DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. APHIS–2008–0023]

RIN 0579–AC31

Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; notice of public forums.

SUMMARY: We propose to revise our regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms in order to bring the regulations into alignment with provisions of the Plant Protection Act. The revisions would also update the regulations in response to advances in genetic science and technology and our accumulated experience in implementing the current regulations. This is the first comprehensive review and revision of the regulations since they were established in 1987. This rule would affect persons involved in the importation, interstate movement, or release into the environment of genetically engineered plants and certain other genetically engineered organisms.

DATES: We will consider all comments that we receive on or before November 24, 2008. We will also consider comments made at public forums to be held in Davis, CA; Kansas City, MO; and Riverdale, MD.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0023* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2008–0023, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0023.
- *Public Forums.* Written and oral comment will be accepted at three public forums held during the comment period. See *Public Forums* below.

Reading Room: 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.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–5710.

For information about the public forums, contact: Dr. T. Clint Nesbitt, BRS, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1238; (301) 734–5673.

SUPPLEMENTARY INFORMATION:

Public Forums

In order to provide additional opportunities for the public to comment on the proposed rule, APHIS will hold public forums in three locations: Davis, CA; Kansas City, MO; and Riverdale, MD (see *Meeting Locations* below). These informal forums are designed to engage interested individuals from the public and elicit comments related to the proposed rule. The format will consist of informational posters and comment stations. Attendees will be able walk through the forum during the open hours and interact with other attendees and APHIS personnel. Short welcoming remarks will be given by APHIS personnel at 4:30 p.m. and again at 6 p.m. (local time), but there is no set schedule for each poster station, so the public may come and go at any time during the forum period. Participants will have the opportunity, if desired, to record brief oral comments with a court reporter or to submit comments in writing, following directions provided at the comment stations. A transcript of the oral comments and a copy of any written comments submitted at the public forums will be placed in the rulemaking record and will be available for public inspection.

The purpose of these public forums is to allow the public a venue in which to interact with APHIS representatives and to allow APHIS to solicit further information from the public. Comments received at these public forums will be added to this Docket.

Dates: The public forums will be held in Davis, CA, on October 28, 2008; in Kansas City, MO, on October 30, 2008; and Riverdale, MD, on November 13, 2008. Each public forum will be held from 4 p.m. to 7 p.m., local time.

Meeting Locations: The public forums will be held at the following locations:

USDA Riverside, Oklahoma City Memorial Conference Rooms B, C, and D, 4700 River Road, Riverdale, MD, 20737. For directions or facilities information, call (301) 734–8010.

Walter A. Buehler Alumni & Visitors Center, Alpha Gamma Rho Hall, University of California, Davis, CA, 95616. For directions or facilities information, call (530) 754–9195 or visit *http://www.alumnicenter.ucdavis.edu/*.

Hilton Kansas City Airport, Shawnee Room A, 8801 NW 112th Street, Kansas City, MO, 64153. For directions or facilities information, call (816) 891–8900 or visit *http://www.hiltonkci.com/*.

Table of Contents

I. Introduction

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) regulates the safe introduction (environmental release, interstate movement, and importation) of certain genetically engineered (GE) organisms under its regulations in 7 CFR part 340. The regulations govern the introduction of GE organisms that might be plant pests. APHIS has amended the regulations several times in an effort to respond to the need for streamlined procedures and has established clear procedures to remove GE organisms that do not pose a plant pest risk from obligations under the regulation.

The APHIS regulations have been used most frequently for permits and notifications for importation, interstate movement, or environmental releases of GE plants, although a smaller number of permits have been issued for GE microorganisms and insects. To date, APHIS has authorized more than 13,000 environmental releases of GE plants, most of which have been part of the development of improved crop varieties for agriculture. These controlled environmental releases are sometimes referred to as field tests or field trials, in recognition of their relationship to field tests done in the traditional development of plant varieties, and in this document the terms field test or field trial should be understood to mean environmental release. In addition to permits and notifications, APHIS has completed reviews in response to petitions requesting nonregulated status under these regulations. To date, APHIS has granted 74 determinations of nonregulated status, and all of these have been for GE plants (more information about these is posted at *http://www.aphis.usda.gov/brs/not_reg.html*). Many of these plants have since been used to develop plant varieties that have become part of the options that growers have for agricultural production in the United States and other countries. The APHIS determinations of nonregulated status have been for the GE plant(s) and their progeny. The GE plant with nonregulated status can be used subsequently in plant breeding programs or in agriculture just like other plant lines. A GE plant that has received nonregulated status can be bred with another GE plant with nonregulated status, and the resulting progeny which could contain multiple GE traits still retains nonregulated status.

The bulk of APHIS-authorized introductions have been crop plants bearing genes which confer resistance to certain insects or tolerance to certain herbicides. Although the current program has been effective in ensuring the safe environmental release, interstate movement, and importation of certain genetically engineered organisms, technological advances have led to new uses and questions about how the current regulations and APHIS authorities will be used to maintain appropriate oversight. Advances in technology have created possibilities for new and different traits, such as those that would produce a compound for pharmaceutical or industrial use. In addition, researchers have been producing organisms that may not fall under the scope of our current regulations and are also beginning to focus more on perennial plants, such as grasses or trees, which may be capable of establishing and persisting outside the site of introduction.

APHIS is proposing to revise its regulations in order to respond to emerging trends in biotechnology, to address the current and future needs of the agency, to continue to ensure a high level of environmental protection, to improve regulatory processes so that they are more transparent to stakeholders and the public, to more efficiently use agency resources and to eliminate unnecessary regulatory burdens.

Given the diversity of U.S. agriculture, the USDA Advisory Committee on Biotechnology and 21st Century Agriculture recently in its March 2008 consensus report encouraged the continuing support of coexistence among various agricultural production systems in U.S. agriculture. APHIS concludes that the changes it is proposing will continue to support coexistence in U.S. agriculture.

In addition, APHIS is proposing changes to the regulations to reflect provisions of the 2008 Farm Bill recently enacted. Section 10204 of Title X of the Food, Conservation, and Energy Act of 2008 (Farm Bill) requires the Secretary of Agriculture to take action on each issue identified in the document entitled ''Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework,'' and where appropriate, promulgate regulations. APHIS is proposing certain regulatory changes concerning permit application information requirements, permit conditions, records, and reports that address many of the considerations outlined in Section 10204.

APHIS is also aligning this proposed rule with recommendations arising from the 2005 audit of the USDA Office of Inspector General entitled ''Controls Over Issuance of Genetically Engineered Release Permits.''

II. Background

A. APHIS Role in Federal Regulation of Genetically Engineered Organisms

Under the Coordinated Federal Framework for Regulation of Biotechnology,[1] USDA works with the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) to ensure that the development and testing of biotechnology products occur in a manner that is safe for plant and animal health, human health, and the environment. USDA and EPA are the agencies responsible for protecting U.S. agriculture and the environment. EPA is responsible for the human health, animal health, and environmental safety issues raised by any pesticidal substance produced in genetically engineered (GE) organisms. FDA has authority over the safety of the whole food product other than the pesticidal components regulated by EPA.

B. Current Regulations in 7 CFR Part 340

APHIS administers regulations in 7 CFR part 340, ''Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests'' (referred to below as the regulations). The current regulations govern the introduction (importation, interstate movement, or release into the environment) of certain GE organisms termed ''regulated articles.'' Regulated articles are essentially GE organisms which might pose a risk as a plant pest.

APHIS first promulgated these regulations in 1987 under the authority of the Federal Plant Pest Act of 1957 (FPPA) and the Plant Quarantine Act of 1912 (PQA), two acts that were subsumed into the Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) in 2000, along with other provisions.

