The additional data requirements for applications to release a regulated organism into the environment are:

19. The purpose of the release into the environment of the regulated organism. This information would be used by APHIS during its preparation of an environmental assessment.

20. The anticipated date(s) of the release into the environment of the regulated organism. This information would be used to determine the possible effects on nontarget species that may be particularly susceptible or exposed to the regulated organism at the time of its release into the environment.

21. A description, including methods of release and release site(s), of the intended release into the environment of the regulated organism. The method of release may impact the risk presented by the regulated organism to the environment or plants, and APHIS may specify conditions on a permit to mitigate that risk. The locations of planned release sites would be needed to facilitate the evaluation of future applications for releases of regulated organisms into the environment at the same sites in the future.

22. A description of all testing and review that has been conducted to assess the effects of the regulated organism on the environment. This data element would be used to help APHIS evaluate whether sufficient testing and review to determine the potential environmental effects of a regulated organism had been conducted prior to issuing a permit for release into the environment. If the regulated organism is to be used as a biological control agent, any testing and review that has been conducted to assess the effects of the biological control agent on nontarget organisms must be described.

23. The effect of the regulated organism on the environment in its established range. This information would be used to help APHIS evaluate the anticipated effects, including potential effects on threatened and endangered species, of releasing the regulated organism into the environment. These effects may include destruction or lessening of the aesthetic, recreational, or commercial value of the environment, including threatened and endangered species. If APHIS determined that there would be negative effects on the environment or on threatened or endangered species, APHIS would report that information to the proper Federal authorities.

24. The host specificity of the regulated organism under both artificial and natural conditions. This information would help focus APHIS' investigation of the nontarget effects of

the regulated organism. Of particular interest to APHIS would be the regulated organism's potential effects on any biological control agents that already might be in use in the area of the proposed release. This data element, as well as those data elements dealing with the regulated organism's effects on nontargets and the environment, would help APHIS address that concern.

25. References to any published and unpublished documents that support the information required by paragraphs (e)(4), (e)(5), and (e)(6) of this section. If available to the applicant, copies of any unpublished referenced documents must be attached to the application. If the application contains information that is supported by available literature, it would be useful for APHIS to review that literature to assess plant pest risk and potential environmental effects. APHIS could reasonably expect to have access to any published material cited in the application, but the unpublished documents available to the applicant must be attached to the application.

Facility and Release Site Inspection

Paragraph (f) of proposed § 335.4 would provide that the Administrator may inspect the facility into which a regulated organism proposed for importation or interstate movement would be moved to determine whether the procedures, processes, and safeguards at the facility meet the requirements of proposed § 335.7. Similarly, the Administrator would be allowed to inspect the site where a regulated organism would be released into the environment so that a determination could be made as to the effects on the environment of the proposed release of the regulated organism.

Administrative Action on Applications

Paragraph (g) of proposed § 335.4 would provide that a permit would be either issued or denied upon completion of APHIS' review of the

application.

If a permit is issued, it would be numbered and would specify the conditions that would apply to the introduction of the regulated organism. There may be considerations based on the particular characteristics of a regulated organism that APHIS would take into account when determining the length of time for which a permit would be valid. Thus, to allow both APHIS and the permittee the greatest degree of flexibility, all permits would not be valid for the same predetermined length of time; rather, the length of a permit's validity would be based on the circumstances of that particular

introduction. Therefore, we are proposing that a permit could be valid for as long as 10 years following the date of issuance, unless the permit was revoked in accordance with proposed § 335.4(h). The expiration date would be specified on the permit.

Proposed paragraph (g)(2) states that if a permit is denied, the applicant would be promptly informed, in writing, of the reasons the permit was denied and given the opportunity to appeal the denial in accordance with proposed § 335.4(h).

A permit application would be denied to an applicant from whom a permit had been revoked within the past 12 months due to the failure of the applicant or the applicant's agents or employees to comply with the proposed regulations or any condition specified on the permit, unless the permit has been reinstated upon appeal. We believe that this provision is necessary to ensure that applicants who have had a permit revoked for cause are not able to immediately reapply for a new permit. We believe this would discourage violations of the regulations and would help advance the effectiveness of the permit system as a means of excluding plant pests from the United States.

Proposed paragraph (g) would further provide that a permit would be denied if an APHIS inspector is not allowed to inspect the facility into which a regulated organism proposed for importation or interstate movement would be moved or the site where a regulated organism is proposed to be released into the environment. In order to prevent or mitigate the potential plant pest risks that may be associated with an introduction, we believe that it is essential that APHIS have the opportunity to assess the conditions under which a regulated organism would be held after movement or released into the environment.

A permit would also be denied if the Administrator determines, based on a review of the available information, that the introduction of the regulated organism would present a significant risk of plant pest dissemination and that no adequate safeguards could be arranged to mitigate the risk presented by the proposed introduction.

Denial or Revocation of Permit; Appeals

Proposed paragraph (h) would provide that APHIS may revoke a permit that has already been issued if the conditions of the permit or any part of the proposed regulations were violated by the person to whom the permit was issued, or his or her agents or employees. We believe that the proposed regulations are necessary to