section rather than under permit.

(2) *Arranging a compliance agreement.* You may request a compliance agreement by contacting a local office of APHIS Plant Protection and Quarantine (which are listed in local telephone directories) or by contacting Permits and Risk Assessment, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236. The terms of the compliance agreement, which will be prepared with the participation of all parties involved,



will be based on the plant pest risks presented by the specific types of regulated organisms you wish to receive in your facility and the intended use of those organisms, and will address safeguarding issues such as the degree of physical and operational security needed to prevent the escape or dissemination of the regulated organisms. The compliance agreement will also include provisions for the notification of APHIS when you receive a shipment of regulated organisms, the disposition of host material and other media included in the shipment, the handling of regulated organisms while in your facility, and recordkeeping.

(3) *Cancellation of a compliance agreement.* You may terminate your compliance agreement at any time by informing APHIS, in writing, of your desire to do so. APHIS may cancel your compliance agreement if an inspector finds that you have failed to comply with the terms of the compliance agreement or the regulations in this subpart. You may be notified of the cancellation either orally or in writing. An oral cancellation will be confirmed in writing as promptly as circumstances allow. The written cancellation or confirmation will document the reasons for the cancellation.

(b) *Notification for the importation and interstate movement of regulated organisms.*

(1) *Eligibility.* You may use the notification process described in this paragraph for the importation and interstate movement of regulated organisms only if you are operating under a valid compliance agreement with APHIS and your State as provided for under paragraph (a) of this section.

(2) *Notification process.* (i) You must notify APHIS within 3 business days after your receipt of a regulated organism. You must provide the notification to APHIS through one of the following means:

(A) By mail to Permits and Risk Assessment, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236; or

(B) By facsimile at (301) 734-8700; or  
(C) By electronic mail to Notification@aphis.usda.gov.

(ii) In your notification, you must provide the following information:

(A) Your name, organization, and compliance agreement number.

(B) The date you received the regulated organisms.

(C) The scientific name(s) of the regulated organisms.

(D) The life stage(s) of the regulated organisms.

(E) Total number of regulated organisms received.

(F) Origin of the regulated organisms.  
(iii) APHIS will acknowledge your notification within 3 business days of its receipt.

#### **§ 330.205 Applying for a permit.**

To apply for a permit, you must be a U.S. resident and you must supply, either on a completed PPQ Form 526 or in some other written form, the following information:<sup>1</sup>

(a) *Applicant information.* Your name, title, organization, address, telephone number, facsimile number, and electronic mail address (provide all that are applicable).

(b) *Application type.* New permit, permit renewal, or amendment to existing permit (if a renewal or amendment, provide the current permit number).

(c) *Type of movement.* Importation, interstate movement, or environmental release. (See § 330.206 for additional information that is required if your application is for a permit for the environmental release of a biological control organism for the control of noxious weeds.)

(d) *Scientific name of organism.* Genus, species, and author (if known).

(e) *Type of organism.* Invertebrate animal, parasitic plant, plant pathogen, entomopathogen, other (specify).

(f) *Taxonomic classification.* Fungi—class. Insects, nematodes, and plants—family.

Mites—order and family. Mollusks—order. Viruses—general group (e.g., geminivirus, baculovirus, potyvirus, etc.). Bacteria—not applicable.

(g) *Life stage(s).* Invertebrate animals—eggs, juvenile, larvae, nymphs, pupae, adults. Fungi—spores, mycelia, fruiting bodies. Plants—seeds, whole plants, plant parts (specify parts, e.g., leaves, stems, fruits, etc.). Bacteria and viruses—not applicable.

(h) Number of shipments.

(i) Number of specimens or cultures per shipment.

(j) Is the organism established in the United States?

(k) Is the organism established in the destination State?

(l) Major hosts(s) of the organism.

(m) Media or species of host material accompanying the organism.

(n) *Source of organism (include any that apply, and list country or State of origin).* Supplier (provide supplier's name and address and catalog number of organism), wild collected, reared

<sup>1</sup> Mail your completed application to Permits and Risk Assessment, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236. A PPQ Form 526 may be obtained by writing to the same address, or by calling toll-free (877) 770-5990, or by faxing your request to (301) 734-8700.

under controlled conditions, or culture or seed collection.

(o) *Method of shipment.* Air mail, air freight, express delivery (list company name), baggage, auto.

(p) Port(s) of entry.

(q) Approximate date(s) of initial import or movement.

(r) *Destination.* Provide the address of the location where the organism will be received and maintained.