Under the current regulations, a GE organism is a regulated article if it is a plant pest or if the Administrator has reason to believe it is a plant pest; more specifically:

[1] The Coordinated Framework is described in a notice published in the **Federal Register** on June 26, 1986 (51 FR 23302). The notice may be viewed at *http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.*

''if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator determines is a plant pest or has reason to believe is a plant pest.'' (Definition of *regulated article,* § 340.1)

In other words, APHIS regulates the introduction (importation, interstate movement, and environmental release) of GE organisms if (1) any of the recipient, genetic donor, or vector organisms are plant pests or of unknown classification or (2) the Administrator has determined or has reason to believe the GE organism is a plant pest. As constructed the regulations apply to GE microorganisms, insects, and other traditional types of plant pests and to any GE plants if plant pest organisms (bacterial and viral plant pathogens) are the donor organisms and vector agents used in the creation of these GE plants.

Taxa containing ''known plant pests'' are those listed in current § 340.2. Current regulations also include a petition procedure (§ 340.5) which allows petitioners to ask APHIS to add or subtract taxa from the list in § 340.2. That list has not been amended since it was established in 1987.

As defined under the current regulations and the PPA, most plants are not plant pests, with the exception of a few parasitic plant species, such as striga, witchweed, and dodder.

The primary procedure for regulation under the PPA is the issuance of a permit, which is an authorization by the Secretary to move plants, plant products, biological control organisms, plant pests, noxious weeds, or articles under conditions prescribed by the Secretary. The PPA also authorizes the Secretary to determine which classes of the above articles must have a permit to be moved. Conditions associated with those permits can be tailored to achieve the appropriate level of regulatory control to make it unlikely that actions under the permit would result in the introduction or dissemination of a plant pest or noxious weed.

APHIS currently uses a permit and notification system to authorize importation, interstate movement and release into the environment (currently referred to as ''introductions'') of certain GE organisms. Under the current regulations, all regulated articles are eligible for the permitting procedure, but only certain plants are eligible for the notification procedure. Currently, most regulated GE plants are introduced under notification, which is a streamlined procedure. Examples of GE plants introduced under the notification procedure are those GE plants altered to be resistant to certain insects or herbicides. GE plants that do not meet the notification eligibility criteria and all other GE organisms, such as microbes and insects, must be introduced under the permit procedure in current § 340.4. In recent years, APHIS has processed most notifications and permits through its electronic, e-permitting system that is accessible by the internet at *http://www.aphis.usda.gov/permits/learn_epermits.shtml*.

In making a regulatory determination for a permit or notification for a GE organism subject to the part 340 regulations, APHIS makes such a determination on whether the actions under notification or permit are unlikely to result in the introduction or dissemination of a plant pest. This determination takes into account various risk factors, including, among other things, a low risk that the GE organism or its progeny can persist, reproduce, and establish without human assistance. Other risk factors that would support an ''unlikely'' determination would be minimal availability of suitable hosts or habitats for the organism and low risk that the organism may cause damage to plants and plant products.

Regarding the risk of introduction or dissemination of the GE organism as a plant pest, an ''unlikely'' determination takes into consideration both the nature of the organism (i.e., low risk that the organism or its progeny can persist, reproduce, establish, and spread without human assistance) *and* any additional mitigations that are placed upon the organism that restrict its movement and make its unauthorized introduction or dissemination unlikely.

The notification procedure was first added to the regulations in 1993, and then amended in 1997 to allow a broader range of plant species to be eligible for the procedure. The notification procedure was designed to be a streamlined procedure with the eligibility criteria and performance standards already built into the regulations. Over the past decade, APHIS has typically authorized 700–1200 notifications per year.

As part of the notification procedure, applicants must adhere to performance standards set forth by APHIS for proper confinement of the GE plants. The goal of proper confinement is to ensure that the GE plants do not persist in the environment. Under the notification procedure applicants provide information about the introduction sufficient for APHIS to evaluate eligibility for the procedure and impacts on the environment. This information includes information on the plant species, introduced gene(s), location(s), and anticipated time frame for the introduction.

For notifications, the eligibility criteria and the performance standards stated in the regulations must be met, but APHIS does not prescribe how the performance standards must be met. For example, one of the performance standards in § 340.3(c)(5) requires that ''The field trial must be conducted such that (i) The regulated article will not persist in the environment, and (ii) No offspring can be produced that could persist in the environment.'' The responsible person might meet this standard in a field trial by isolating the regulated GE plants at a sufficient distance to preclude gene flow from the GE plant to sexually compatible plants in the vicinity. Another design protocol might meet the same performance standard by planting the GE plant at a time in the growing season when surrounding plants of the same species would not be biologically capable of being fertilized by pollen from the GE plant (temporal isolation).

The regulations in current § 340.3(e) specify that the APHIS notification procedure must be completed within 30 days for environmental release and importations and within 10 days for the interstate movement of a regulated article. If APHIS completes the review process and finds that all regulatory requirements have been met, the notification is authorized in a process termed ''acknowledgement,'' and the applicant can proceed with the introduction under the terms of the notification. Notifications are valid for one year from the date of introduction.

Approximately 10% of APHIS authorizations are done under the permitting procedure. The permitting procedure, found in § 340.4 of the current regulation, describes the types of permits, information required for permit application, the standard permit conditions, and administrative information (e.g., time frames, appeal procedure, etc.). Permits include specific conditions that must be followed by the permit holder. Standard permit conditions are listed in the regulation, and APHIS can supplement these with additional conditions as necessary. The current regulations specify the amount of time that APHIS is allotted for review of complete permit applications: 60 days for permits for importation and interstate movement; 120 days for environmental release.

Some regulated articles are conditionally exempt from the requirement for permits when moved interstate under the conditions stipulated in the regulation. Conditional exemptions currently exist in the regulations for the interstate movement of certain GE bacteria (*Escherichia coli, Bacillus subtilis*), fungi (*Saccharomyces cerevisiae*), as well as the plant species *Arabidopsis thaliana.* APHIS established these conditional exemptions from interstate movement permit by amending the regulations in 1988 and 1990.

APHIS forwards the applications for all permits, and notifications, with any confidential business information redacted, to State regulators in the States to which regulated articles will be moved and/or in which environmental release is planned. This is done to notify States of the requested action and to allow States to review and comment on proposed releases or importations or movements.

The current regulations also include various provisions and prescribed standards for containers, marking, and identity that apply to shipments of regulated articles. For example, there are instructions regarding how to label containers of imported regulated articles with the nature of the contents, origin and destination, and other information, and detailed instructions on what materials (plastic, metal, etc.) and dimensions may be used for containers of regulated articles.

Under the current regulations, APHIS may also grant ''nonregulated status'' to a GE organism in accordance with the procedure described in § 340.6. A determination of nonregulated status means that the organism is no longer subject to the part 340 regulations, and therefore there is no longer any requirement for APHIS authorization under part 340 for a permit or notification when the GE organism is imported, moved interstate, or released into the environment.

C. Plant Protection Act Authority to Regulate Plant Pests, Noxious Weeds, and Biological Control Organisms

Under the provisions of the PPA, Congress has granted the Secretary of Agriculture authority to develop regulations in order to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests or noxious weeds. The PPA grants the Secretary authority to regulate the movement into and through the United States of any plant, plant pest, plant product, biological control organism, noxious weed, article, or means of conveyance, in order to prevent the introduction or dissemination of *plant pests* and *noxious weeds.*

The current regulations were promulgated under former statutes, i.e., the FPPA and PQA, which provide USDA authority to regulate articles that present a risk of *plant pest* introduction or dissemination. In addition to the provisions of the FPPA and PQA, the PPA incorporates authority that previously was under the Noxious Weed Act of 1974. In order to best evaluate the risks associated with these GE organisms and regulate them when necessary, APHIS needs to exercise its authorities regarding noxious weeds and biological control organisms, in addition to its authority regarding plant pests.

