Act: "Any living stage of any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts of parasitic plants, viruses, or any organisms similar to or allied with any of the organisms previously identified in this definition, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or plant parts, or any processed, manufactured, or other products of plants."

We would define *release into the environment* as "the use of a regulated organism outside the constraints of physical confinement." Given the nature of many regulated organisms, we believe that it is necessary to treat any use of a regulated organism outside of the constraints of physical confinement, such as those found in a laboratory or greenhouse, as a release into the environment.

Regulated Organisms (§ 335.2)

Paragraph (a)(1) of proposed § 335.2 contains a list of taxonomic groups that include known plant pest species. We have reason to believe that other species within those taxonomic groups may also be plant pests; therefore, we believe that nonindigenous organisms within those taxonomic groups should be evaluated prior to their introduction into the United States. The list was drawn from a similar list contained in 7 CFR part 340 and was developed based on APHIS' experience with issuing plant pest permits. (The list in proposed § 335.2(a)(1) differs from the list in 7 CFR part 340 in two respects. First, parasitic weeds of the species Alectra are included on the list in 7 CFR part 340 but have been omitted from the list in proposed § 335.2(a)(1) because Alectra spp. are listed noxious weeds in 7 CFR 360.200. The second respect in which the two lists differ is that the list in proposed § 335.2(a)(1) contains additional taxonomic groups under the class Insecta. These additional groups, which are listed below, were included on the list in proposed § 335.5(a)(1) based on APHIS' experience with issuing plant pest permits:

Family Aphelinidae Family Braconidae Genus Perilitus Family Diapriidae Genus Ismarus Family Encyrtidae Family Eulophidae Family Ichneumonidae Subfamily Cryptinae Subfamily Diplazontinae Subfamily Gelinae Subfamily Mesochorinae Subfamily Ephialtinae Family Pteromalidae Family Scelionidae Genus Gryon Genus Scelio Family Signiphoridae Family Trichogrammatidae

If the list in proposed $\S 335.2(a)(1)$ is adopted and a person believes that an

organism should be added to the list, that person could petition APHIS for a change in the regulations under the Administrative Procedure Act (5 U.S.C. 553(e)) and the USDA's regulations in 7 CFR part 1.

The taxonomic scheme used in proposed § 335.2(a)(1) is a five-kingdom system, found in S.P. Parker's "Synopsis and Classification of Living Organisms" (McGraw Hill, 1984). Within each taxon, all nonindigenous species are regulated organisms, unless there are taxa of lower rank specifically listed, in which case only those specifically listed, lowerranked taxa are regulated organisms. Other classified organisms not listed are not regulated organisms.

We believe that organisms that are currently unclassified or whose classification is unknown should be evaluated prior to their introduction into the United States because of the possibility that the organisms contain plant pests or are themselves plant pests; therefore, such organisms would also be regulated organisms under § 335.2(a)(2).

As mentioned above, the proposed regulations would not supplant our existing plant pest regulations in 7 CFR 330.200. Additionally, there are other organisms covered elsewhere in existing regulations that would also remain regulated under the existing regulations. To make that clear, paragraph (b) of proposed § 335.2 would specify that the following categories of organisms would continue to be regulated under their existing regulations: Live bees other than honeybees of the genus Apis regulated under 7 CFR 319.76; plant pests regulated under 7 CFR 330.200; live honeybees of the genus Apis regulated under 7 CFR part 322; organisms genetically engineered through recombinant DNA techniques regulated under 7 CFR part 340; noxious weeds regulated under 7 CFR part 360; organisms and vectors that may introduce or disseminate contagious animal diseases regulated under 9 CFR part 122; and etiologic microorganisms that cause disease in humans (including bacteria, bacterial toxins, viruses, fungi, rickettsia, protozoans, arthropods, parasites, and the hosts and vectors that may carry these etiological microorganisms) that are regulated by

the Centers for Disease Control and Prevention under 42 CFR part 71, unless the microorganism, host, or vector could also be a plant pest.

General Restrictions on the Introduction of Regulated Organisms (§ 335.3)

This section of the proposed regulations prohibits the introduction of any regulated organism unless the regulated organism is introduced in accordance with the proposed regulations. This means that a regulated organism may not be imported, moved interstate, or released into the environment unless APHIS has given its authorization to do so. Under the proposed regulations, that authorization would entail the issuance of a permit for the introduction in accordance with proposed § 335.4. The permit application process is discussed in detail below.

Section 335.3 of the proposed regulations also provides that any introduction of a regulated organism that is not in compliance with the provisions of the proposed regulations makes that regulated organism subject to destruction, disposal, or the remedial measures that the Administrator determines to be necessary to prevent a plant pest from being introduced into, or disseminated within, the United States.

We believe that these restrictions on the introduction of regulated organisms are necessary to prevent the introduction and dissemination within the United States of plant pests.

Permits for the Introduction of Regulated Organisms (§ 335.4)

Section 335.4 of the proposed regulations sets forth the proposed process by which a person may obtain a permit from APHIS for the introduction of a regulated organism. The section also sets forth the procedure that would be followed by APHIS in response to the receipt of a permit application and the appeal procedure that would be available in the event of APHIS' denial of a permit application or revocation of a permit.

Proposed paragraph (a) provides that an application for a permit must be submitted to the Administrator in care of Biological Assessment and Taxonomic Support (BATS), which is the staff within APHIS that would be responsible for the processing of permit applications submitted under the proposed regulations. The application would have to state the type of permit being requested by the applicant (import, interstate movement, or release into the environment). Although the mailing address of BATS is provided in

5290