(s) If you are applying for a permit for release into the environment, provide the name, address, telephone number, and affiliation of the species determiner.

(t) Proposed date and method of environmental release or final disposal.

(u) *Intended use (include any that apply).* Release into the environment, inoculation or propagation on plants, educational display, laboratory use, culture collection, greenhouse or growth chamber use, other (describe).

(v) Has your facility been inspected by APHIS or by your State? If yes, list date(s) of approval. Is your facility approved for the species of organism for which you are seeking a permit?

(w) Provide your signature and the date of your signature under the following certification: "I certify that all statements and entries I have made on this document are true and accurate to the best of my knowledge and belief. I understand that any intentional false statement or misrepresentation made on this document is a violation of law and punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both. (18 U.S.C. 1001)."

#### **§ 330.206 Additional application data for permits for the environmental release of biological control organisms for the control of noxious weeds.**

As stated in § 330.203(b), when applying for a permit for the release into the environment of a biological control organism (agent) for the control of a noxious weed, you must submit a petition that will be reviewed by the interagency Technical Advisory Group for Biological Control Agents of Weeds (TAG). The information requested in this section is designed to gather information concerning the safety of the agent being considered, the potential risks that might be involved in its release, and the long-term ecological consequences of a successful release. It is recognized that for some situations, you will provide more information, while for others not all points will be addressed. (See § 330.203(b)(3) for guidance regarding early consultation.)

(a) *Cover page.* Prepare a cover page for the petition with the following information. This information provides TAG with a contact point for questions and with references for tracking.

(1) Date of petition and mailing.  
 (2) Name of petitioner with affiliation and a contact point within North America including an address, telephone number, fax, and e-mail address.

(3) Nature of the petition: Proposed field release of a [identity of biological control agent] of a [identity of target weed(s)]. Include species, genus, family, order, author, and geographical origin.

(4) Where have the studies been conducted?

(5) If at least part of the study has been conducted in a U.S. quarantine facility, then list the location of the quarantine facility. Also list the quarantine facilities the candidate agents intend to pass through for initial releases. Note that different quarantines are required for insects and pathogens.

(6) Identify the State(s) for the initial release.

(7) Who will conduct the release and monitoring in the United States?

(b) *Petition introduction.* (1) *Nature of the problem.* Give a brief summary (one to two paragraphs) of the problem caused by the weed. Topics to consider including in the summary are as follows:

(i) History of introduction and/or spread of the target weed.

(ii) The weed's present distribution in North America.

(iii) Sectors affected and magnitude of program (e.g., agricultural, natural, rangeland).

(iv) Pending issues about the taxonomy of the candidate agents or the target weeds, or about the agents, or about the location of the release.

(2) *Proposed action.* Provide a statement of proposed action. For example, to introduce a [biological control agent] from [a foreign area] for field release in [a specific area] to control [target weed] in [State(s)].

(3) *Target weed information.* (i) *Taxonomy.* (A) Full classification, synonymy, and common name including species, genus, family, and order.

(B) Who identified the target weed including names, organizations, and locations.

(C) Problems in identification or taxonomy of the group.

(D) Origin and location of herbariums containing voucher specimens, and the date of depository. (The voucher specimens referred to here are the ones used as representative of the population that occurs in the area where the researcher has conducted the studies.)

(ii) *Description.* Provide a general description of the target weed, complete enough that a person encountering it in the field could identify it.

(iii) *Distribution of the target weed.*

Describe the distribution of the target weed using maps, as appropriate.

Include the following information:

(A) Native range (map).

(B) Areas of introduction throughout the world (map), pattern of movement, and apparent limits.

(C) North American distribution (map).

(D) Range areas of the present distribution and the potential spread in North America (a map is useful).

(E) Genetic variability.

(F) Habitats or ecosystems where this weed is found in North America.

(iv) *Taxonomically related plants.*

Identify economically and environmentally important plants that are closely related to the target weed. These are crops, ornamentals, and native plants including threatened and endangered species and those with cultural or aesthetic value. If possible, identify how closely these plants relate to the target weed.

(v) *Distribution of taxonomically related plants.* Describe the distribution and habitats in North America of the closely related plants identified in paragraph (b)(3)(iv) of this section.

(vi) *Life history.* Explain the life history and general biology of the target weed. Discuss the factors that are believed to contribute to the plant's weediness.

(vii) *Impacts.* Indicate any and all impacts. Use the following list as a guide; not all areas listed below are applicable to all petitions:

(A) Beneficial uses (honey bees, forage, ground cover, fruit, etc.).