The definition of plant pest in the PPA is broad and includes living organisms that could directly or indirectly injure, damage, or cause disease in any plant or plant product (7 U.S.C. § 7702(14)). Under the PPA, organisms which could be plant pests include:

- Protozoans
- Non-human animals
- Parasitic plants
- Bacteria
- Fungi
- Viruses or viroids
- Infectious agents or other pathogens
- Any article similar to or allied with any of the above articles.

The definition of noxious weed in the PPA includes:

> * * * 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. (PPA § 7702(10))

An important distinction between noxious weeds and plant pests is that noxious weeds under the PPA are always plants or plant products. Plant pests are usually not plants (with the exception of certain parasitic plants such as dodder, striga, and witchweed), but are other types of organisms that harm plants.

III. Proposed Rule

A. Proposed Regulatory Scope (§ 340.0 Scope and general restrictions)

We propose to better align the regulations with the PPA authorities in order to ensure that the environmental release, importation, or interstate movement of GE organisms does not pose a risk of introducing or disseminating plant pests or noxious weeds. Although the current program has been effective in ensuring the safe environmental release, interstate movement, and importation of genetically engineered organisms, technological advances have led to the possibility of developing GE organisms that do not fit within the plant pest definition, but may cause environmental or other types of physical harm or damage covered by the definition of noxious weed in the PPA. Therefore, we consider that it is appropriate to align the regulations with both the plant pest and noxious weed authorities of the PPA.

1. Genetically Engineered Organisms Subject to 7 CFR part 340

We are proposing to revise the scope of the regulations in § 340.0 to make it clear that decisions regarding which organisms are regulated remain science-based and take both plant pest and noxious weed risks into account. The proposed scope of the regulations states that genetically engineered organisms whose importation, interstate movement, or release into the environment would be subject to the regulations are:

Genetically engineered plants if:

(i) The unmodified parent plant from which the GE plant was derived is a plant pest or noxious weed, or

(ii) The trait introduced by genetic engineering could increase the potential for the GE plant to be a plant pest or noxious weed, or

(iii) The risk that the GE plant poses as a plant pest or noxious weed is unknown, or

(iv) The Administrator determines that the GE plant poses a plant pest or noxious weed risk.

Genetically engineered non-plant, non-vertebrate organisms if:

(i) The recipient organism can directly or indirectly injure, cause damage to, or cause disease in plants or plant products; or

(ii) The GE organism has been engineered in such a way that it may increase the potential for it to be a plant pest: or

(iii) The risk that the GE organism poses as a plant pest is unknown, or

(iv) The Administrator determines that the GE organism poses a plant pest risk.

Under the current regulations, there is no explicit statement of the relative responsibilities of the Administrator and regulated parties in determining whether an organism met the definition for *regulated article* and therefore would be subject to the regulations. Under the proposed regulations, the responsible person for a GE organism could correctly apply the criteria in § 340.0 to determine whether the GE organism is subject to the regulations. Alternatively,

the Administrator could determine any GE organism to be regulated after determining that the GE plant poses a plant pest or noxious weed risk.

In many cases, it will be very straightforward for a responsible person to apply these criteria and determine that a GE organism is subject to the regulations. For example, the GE organism would clearly be subject to the regulations if the recipient organism were a plant pest or noxious weed. A GE organism would also clearly be subject to the regulations if there was little data or previous experience available concerning the recipient organism's plant pest or noxious weed potential, or the type of modification, with the result that it is difficult to do a reliable evaluation of the risks that the GE organism may be a plant pest or noxious weed.

In other cases, it may not be readily apparent to the responsible person for a GE organism whether or not the organism falls within the scope of § 340.0 and is regulated. For this reason, persons who are not sure about whether a GE organism falls within the regulations or who maintain that a particular GE organism is not subject to the regulations based on their belief that it is not an organism within the scope of § 340.0 may consult with APHIS.

A GE organism may be within the scope of the regulations based on the information available at the time of the determination, which is usually less information than is available when the Administrator evaluates, for example, whether a regulated GE organism should be considered for an exemption from the requirement for a permit, or should be considered for a determination of nonregulated status (see discussion of § 340.6 below regarding nonregulated status). In other words, this scope determination has one purpose (to determine whether regulation is necessary at all) and is based on one level of knowledge about a GE organism, while determinations regarding such things as necessary permit conditions or exemptions or nonregulated status have a different purpose and are based on a different level of knowledge about a GE organism.

It is important to note that while a GE organism may be within the scope of the regulations due to certain identified plant pest or noxious weed risks, it may also be within the scope of the regulations if there is not enough information about the GE organism's potential plant pest or noxious weed risks to make a decision regarding those risks. At the early stages of developing a GE organism, there may not be sufficient information available about the organism to clearly determine the potential associated plant pest or noxious weed risks. Unknown risks might lead to a determination by the Administrator that a GE organism should be subjected to regulatory oversight if APHIS lacks familiarity with the non-transformed recipient organism or the introduced trait.

The proposed scope makes it clear that the mere act of genetic engineering does not trigger regulatory oversight or mean that a GE organism will pose risks as a plant pest or noxious weed. Instead, it clarifies that APHIS would subject a GE organism to regulatory oversight based upon known plant pest and noxious weed risks of the parent organisms, or based upon the traits of the GE organism, or based upon the possibility of unknown risks as a plant pest or noxious weed when insufficient information is available.

Consultation With APHIS Regarding the Scope of These Regulations

The criteria described in the scope should help developers form a reasonable expectation as to whether their GE organism is within the scope of the regulations, based on the nature of the parent organisms, the engineered traits, and the amount of information available regarding the organism and similar organisms.

APHIS anticipates that initially the range of GE organisms that the Administrator may determine to be covered by the proposed regulatory scope will be broad. This will be due to both an initial measured implementation of the revised regulatory oversight as well as to the application of the scope criteria to the transformed organisms and recipient traits. Over time, the range of GE organisms subject to oversight is expected to decrease as APHIS becomes more familiar with these organisms and receives information from which it can reach a conclusion that these GE organisms or groups of organisms do not present increased or unfamiliar plant pest or noxious weed risks. Because the Administrator may make such a determination at any time the Administrator receives information that a GE organism is within the scope, APHIS expects that developers will seek early consultation with APHIS on whether the regulatory scope covers their GE organism. Since it is generally necessary for research or business plans to include, as early as possible, elements addressing regulatory processing, approval, and compliance, it will be in the interest of the developers to determine the regulatory status of their GE organism prior to contemplating its movement or environmental release. Therefore, APHIS will offer to consult with a developer of a GE organism regarding whether the GE organism is within the scope of the proposed regulations.

After consultation and review of available information, the Administrator will respond in writing as to whether the Administrator has determined that the GE organism is within the scope of the regulations. APHIS plans to make information publicly available by posting and maintaining information on its Web site about the determinations it makes pursuant to this consultation process to help the public and regulated entities understand which organisms are subject to the regulations.

We welcome suggestions from the public on the most appropriate ways to provide administrative guidance to the public on the issue of which GE organisms are within the scope of the regulations. The Agency is especially interested in ways which will balance transparency with the efficient use of Agency resources in conducting consultations and communicating information to the public regarding which GE organisms are within the scope of the regulations.

Organisms Specifically Excluded From the Scope of the Regulations

Specifically excluded from the proposed regulatory scope are GE microorganisms that are regulated as biological control organisms by the EPA under provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). APHIS concludes that there is no need for such GE organisms to be evaluated by both agencies. EPA is already evaluating the environmental safety of such organisms with respect to their impact on the entire environment, including plants. We also propose to retain an exclusion from the current regulations for GE microorganisms where the recipient microorganism is not a plant pest and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.

