ensure that the introduction of regulated organisms would be conducted under conditions that prevent the introduction and dissemination of plant pests; that desired level of safety could not be reached if a regulated organism was introduced contrary to the conditions of the permit or the proposed regulations. If a person believed that a permit was wrongfully revoked or a permit application was wrongfully denied, that person could appeal to the Administrator, in writing. The appeal process is set forth in paragraph (h) of proposed § 335.4.

Paragraph (i) of proposed § 335.4 would require the person to whom a permit for the introduction of a regulated organism has been issued to maintain records for 10 years that identify the regulated organism as specifically as it can be determined, identify the characteristics of the regulated organism, and state the disposition of the regulated organism. Proposed paragraph (i) provides that an APHIS inspector shall be allowed access to records required to be maintained under the proposed paragraph for inspection and copying during normal business hours. The proposed requirement that the records be kept for 10 years following the issuance of a permit is based on APHIS' belief that most projects involving the introduction of a regulated organism would have been completed by that time, or that substantial information regarding the biology and potential effects on the environment of the regulated organism would have been obtained within 10 years. This information would provide APHIS with data regarding the nature of the organism that may have a bearing on APHIS' review of subsequent applications to introduce the same or similar organisms.

Nonindigenous Organisms Exempted From Regulation Under This Part (§ 335.5)

The taxa listed in § 335.2(a) include species that are known plant pests, which gives us reason to believe that other species within those taxa may be plant pests. However, some taxa may also include species that present no significant plant pest risk and could safely be introduced into the United States without restriction. Therefore, § 335.5 of the proposed regulations provides a process by which a person could request that a taxon of nonindigenous organism be exempted from regulation under proposed part 335.

Under proposed § 335.5(a), exemptions could be obtained for the introduction of a regulated organism into the entire United States, the continental United States (the conterminous 48 States and Alaska), Hawaii, Puerto Rico, the Northern Mariana Islands, or an individual U.S. territory or possession, or a combination thereof.

Paragraph (b) of proposed § 335.5 sets forth the information that would have to be submitted to the Administrator with a person's request to have a regulated organism exempted from regulation:

(1) The name, address, telephone number, and facsimile number of the person submitting the request;

(2) The scientific name, common name, and any other information that serves to identify the regulated organism as specifically as possible (including the subspecies, race, and strain of the regulated organism) that the person believes should be exempted from regulation under this part and a description of the methods used to establish the identity of the regulated organism;

(3) A description of the life cycle, biology, and ecology of the regulated organism;

(4) Whether the regulated organism has been genetically modified (if so, include a description of the genetic modification);

(5) The established range of the regulated organism in the United States;

(6) Whether the regulated organism has been released into the environment in the area or areas of the United States for which the exemption is being requested and, if so, the location and date of the release;

(7) A description of all testing and review that has been conducted to assess the effects of the regulated organism on the environment;

(8) The effect of the regulated organism on the environment in its established range;

(9) The host specificity of the regulated organism under both artificial and natural conditions;

(10) References to any published and unpublished documents that support the information required by paragraphs (b)(1)(ii) through (b)(1)(ix) of this section. If available to the applicant, copies of any unpublished referenced documents must be attached to the application; and

(11) A list of at least three universities, museums, scientific societies, or other organizations that maintain collections of organisms to which specimens of the regulated organism have been submitted, and the identification numbers assigned to the specimens.

Ten of these 11 data elements are similar to those found in paragraphs (b)

and (e) of proposed § 335.4, which contain the data elements that must be addressed in an application for a permit to release a regulated organism into the environment. The eleventh proposed element (a list of at least three universities, museums, scientific societies, or other organizations that maintain collections of organisms to which specimens of the regulated organism have been submitted, and the identification numbers assigned to the specimens) would provide a reference for APHIS and is also proposed as a permit condition for the release of a regulated organism into the environment in proposed § 335.6(c). These 11 data elements are intended to provide APHIS with information necessary to assess the environmental and plant pest risks associated with exempting a nonindigenous organism from regulation under proposed part 335.

Proposed § 335.5(b)(2) provides that after receiving a request for exemption, APHIS would conduct a review to determine whether the request for an exemption contained all the information required by proposed § 335.5(b)(1). This review would be completed within 30 days of APHIS' receipt of the request for an exemption. Upon completion of that review, we would inform the person requesting the exemption of the date the request was received, which would be the date that the review period had commenced (or, if the request was incomplete, what additional information was needed). Once the request for exemption is complete, APHIS would commence its review of the request. When the request contains all the information required by proposed § 335.5(b)(1), we believe that a 120-day review period—which is proposed in § 335.5(b)(2)—would be sufficient for APHIS to thoroughly examine all aspects of the request for an exemption.

If, based upon its review of the request, APHIS finds that exempting the regulated organism from regulation would not present a significant plant pest risk, APHIS would publish a notice of proposed rulemaking in the Federal **Register**, proposing to add the organism to the list of regulated organisms exempted from the regulations in proposed part 335. If the public comments do not contain any supportable information that indicate the organism should not be exempt from regulation under proposed part 335, a final rule adding the organism to the list of exempted nonindigenous organisms would be published in the Federal Register.