(B) Social and recreational uses (value as ornamentals).

(C) Impact on threatened and endangered species.

(D) Economic losses, including direct control costs.

(E) Health (poisonous, allergenic, etc.).

(F) Regulatory (noxious weed, restricts trade, etc.).

(G) Effects on native plant and animal populations.

(H) Impact of weed control on nontarget plants.

(I) Effects on ecosystem functions and ecological relationships.

(J) Other impacts (e.g., aesthetic).

(viii) *Alternative management options.* Describe alternative options for managing the target weed.

(A) Historical options (what has been done before and effectiveness).

(B) Current options (biological, chemical, cultural, etc., and effectiveness).

(C) Potential options (new herbicides or biological control agents used or released in other countries).

(c) *Biological control agent*

*information.* (1) *Taxonomy.* (i) Full classification (species, genus, family, and order), synonymy, and common name. (For pathogens, include strain, race, type.)

(ii) Reason for choosing the agent and a general description of the agent including helpful morphology and general characteristics that could be used to identify it in the field.

(iii) The taxonomist who identified the agent, including names and organizations with locations.

(iv) For pathogens, description of the methods used to identify life stages.

(v) Problems in identification or taxonomy of the genus.

(vi) Origin and locations of voucher specimens for insects (or type cultures for pathogens) including date of depository, and how they are preserved.

(2) *Geographic range.* (i) Origin (maps and literature citations describing the native range of the agent).

(ii) If the agent is being used in other countries, give countries of introduction and present range and effects.

(iii) Expected attainable range in North America (based on climatic, environmental, and vegetative parameters).

(3) *Known host range (specificity).* (i) Literature records indicating what other plants have been attacked.

(ii) Field collections and observations, including maps and data.

(iii) Literature on the host range (specificity) of organisms closely related to the agent, no matter where the organism occurs.

(4) *Life history.* (i) Biology, i.e., diapause, life cycle, dispersal capability, etc. from literature, field observations, and laboratory studies.

(ii) Known mortality factors.

(iii) Extent of damage or control of the target weed.

(iv) Extent of damage or control of nontarget plants.

(5) *Population of the agent studied.* (i) Geographical source, including maps and site description, if available. Be as accurate as possible so that the same population could be located, if needed.

(ii) How pest-free populations of the agents were obtained and maintained in quarantine, if applicable.

(iii) Site of field and lab studies (the location if in a foreign country, if available), or the location of U.S. quarantine facility used.

(6) *Experimental methodology and analysis.* A test plant list shows the species of host plants on which the agent was tested to determine its potential feeding range. List the test plants and provide the rationale for selecting them. Include considerations

given to threatened and endangered plant species and economically important plants. A suggested format for test plant lists may be obtained by writing to Permits and Risk Assessment, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236 or by calling (301) 734-8896.

(i) *Design of tests:*

(A) Part or stage of plants tested.

(B) Source of population of plant (and weed) used in test.

(C) Number of replicates.

(D) Number of individual agents, target weeds, and test plants in each replicate. May be synonymous with number of replicates depending on test design (i.e., in no-choice tests, the number of individual plants of a species is the number of replicates).

(E) Describe how results were measured, recorded, and evaluated.

(F) If the weed has been targeted previously, compare this design with previous test designs including plant species tested.

(ii) *Positive controls.* Were adequate positive controls used in all tests? For example, the target weed should be challenged with the agent during each testing procedure (except in no-choice testing for insects).

(iii) *Reason for decisions.* Explain why you selected the test procedures and how they are appropriate for the biology of the agent being tested.

(d) *Summary of results.* Provide a summary about the safety of this organism as a biological control agent and any risk associated with its release. Include literature, results of host specificity testing, and field observations. Present results in a manner that supports your conclusion (tables, graphs, narratives).

(e) *Protocol for releasing the agent.* (1) Method to ensure pure cultures and correct identification of the agent to be released, including:

(i) For insects: species, genus, family, and order (for pathogens: strain, race, type);

(ii) Names and organizations with locations of identifier;

(iii) Description of identification methods;

(iv) Problems in identification; and

(v) Date and place of depository containing voucher specimens.

(2) General release protocol to ensure the absence of natural enemies and cryptic or sibling species.

(3) Specific location of rearing or culturing facility.

(4) Intended sites for initial release, timing of release, release methods to be used. For insects, number to be released, if known. For pathogens, method of preparing inoculum and inoculum concentration.