Effect of Noxious Weed Authority on the Scope of the Proposed Regulations

The definition of noxious weed encompasses plants that pose risks akin to plant pests, because it includes ''any plant or plant product'' that can ''injure or cause damage to crops * * * other interests of agriculture * * * or the environment'', but also includes plants that can pose harm to non-plant organisms, such as humans. Therefore

evaluation of noxious weed risk expands what we can consider, while still including those risks examined under the plant pest approach. When considering risks associated with a GE plant, we would continue to consider whether it can harm plants, as well as whether it can cause the other types of physical harm or damage described in the definition for noxious weed.

The first consideration in determining if a plant is a noxious weed is identifying what direct injury or damage (physical harm) the plant causes. If direct harm or damage is established, the next consideration is to evaluate any indirect damage the plant may cause to interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment. In general, federally listed noxious weeds are plants that are likely to be aggressively invasive, have significant negative impacts, and are extremely difficult to manage or control once established.

The distinction between a weed and a noxious weed warrants emphasis. ''Weeds,'' in the broadest sense of the word, could include any plant growing where and/or when it is unwanted; even plants that are desirable in some settings may be considered weeds in others. In a narrower sense, weeds are invasive, often non-native, plants which impact natural and managed ecosystems, often with significant negative consequences due to lost yields, changes in management practices, altered herbicide use, etc. Only a fraction of these problematic weeds are considered to be so invasive, so harmful, and so difficult to control that Federal regulatory intervention to prevent their introduction or dissemination is justified, and these are the focus of the regulatory controls placed on them by APHIS. However, any weed, and virtually any plant or plant product, can be evaluated by APHIS to determine whether its characteristics and potential impacts warrant its listing as a noxious weed.

APHIS currently lists 98 aquatic, terrestrial, or parasitic plant taxa as noxious weeds. The species included in the list illustrate the kinds of plants APHIS considers to be sufficiently invasive, damaging, and difficult to control to be deemed noxious weeds. Table 1 describes some specific examples from the Federal noxious weed list and the kinds of impacts noxious weeds can have, to illustrate the types of effects APHIS will be looking for when evaluating whether GE plants reviewed under part 340 have any potential noxious weed traits. The experience and precedents developed by the APHIS–PPQ noxious weed program provide a guide for the regulation of plants that may be noxious weeds, and we intend to apply it to the consideration of GE plants in the same way.

TABLE 1—EXAMPLES OF IMPACTS CAUSED BY FEDERALLY LISTED NOXIOUS WEEDS

Impact	Description of impact	Example species
Lost productivity of crop fields.	Noxious weeds may directly compete with crop plants for limited resources, dramatically reducing yields.	Cogongrass (*Imperata cylindrica*) infests over 20 crop species; it releases chemicals into the soil that suppress crop growth and causes damaging puncture wounds to plant roots, bulbs, and tubers. Other examples include Benghal dayflower (*Commelina benghalensis*), red rice (*Oryza* spp.), and kikuyugrass (*Pennisetum clandestinum*).
Parasitic damage to crops.	Parasitic plants can cause significant reductions in yield by attaching themselves to a host plant, removing nutrients and ultimately killing it.	Federally listed noxious parasitic plants include the dodders (*Cuscuta* spp.)—with common names like strangleweed, devil's-guts, hellbine, and witch's hair—and witchweed (*Striga* spp.), which causes devastating losses in corn, sorghum, and rice.
Reduced productivity of pasture.	Grazing animals may avoid noxious weeds and consume the more favorable pasture species, resulting in increased noxious weed populations at the expense of more favorable species. Noxious weeds may also outcompete desirable pasture species.	Serrated tussock (*Nassella trichotoma*) has heavily infested large areas, leaving them completely incapable of supporting livestock.
Injury to humans or livestock.	Many noxious weeds are toxic, harming humans or livestock either when consumed or by direct contact.	Cape tulip (*Homeria* spp.) contains a cardiac glycoside, which can be fatal to livestock. Contact with giant hogweed (*Heracleum mantegazzianum*) causes painful skin blisters. Three-cornered jack (*Emex australis*) and devil's thorn (*Emex spinosa*) both bear spiny fruits that can cripple or cause injury to livestock or other animals.
Unchecked overgrowth.	Noxious weeds may be capable of completely dominating the landscape and preventing the use of cultivated or pasture lands for agriculture.	Mile-a-minute vines (*Mikania cordata* and *M. micrantha*) can entirely smother fields and forests in a dense, tangled mass of vines. A single plant of the aquatic weed giant salvinia (*Salvinia* spp.) can blanket 40 square miles in 3 months, and produce an underwater mat 3 feet thick.
Physical obstructions.	Growth rate and habit of some noxious weeds may physically hamper the movement of livestock and humans, or interfere with navigation of waterways.	Certain mesquites (*Prosopis* spp.), jointed prickly pear (*Opuntia aurantiaca*), and African boxthorn (*Lycium ferocissimum*) form impenetrable thickets filled with thorns or needles, blocking the movement of grazing animals, injuring them or preventing access to food and water.
Disruption of water flow.	Aquatic noxious weeds may disrupt water flow, adversely affecting irrigation, drainage and flood control canals, city water intakes, and recreational water use.	Notable examples include hydrilla (*Hydrilla verticillata*), giant salvinia (*Salvinia* spp.), and Chinese waterspinach (*Ipomoea aquatica*). Dense mats of oxygen weed (*Lagarosiphon major*) can completely shut down operation of hydroelectric plants.

TABLE 1—EXAMPLES OF IMPACTS CAUSED BY FEDERALLY LISTED NOXIOUS WEEDS—Continued

Impact	Description of impact	Example species
Habitat alteration	Noxious weeds may severely alter water quality by changing oxygen and nutrient content, may dramatically lower local water tables, or could so significantly outcompete or overgrow other vegetation resulting in a complete ecological shift of the habitat.	Infestation of lakes and ponds with hydrilla (*Hydrilla verticillata*) can alter aquatic ecosystems so drastically that native plants are entirely eliminated, rendering the habitat unsuitable for fish and other wildlife.

As discussed above, APHIS' determination that a plant is a noxious weed is based on notable physical harm or injury caused by the plant. The elements of the noxious weed definition include a number of interests that might be damaged by noxious weeds including not only plants but irrigation, navigation, the natural resources of the United States, the public health, the environment and interests of agriculture. Often APHIS quantifies the physical harm or injury in terms of economic losses. Loss in commodity value due to the presence of noxious weeds in seeds, for example, is a consequence of the anticipated physical damage that would be caused if the seed containing a noxious weed were distributed and planted; the economic loss is never simply the result of market preference to have commodities free of certain noxious weed seeds in and of itself, in the absence of any potential physical damage or harm. APHIS does not consider significant economic effects alone that are not linked to physical damage to be sufficient to determine a plant is a noxious weed.

Certainly, some noxious weeds can cause physical harm to the health of humans or livestock and other animals. In general, these impacts occur when individuals come into direct contact with the noxious plants or plant parts, which may cause physical injury or are toxic or otherwise harmful when consumed. Conceivably, noxious weeds growing in crop fields could potentially threaten public health, for example, if toxic parts of the noxious weeds are harvested and inadvertently enter the food supply. If such toxic or otherwise harmful noxious weed parts were found in food and caused the food to be ''adulterated'' within the meaning of the FFDCA, FDA could take regulatory action against the food.

Whereas APHIS has no direct role in evaluating the safety of foods, the agency plays an important supporting role in safeguarding the food supply by protecting the health of plants and animals at the farm level. When evaluating whether a particular GE plant may be a noxious weed because it poses a public health risk when growing in the environment, APHIS considers toxicity and other food safety information, including the type reviewed by EPA and FDA. In the case of GE plants, APHIS would not assess the safety of the GE plant for human or animal consumption, but would consider available information about toxicity and other food safety information in assessing noxious weed risk posed by the plants growing in the environment.