(f) *Post-release monitoring.* Provide an explanation of the post-release monitoring plan. Include the following information:

(1) When the anticipated initial release of the agents will occur.

(2) Groups to best perform monitoring.

(3) Monitoring techniques to determine if the agents become established.

(4) Monitoring techniques to determine the spread and impact on target and nontarget plants.

(g) *Benefits and risks.* Offer your perspective about weighing the probable benefits of releasing the agent against the unknowns and possible negative impacts.

(h) *Potential environmental impacts.* Discuss the potential ecological, economic, social, biological, health regulatory, and environmental impact. Present as clear a picture as possible of the long-term ecological consequences that could possibly result from the successful establishment of this agent in the North American environment. This information should go beyond the risk associated with attack on a few closely related species of plants, as indicated in the host testing results. This discussion should look at the overall potential impact of populations of this insect building up on the weed in a large variety of different habitats. This information will be critical in preparing an environmental assessment, which will be the next step in the approval process if the TAG recommends that this agent should be released in North America. (**Note:** The elements contained in this paragraph do not need to be addressed for the proposed release into a State's environment of pure cultures of organisms that are either native or established introductions. See § 330.203(b)(1)(ii).) Impacts to be considered include:

(1) *Human impacts.* Include positive and negative impacts to humans. For example, health, recreational, aesthetics, nuisance, poisonous, allergens. Discuss ways to overcome negative effects.

(2) *Potential economic impacts.* Provide the potential gains and losses regarding the ecological, social, aesthetic, and biological impacts.

(3) *Plant impacts.* Describe the direct and indirect impacts (positive and negative) of the organism on the local plant populations. Cover the intended effects on the target weed and on nontargets, including potential impacts on agricultural, horticultural, and threatened and endangered plants.

(4) *Non-plant impacts.* Describe the indirect effects (positive and negative) on organisms (other than plants) that

depend directly or indirectly on the target weed or affected nontarget plants based on test results.

(5) *Proposed methods for mitigation.* Identify proposed methods

(management and other alternatives) to mitigate potentially undesired effects.

(6) *Abiotic and edaphic effects.*

Identify the potential abiotic and edaphic effect, i.e., water, soil, air.

(7) *Outcome of no action.* Provide a statement of the outcome if no release was made.

(i) *Petitioner's conclusion.* Offer your conclusions on the potential risks and benefits regarding the consequences of the release of this agent and its successful establishment in the North American environment throughout the range of its target weed and susceptible nontarget hosts. Summarize all the results of your study of this agent, its host testing, and your evaluation of the potential environmental impact. Include a quantitative risk assessment, if available.

**§ 330.207 APHIS review of permit applications; denial or cancellation of permits.**

(a) *Inspection of premises.* APHIS may inspect the facility where you are proposing to receive and handle regulated organisms to determine whether the facility will be adequate to prevent plant pest dissemination. When inspecting your facility, we will consider the following areas to the degree to which they are appropriate to the plant pest risks presented by the particular regulated organism for which you are seeking a permit:<sup>2</sup>

(1) Does the facility have entryways, windows, and other structures, including water, air, and waste handling systems, to contain the regulated organisms and prevent the entry of other organisms and unauthorized visitors?

(2) Does the facility have operational and procedural safeguards in place to prevent the escape of the regulated organisms and prevent the entry of other organisms and unauthorized visitors?

(3) Does the facility have a means of inactivating or sterilizing regulated organisms and any host material, containers, or other material?

(b) *Denial of permits.* APHIS will deny an application for a permit to move or release an organism regulated under this subpart when, in its opinion, such movement would involve a danger

<sup>2</sup> Guidelines describing suggested physical and operational characteristics for facilities may be obtained by writing to Permits and Risk Assessment, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236, or by calling (301) 734-8896, or by faxing your request to (301) 734-8700.

of dissemination of a plant pest. Danger of plant pest dissemination may be deemed to exist when:

(1) Existing safeguards against plant pest dissemination are inadequate and no adequate safeguards can be arranged; or

(2) The destructive potential of the regulated organism to plants, plant parts, or plant products, should it escape despite the proposed safeguards, outweighs the probable benefits that could be derived from the proposed movement and use of the regulated organism; or

(3) When you, as a previous permittee, failed to maintain the safeguards or otherwise observe the conditions prescribed in a previous permit and have failed to demonstrate your ability or intent to observe them in the future; or

(4) The proposed movement of the regulated organism is adverse to the conduct of an eradication, suppression, control, or regulatory program of APHIS.