It should be noted, moreover, that most GE plants that APHIS has been regulating in the past, such as varieties of GE corn and soybeans modified with common agronomic traits, do not qualify as ''noxious weeds''. But with the increasing diversity of both agronomic and non-agronomic traits being engineered into plants it is appropriate to place regulatory controls upon GE plants proportionate to the likelihood that they may present a noxious weed risk until the potential risk can be appropriately evaluated.

How Non-Plant, Non-Vertebrate GE Organisms Fall Within the Scope of the Regulations

The proposed revision of the regulations retains control for potential plant pest risks posed by non-plant, non-vertebrate GE organisms. We would continue to explicitly use the plant pest provisions of the PPA for regulating non-plant, non-vertebrate GE organisms which align with the taxa listed in the PPA definition of plant pest. In its reviews of GE non-plant and non-vertebrate species, APHIS will continue to assess GE insects, fungi, bacteria, and other non-plant, non-vertebrate organisms for their potential to pose risks as plant pests.

The scope of the regulations as defined above makes it clear that it is the Administrator, and not the public, who determines whether a non-plant organism is within or outside the proposed scope of the Part 340 regulations. APHIS welcomes public comment on the proposed concise criteria that the Administrator would consider when concluding that a GE organism is not a plant pest. We envision providing additional information on the Administrator's interpretation on such criteria at the time of the final rule or in subsequent administrative guidance.

GE Vertebrate Animals Do Not Fall Within the Scope of the Regulations

Although the PPA definition of plant pest includes the potential for a nonhuman, vertebrate animal to be considered a plant pest, APHIS decided at this time that there are no demonstrated risks or pending GE animal developments indicating that it is necessary for the proposed regulations to evaluate vertebrate GE animals as potential plant pests. Because other statutory authorities exist for addressing GE animals, APHIS could guard against any plant pest risks that might be presented by GE vertebrate animals without directly regulating them under the regulations in part 340. On the other hand, we propose to regulate GE invertebrate animals under part 340 because many classes of invertebrates include known plant pests (e.g., insects, arachnids, nematodes, gastropods, etc.).

How GE Biological Control Organisms (BCOs) Fall Within the Scope of the Regulations

The PPA defines biological control organism (BCO) as ''any enemy, antagonist, or competitor used to control a plant pest or noxious weed'' (7 U.S.C. 7702(2)). The PPA gives the authority to regulate plant pests and noxious weeds, not specifically biocontrol organisms. APHIS recognizes that BCOs may have the potential to affect populations of noxious weeds or plant pests, or become plant pests themselves. To fall within the scope of the proposed regulations, the GE BCO would have to pose a threat as a plant pest or noxious weed. There are relatively few examples today of GE BCOs, but these may become more common in the future. For example, some researchers are developing GE biological control pink bollworms that

are sterile, which achieve their controlling effect by reducing the ability of fertile, non-GE pink bollworms to produce offspring. Such GE pink bollworm BCOs would fall within the scope of the proposed regulation, because they are plant pests. Although there are currently no examples of using GE plants as BCOs, such a GE plant would be evaluated under the proposed regulations to evaluate whether it is a noxious weed or a plant pest.

Currently, the federal regulation of microbial BCOs is regulated by EPA under FIFRA, and this covers GE as well as non-GE microorganisms used to mitigate the effect of pests. Unlike the PPA, which limits the definition of BCO only to organisms used to control plant pests and noxious weeds, FIFRA covers microorganisms used as biological control for any pest. APHIS considers it duplicative to have these regulations include GE microbial BCOs under its scope since FIFRA already adequately covers them, so APHIS is proposing that the regulatory scope language in § 340.0(d) would explicitly exclude GE microorganisms if they are already being regulated as BCOs by EPA under FIFRA. We are proposing to only regulate GE BCO macro-organisms that fall under the proposed regulatory scope (APHIS–PPQ currently regulates the macro-organism non-GE BCOs used to control plant pests and noxious weeds pursuant to other regulations). APHIS welcomes public comment on this aspect of its proposal.

Intrastate Movements of GE Organisms Between Contained Facilities and Activities in Contained Facilities Do Not Fall Within the Scope of the Regulations

Under the current regulations, certain GE organisms are only regulated by APHIS if they are imported, moved interstate, or released into the environment. The regulations do not govern intrastate movements between contained facilities such as laboratories, nor do they govern such activities as creating GE organism in a contained research laboratory. The proposed revision does not change this aspect of the regulations.

2. Deleting the List of Organisms Which Are or Contain Plant Pests

In § 340.2 of the current regulations, there is a list of taxa that are considered to be plant pests. Under the proposed scope, this list is not needed because we would not use taxonomic classification of donor and recipient organisms to determine if a GE organism is regulated. When in the course of evaluating a GE organism APHIS considers whether a donor or recipient species is likely to be a plant pest or noxious weed, we would consider the most up-to-date pest information maintained by PPQ. This information is more specific than the information in the list of plant pest taxa in the current regulations, and should be more useful and reliable than static lists of taxa. APHIS welcomes public comment on deletion of the taxa list and preferred sources of plant pest and noxious weed information for use under the proposed regulations.

With deletion of this list from the regulations, there is also no longer a need for the procedure currently described in § 340.5 for amending this list.

3. Regulating Whole Organisms, Parts, and Nonliving Products

APHIS proposes to clarify the regulated status of nonliving plant products in the regulations. First, the PPA defines a plant pest only as any *living* stage of any of the articles specifically named in the plant pest definition that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product. Moreover, APHIS does not consider most GE organisms or parts of GE organisms which cannot reproduce to present a risk as plant pests or noxious weeds.

Conversely, we would regulate importation, interstate movement and release into the environment of GE seedlings, seeds, tubers, cuttings, bulbs, spores, etc., because there is a reasonable, albeit small, possibility of reproduction, establishment, and spread if these were deliberately or accidentally released into the environment without authorization.

Viable pollen from GE plants imported, moved interstate, or released into the environment would be subject to the regulations because such movements of pollen can reasonably lead to genomes becoming established in the environment. Similarly, in circumstances where an article incidentally contains viable pollen, during movement, APHIS would consider the movement regulated. There are many cases, however, when pollen may be present but is no longer capable of producing offspring, e.g., nonviable or immature pollen. In such cases, APHIS would not require permits under this part. The commercial distribution of cut flowers is one pollen movement situation that APHIS has considered in light of the regulations, especially in cases where the flowers are grown in other countries then imported only as cut flowers. APHIS considers these circumstances to pose little, if any risk, and therefore would not require permits for these activities.

The PPA defines a noxious weed as encompassing both plants and plant products. A plant product is defined as ''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.'' APHIS has regulated GE organisms under part 340 for over 20 years, and there is no strong evidence to suggest the need to regulate nonliving (nonviable) plant products in most cases. However, if in a specific case the importation, interstate movement, or environmental release of nonliving products of a GE plant may pose noxious weed risks, APHIS has clear authority to address those risks by imposing permit conditions on the handling of such nonliving products of the GE organism in the permit issued for the associated living GE organism. The proposed regulations state clearly in § 340.3(b) that the Administrator may also assign permit conditions addressing nonliving plant materials associated with or derived from GE organisms when such conditions are needed to make it unlikely that the nonliving materials would pose a noxious weed risk. APHIS invites consultation from any person considering a movement or release of nonliving materials derived from a GE organism who is uncertain as to whether it would be regulated.

B. Permits for Authorizing Importation, Interstate Movement and Release Into the Environment of Certain GE Organisms

1. Elimination of the Notification Procedure

APHIS first added the notification procedure to the regulations in 1993 as an administratively streamlined procedure for certain GE plants that met the eligibility criteria described in the regulation. Rather than using customized requirements, like the permit conditions used for the permitting procedure, the notification procedure uses generalized performance standards that are described in the regulation itself. The use of the performance standards that do not vary from one notification to the next is one of the ways that the more rapid administrative turnaround was achieved. In some ways, the term ''notification'' has been misleading to the public, since they do not realize that sending a notification does not mean automatic authorization by APHIS.

APHIS reviews notifications to verify that the GE plant meets the eligibility criteria, and also evaluates whether the

proposed importation, interstate movement or environmental release can be done in a manner that meets the performance standards described in the regulation. In many ways, these APHIS evaluations for notifications are very similar to those done for permit applications, but the notification procedure relies on applicants agreeing to meet the performance standards described in the regulation rather than submitting an application for APHIS review describing the specific measures they will employ for the activity (as is the case for permits). With permits, but not with notifications, APHIS can accept the proposed measures or add to them and the result is a set of binding customized permit conditions.

Because the notification procedure uses only the performance standards in the regulations, it is more administratively streamlined, but the general nature of the standards has made it difficult for APHIS inspectors to determine if a notification holder is in compliance and can also make enforcement more difficult. For example, under the current regulations, one of the performance standards for notifications relevant to environmental releases states that: ''The field trial must be conducted such that (1) the regulated article will not persist in the environment, and (2) no offspring can be produced that could persist in the environment.'' Conversely, specific conditions which APHIS places on permits are unambiguous, easy to verify at inspection, and easier to enforce. A specific permit condition that could be used to address just part of the performance standard described above might read: ''After final harvest of the GE corn plants covered under this environmental release permit, the site will be monitored every 4 weeks for the emergence of volunteer corn seedlings for one year, and any emerging volunteer plants will be devitalized before they produce pollen. Records of the monitoring and management of volunteers must be maintained by the permit holder and made available to APHIS upon request.''

APHIS employs performance standards in many of its regulations, where appropriate. For example, we propose to employ a performance standard in another part of this proposal, container requirements for shipments of GE organisms. In that case, it is possible to employ a straightforward standard that the container must not break or leak when subjected to ordinary handling in transportation. The use of performance standards under the notification procedure has some benefits, such as providing the responsible person with flexibility in how the standard is met, e.g., allowing for appropriate change in protocols used during the growing season. However, there are some disadvantages in not specifically enumerating the specific measures that constitute compliance with the regulations. The permitting procedure does not have this disadvantage, because the permit conditions specify which actions need to be taken by the responsible person to be in compliance.

APHIS considered revising the performance standards and retaining the notification procedure, but this would not have remedied its shortcomings, especially the lack of specificity that is a necessity of using broadly applicable, performance standards in the regulations.

Under the proposed regulations where all authorizations will be done under a permitting procedure, the permit conditions will provide more specific information about what procedures the permit holder must follow in order to be in compliance. In the proposed rule, we are describing in detail the types of core permit conditions that will be imposed, plus the additional permit conditions that the Administrator can place upon the permit holder in order to make it unlikely that actions under the permit would result in the introduction or dissemination of a plant pest or noxious weed.

In view of the above discussion, APHIS has determined that it would have more flexible, risk-appropriate oversight, better regulatory enforcement and improved transparency if all regulated importations, interstate movements, and releases into the environment are authorized under the permitting procedure. The use of the permitting procedure in lieu of notifications is also necessary for APHIS to address some of the recommendations arising from the OIG Report and the provisions of the 2008 Farm Bill. For example, the OIG recommendations have led to proposed provisions in the regulations that will enable APHIS to add permit conditions to require additional reports during the course of an environmental release, the submission of notices to APHIS if the permit holder decides not to conduct the environmental release, and 7-day, pre-plant notices in the case of GE plants engineered to produce pharmaceutical or industrial substances. The last recommendation is already being implemented as a permit condition, because all of these authorizations are done under the permitting procedure. The OIG recommendations cannot be implemented under the notification procedure, because under the current regulations APHIS does not have the ability to attach conditions to notifications. This provides additional justification for APHIS to propose the elimination of the notification procedure. The APHIS proposal to eliminate the notification procedure is an effective way to address several of the provisions of the Farm Bill, such as the changes to the requirements for recordkeeping and reporting.

2. Revisions to Permit Procedures

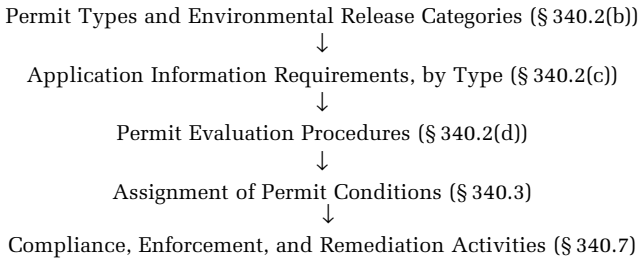
APHIS proposes to reorganize the regulations to improve the clarity of the permit application and evaluation procedures. The proposed change is more a reorganization than substantive change, and should enhance the transparency of the regulations to the public. The permitting procedure will continue to identify and obtain information relevant to evaluating the risks associated with a proposed importation, interstate movement, or release into the environment, and determine and document whether, and under what conditions, the activity should be allowed. The proposed regulations related to the issuance of permits are divided into two sections. The first is proposed § 340.2, *Procedure for permits*, which describes permit types, the procedure for permit application (including information requirements), and the Agency's administrative actions for permits. The second is proposed § 340.3, *Permit conditions*, which describes the general types of conditions that APHIS may add to a permit, and the obligations of the responsible person after permit issuance.

APHIS is proposing explicit procedures for amendment, transfer of responsibility, and revocation of permits in order to establish clear regulatory procedures that can increase efficiency yet maintain adequate safety. Currently the APHIS administrative practices to amend, transfer, and revoke permits have not been explicit in the regulation, and this addition will provide increased transparency and efficiency.

The proposed changes organize the regulations to more clearly reflect the procedural steps in the application, evaluation, and issuance of a permit (see Figure 1). First, the different types of permits (importation, interstate movement, and environmental release) are described in § 340.2(b), as are new subcategories of environmental release permits. Second, the types of information that must be submitted with a permit application are described in § 340.2(c). The permit type, as well as

the nature of the environmental release (if the permit is for a release), affect the application information requirements. Third, § 340.2(d) outlines the procedural and administrative steps of issuing a permit. Finally, the attachment of conditions to permits, which is also dependent upon permit type and release category, is described in § 340.3. Each of these permit-related sections of the proposed regulations is discussed below.

Figure 1. Schematic of activities associated with issuance and enforcement of permits, showing associated sections of the proposed regulation.



3. Permit Types and Environmental Release Categories (§ 340.2(b))

As discussed above in the background section, APHIS currently uses two procedures—notification and permits—to authorize the importation, interstate movement and release into the environment of GE organisms considered to be regulated articles under this part. The permitting procedure can be used for all regulated articles, but the notification procedure can be used only for certain GE plants that meet the eligibility criteria described in the regulations. Whereas permits are issued with explicit permit conditions which must be met by the permit holder, notifications have generalized ''performance standards'' described in the regulation and therefore do not vary from one notification to the next. Currently, approximately 90% of APHIS authorizations are done under the notification procedure.