(c) *Cancellation of permits.* APHIS may cancel any outstanding permit whenever:

(1) We receive information subsequent to the issuance of the permit of circumstances that would constitute cause for the denial of an application for permit under paragraph (b) of this section; or

(2) You, as the permittee, fail to maintain the safeguards or otherwise observe the conditions specified in the permit or in any applicable regulations.

#### **§ 330.208 Permit conditions.**

(a) If your permit application is approved, APHIS will issue a permit that will include any requirements that are, in the opinion of APHIS, necessary to prevent the dissemination of plant pests into the United States or interstate. The permit may specify a particular port of entry through which the regulated organism must enter the United States. The following standard conditions will apply to all permits for importation and interstate movement:

(1) After receiving the regulated organisms and removing them from their shipping container, you must immediately sterilize or destroy the shipping container and all packing material, media, substrate, and soil;

(2) You must keep the regulated organisms within the laboratory or other designated holding area at your facility and may not remove them without prior approval from APHIS;

(3) You must allow authorized APHIS and State regulatory officials to inspect, without prior notice and during reasonable hours, the conditions under which the regulated organisms are kept;

(4) You must destroy all regulated organisms kept under the permit at the completion of the intended use, and not later than the expiration date of the permit, unless an extension is granted by APHIS before the expiration of the permit;

(5) In the event of an escape of the regulated organisms, you must inform APHIS immediately, but no later than 24 hours after detecting the escape; and

(6) During the time that the regulated organisms are held in your facility, you must maintain records that identify the organisms, the person from whom you received them, the date the regulated organisms were received at your facility, and the disposition of the organisms. You must maintain those records for a period of 1 year following the final disposition of the regulated organisms. During normal business hours, you must allow an APHIS inspector to inspect and copy those records.

(b) Supplemental conditions may be included on the permit specific to the biology of the organism, the types of activities involved with the movement, or the specific needs of a facility.

(c) Permits authorizing movement of organisms through the United States (i.e., transit movement) will include shipping instructions as to routing, labeling, and similar requirements. Those instructions will be included on the permit as supplemental conditions.

(d) The length of a permit's validity will be indicated on the permit. Permits may be valid for a maximum duration of 10 years.

#### **§ 330.209 Appealing the denial or cancellation of permits and compliance agreements.**

If your permit application has been denied or your permit or compliance agreement has been canceled, APHIS will promptly inform you, in writing, of the reasons for the denial or cancellation. You may appeal the decision by writing to the Administrator and providing all of the facts and reasons upon which you are relying to show that your permit application was wrongfully denied or your permit or compliance agreement was wrongfully canceled. The Administrator will grant or deny the appeal as promptly as circumstances allow and will state, in writing, the reasons for the decision. If there is a conflict as to any material fact, you may request a hearing to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator.

#### **§ 330.210 Packaging of regulated organisms.**

(a) When moving a regulated organism, you must pack the organism

in a container or combination of containers that will prevent the escape of the organism, and the outer container must be clearly marked to indicate its contents.

(b) Only approved packing materials may be used in a shipment of regulated organisms.

(1) The following materials are approved as packing materials: Absorbent cotton or processed cotton padding free of cottonseed; cellulose materials; excelsior; felt; ground peat (peat moss); paper or paper products; phenolic resin foam; sawdust; sponge rubber; thread waste, twine, or cord; and vermiculite.

(2) Other materials, such as host material for the organism, soil, or other types of packing material, may be included in a container only with the advance approval of APHIS.

#### **§ 330.211 Labeling of regulated organisms.**

If you are importing a regulated organism through the mail or through commercial express delivery, you must attach a special mailing label, which APHIS will provide with your permit or compliance agreement, to the container. The mailing label will indicate that the shipment of regulated organisms has been authorized by APHIS. If regulated organisms arrive in the mail without a mailing label, an APHIS inspector may refuse to allow the organisms to enter the United States.

#### **§ 330.212 Exportation of organisms from the United States.**

If you are shipping regulated organisms to destinations outside the United States, the organisms must be packaged in accordance with § 330.210 to prevent their escape during movement.

Done in Washington, DC, this 1st day of October 2001.

**Bill Hawks,**

*Under Secretary for Marketing and Regulatory Programs.*

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## **DEPARTMENT OF TRANSPORTATION**

### **Federal Aviation Administration**

#### **14 CFR Part 39**

[Docket No. 98-NM-36-AD]

RIN 2120-AA64

#### **Airworthiness Directives; Lockheed Model L-1011-385 Series Airplanes**

**AGENCY:** Federal Aviation Administration, DOT.