Under the proposed system, which would eliminate notifications, APHIS would continue to issue three types of permits—interstate movement, importation, and environmental release. The procedures for the first two types of permits are relatively straightforward, and the conditions usually required for these permits address risks that are very similar from one shipment to another. We propose only minor adjustments to the procedures for interstate movement and import permits. In general, deliberate release of GE organisms into the environment presents a greater risk of introducing or disseminating plant pests and noxious weeds, and thus requires more careful oversight, than shipments of GE organisms into and across the country in secure containers. Of the three permit types, only environmental release permits would be differentiated into broad risk-related categories by the Administrator. This categorization would occur prior to the detailed and specific APHIS evaluation of an individual permit application. Table 2 summarizes the relationship of the three permit types and categories that pertain to environmental release permits.

TABLE 2—PROPOSED PERMIT TYPES AND CATEGORIES FOR ENVIRONMENTAL RELEASE PERMITS

Type		Use
Importation permit		For securely moving a GE organism into the United States.
Interstate Movement		For securely moving a GE organism from any State into or through any other State.
Environmental Release:*	Release Category A	For releases into the environment, outside the constraints of physical containment that are found in a laboratory, contained greenhouse, fermenter, other contained structure, or secure shipment.
	Release Category B	
	Release Category C	
	Release Category D	
	Release Category E (non-plants)	

* In some cases, an environmental release permit may also incorporate permits for importation or interstate movement when such movements are incidental to the environmental release.

The proposed sorting system for environmental release permits includes five categories: Four for releases of GE plants (Categories A–D) and one for releases of all other GE organisms (Category E). Releases of GE non-plant organisms (Category E) would be placed into a single category and reviewed on a case-by-case basis. APHIS considered the creation of smaller risk-related subcategories for non-plants, but APHIS has received too few permit applications to warrant the creation of these smaller groupings. Releases of plants would be grouped into four categories, as described below.

APHIS considered a tiered permitting system which would sort proposed environmental releases of plants into a number of risk-based categories. Lowest risk releases would be assigned to Tier 1, slightly higher risk releases in Tier 2, and so on. In such a system, tier assignment is analogous to a risk rating. In developing the specifics of implementing such a system in the regulations, however, APHIS found that it was challenging to pre-assign all conceivable releases into tiers representing discrete levels of risk. There are a large number of risk factors that contribute to the overall risk associated with any given release. These factors include reproductive biology and growth habit of the species, potential for gene flow to other species, phenotype engineered into the organism, familiarity with the genetic material used, safety of any expressed products, scale of the release, location, duration, experience, and compliance history of the applicant, proximity to threatened

and endangered species, and other factors.

Sorting proposed releases considering all relevant factors would lead to an unwieldy system with many risk-based categories, and would essentially require a full risk assessment prior to assigning a proposed release to the appropriate risk category. Consequently, it would be nearly impossible for applicants and the public to predict the risk tier to which a proposed release would be assigned.

APHIS proposes that the permitting system for environmental release permits would assign releases into administrative categories based upon two primary risk-related factors described below, so that the categories would identify the general types of releases of plants which share broadly similar risks and management issues. This initial administrative sorting would be followed by an evaluation that fully characterized the risk of the proposed release, which would then be the primary basis for adding necessary permit conditions. APHIS concludes that such a system could appropriately sort most releases into groupings that are alike enough that they could usually be treated similarly initially, in terms of application information requirements and evaluation of potential risks. In most cases the initial groupings would also result in a similar level of oversight of the release and conditions attached to the permit-but any final determination of the permit category, oversight and permit conditions would depend on the results of the APHIS evaluation.

Using this approach, there is no prior conclusion that every release within the same category poses the same level of risk. Likewise, releases in different categories do not necessarily pose greatly different risks. For this reason, APHIS would not refer to these groupings as ''tiers,'' as this implies an incremental increase in risk from tier to tier, but would instead label them as ''categories'' which are lettered and not numbered.

APHIS developed the proposed sorting scheme by first examining the types of releases that typically are authorized under its current regulations. APHIS then modified the categories to make them more explicitly connected to plant pest and noxious weed risks.

The two primary factors APHIS identified as most relevant to define its sorting system for environmental release permits were the (1) ability of the unmodified recipient plant species to persist in the wild and (2) potential of the engineered trait to cause harm, injury, or damage, as described in the definitions of plant pest and noxious weed. Secondary factors, which in some instances may change the initial categorization, include: how the recipient plant is commonly used (e.g., as a food or feed crop); the impact of the engineered trait on the fitness of the GE plant; and, the degree of uncertainty associated with the trait and its possible impacts.

Regarding the persistence factor, APHIS proposes to group plant species according to the risk of persistence of the plant or its progeny in the environment without human intervention. Based upon the growth habit of the plant species and presence of wild relatives in the United States, APHIS proposes to sort all plants into four groups, listed in order of increasing persistence risk:

- *Low:* Populations of the recipient plant are unlikely to persist in the environment without human intervention, and the recipient plant has no interfertile wild relatives in the United States. Examples include corn, soybeans, and cotton (except in certain areas).
- *Moderate:* Populations of the recipient plant are known to be weakly persistent in the environment without human intervention, or the recipient plant has interfertile wild relatives in the United States. Examples include alfalfa, beets, canola, rice, and tomato.
- *High:* Populations of the recipient plant are known to be strongly persistent in the environment without human intervention, or the recipient plant has interfertile wild relatives in the United States which are aggressive colonizers. Examples include creeping bentgrass, poplar, sorghum, and sunflower.
- *Severe:* The recipient plant is a Federally-listed noxious weed or is known to be similarly aggressive in its ability to colonize and persist in the environment without human intervention. Examples include hydrilla and kudzu.

These aspects of plant biology and growth habit are broad indicators of the increasing likelihood that the plant or its progeny can reproduce and spread without human intervention. ''Interfertile wild relatives'' includes both wild relatives in the traditional sense, as well as feral populations of the same species persisting outside agroecosystems. The distinction between ''weakly persistent'' and ''strongly persistent,'' is intended to mean survival without human intervention for one or very few generations (weakly persistent) versus several to many generations (strongly persistent). APHIS will clarify which species fall into each group by publishing lists in guidance.

Similarly, with regard to the factor for potential harm caused by introduced traits, APHIS proposes to group traits engineered into plants into four simple groupings based upon the definitions of plant pest and noxious weed. The groups are listed in order of increasing potential hazard of the engineered trait:

- *Low:*
  - Any new proteins or substances produced are unlikely to be toxic or otherwise cause serious harm to humans, vertebrate animals, or invertebrate organisms upon consumption of or contact with the plant or plant parts; and
  - No morphological changes which could cause mechanical injury or damage; and
  - Introduced sequences are known not to result in plant disease, and confers no or very low increased disease susceptibility.

An example would include expression of well characterized proteins known not to be toxic or harmful, such as a marker gene that does not pose a food or feed safety concern, or expression of viral genes where it is demonstrated that no protein is produced

- *Moderate:*
  - Any new proteins or substances produced are unlikely to be toxic or otherwise cause serious harm to humans or vertebrate animals upon consumption of or contact with the plant or plant parts ; or
  - Novel resistance to the application of an herbicide; or
  - Has novel ability to cause mechanical injury or damage; or
  - Produces proteins or substances that are associated with plant disease that are not prevalent or endemic in the area of release, or that confer an increased susceptibility to disease.

Examples include expression of new CRY proteins, ,mechanisms of herbicide tolerance (e.g., CP4–EPSPS, which confers glyphosate tolerance), and production of viral movement proteins.

- *High:*
  - Any new proteins or substances produced may be toxic or to otherwise cause serious harm to humans or vertebrate animals, upon consumption of or contact with the plant or plant parts; or
  - Produces an infectious entity which can cause disease in plants.

Examples include mercury hyper-accumulators or production of some pharmaceutical compounds.

- *Severe:*

Any new proteins or substances produced are known or likely to be

highly toxic or fatal to humans or vertebrate animals, upon consumption of or contact with the plant or plant parts.

These aspects of the engineered trait are related to harms or damages associated with plant pests or noxious weeds. This takes into consideration (1) the harmfulness of any substances produced, (2) the possibility of creating morphological changes that would cause physical injury, and (3) the likelihood of increasing plant disease, either due to risk of creating novel pests or increased inoculum source. Novel resistance to an herbicide is included in the ''moderate'' category due to the impacts the trait could have on the ability to manage the plant or its progeny.

The proposed use of plant growth habit and trait harm or injury as the two main factors for the initial sorting of environmental releases into categories uses the two factors to roughly approximate ''exposure'' and ''hazard,'' respectively. Thus, using a combination of these two factors alone, we propose the following initial sorting of plant-trait combinations into release permit categories (see Table 3). Once environmental releases of GE plants have been sorted into the permit categories shown in Table 3, we will review and evaluate the information submitted by the applicant to determine oversight and permit conditions. The information requested from applicants will not be limited to these factors and is, in fact, designed to allow us to evaluate any of the risks associated with noxious weeds and plant pests. In some instances, our review may result in a change to the release category assignment of a GE plant.

TABLE 3—INITIAL SORTING INTO ADMINISTRATIVE PERMIT CATEGORIES (A, B, C, AND D) FOR ENVIRONMENTAL RELEASES OF GE PLANTS, BASED UPON PERSISTENCE RISK OF THE RECIPIENT PLANT SPECIES AND POTENTIAL HARM OR DAMAGE OF THE ENGINEERED TRAIT

Persistence *	Potential harm or damage of engineered trait			
	Low	Moderate	High	Severe
Low	A	A	C	D
Moderate	A	B	C	D
High	B	B	C	D
Severe	D	D	D	D

* Persistence risk of the recipient plant species.

The sorting system above presumes that there is sufficient scientific information available about the GE plant to support the categorization. For example, the phenotype conferred by inserted sequences and the growth habit of the plant species in the U.S. must be well-characterized and based upon direct empirical observation of the genetic construct in the recipient plant species. In cases where less (or nothing) is known about phenotype of the engineered trait in the recipient plant species-such as inference based upon sequence similarity, protein structure modeling, or observation of the genetic construct in other species-the release category may be changed (from A to B or B to C) as a result of this uncertainty. Similarly, lack of familiarity with the plant species' behavior in the U.S. or the techniques needed to mitigate the likelihood of its persistence could also change the release category.

APHIS considered whether to adjust the categories table to acknowledge that an engineered trait could affect (enhance or detract from) the other factor axis, namely the persistence risk of the nonmodified recipient plant. Engineered traits such as resistance to biotic or abiotic stresses could theoretically increase the fitness of the plant, and thereby increase the likelihood that it will persist in the environment without human assistance. Considering the range of persistence risks posed by all of the different plant species sorted into any one of the proposed groupings, however, APHIS has concluded that in most instances the engineered trait would not alter the likelihood of persistence enough to warrant a change in initial release category. However, in cases where the engineered trait significantly alters plant growth habit, metabolism, or reproduction to increase the likelihood of persistence in the environment, APHIS could change the release category accordingly. Examples of such changes might include converting an annual species to a perennial or converting a plant with C3 metabolism to crassulacean acid metabolism (CAM).

The proposed category system should provide a simple, transparent way for APHIS review information in applications to initially sort releases into broad, risk-related categories, which can then be more efficiently assessed for the actual risks posed by the release. However, it should be emphasized that the categories are intended only for initial sorting, and other factors are taken into account in the APHIS evaluation when determining the specific permit conditions.

APHIS intends that release Category A will be associated with a level of regulatory oversight similar to environmental release notifications under the current system, and Categories B and C with a level of regulatory oversight similar to various permits that have been issued under the current system. However, it will be much clearer to the public what types of oversight will be applied broadly within each category. As we discussed above, oversight and permit conditions with each category will be similar, though not necessarily identical, for any plant within the category. Category D was created to acknowledge the possibility that some proposed releases may pose a very high risk of introducing a highly persistent or harmful plant into the environment. To date, APHIS has never been requested to allow releases that would fall into this category. If an applicant were to propose a Category D release, APHIS would only authorize such releases after imposing extremely strict levels of oversight akin to high security quarantine far exceeding that of Category C that would ensure that the GE plants could not persist in the environment. The information requirements, permit conditions, and general levels of oversight associated with each release Category are discussed below.

This simple sorting system places GE plants into categories and provides a relatively clear, simple rationale for placement in a given category. What follows is a series of illustrations of common plant-trait combinations and the release categories to which they would be assigned:

- *Category A:*
  - Bt corn producing CRY1ab toxin. The plant is unlikely to persist in the

environment and the safety of the protein has been assessed by the EPA.

○ Soybeans engineered with glyphosate tolerance conferred by CP4–EPSPS. While herbicide tolerance poses a ''moderate'' hazard, soybean has no interfertile wild relatives in the U.S..

• *Category B:*

○ Corn producing a new CRY protein. The plant is unlikely to persist and the novel CRY protein is likely to be toxic to some species that live or feed on the plant (normally Category A), but its food/feed safety is only inferred from similarity to other CRY proteins.

○ Random ''knock-out'' or antisense libraries of soybean lines. While the lines may not likely produce novel proteins or substances (Category A), because of the uncertainty associated with the impacts of genetic engineering on these lines, they would be treated as Category B. Well-characterized lines taken from such libraries that do not produce new proteins would likely be treated as Category A.

○ Kentucky bluegrass engineered with glyphosate resistance conferred by CP4–EPSPS. Herbicide resistance is a ''moderate'' hazard and bluegrass has interfertile wild relatives in the U.S.

○ Pines producing an enzyme to enhance paper production. Pines are persistent and have interfertile wild relatives in the United States.

• *Category C:*

○ Poplar engineered to produce enzymes for heavy metal bioremediation.

• *Category D:*

○ Any Federally listed noxious weed that has been genetically engineered; any GE plant producing a vertebrate toxin.

Permits for Environmental Releases of Plants Making Pharmaceutical and Industrial (PMPI) Compounds

APHIS considered whether to continue to issue environmental release permits for GE plants engineered to produce pharmaceutical and industrial compounds if the GE plant species is the same as, or sexually compatible with, a species commonly used for food or feed. APHIS concludes that the proposed permitting procedure and the use of stringent permit conditions can continue to effectively minimize the risks that may be associated with the environmental release of such GE plants. APHIS will continue to impose permit conditions that take into account the issues related to the safety of proteins or other substances that these plants have been engineered to produce. Based upon APHIS experience to date, many releases of GE plants producing pharmaceutical or industrial substances would fall in Category C, and would carry the same level of oversight as current permits for PMPI.

4. Permit Application Information Requirements (§ 340.2(c))

In the proposed regulations, we provide greater detail about the basic application information requirements that need to be addressed in all permit applications, as well as additional basic information required for each permit type and the categories in the case of environmental release permits. Under the current regulation, certain areas where APHIS routinely needs information from the applicant do not become apparent until the applicant submits the permit application (and APHIS subsequently follows up for additional information). Some of the information requirements related to recordkeeping, reporting, and contractual arrangements among the permit holder and agents are new to the regulation and reflect, in part, certain provisions of the 2008 Farm Bill and also align with recommendations of USDA's OIG 2005 Report. For example, the OIG recommendations have led to provisions that will enable APHIS to require geographic coordinates for the locations of environmental releases.

The differences between the information required for an application under the current regulations versus the proposed regulations may be seen by comparing current § 340.4 to proposed § 340.2(c). Both the current and proposed application procedures require information characterizing the nature of the GE organism, including detailed molecular biology information about the expression of the introduced genetic material. They also both require information about the type of movement and/or release planned. The proposed rule requires more detail in some of these areas, and more description of the applicant's plans and methods to prevent unauthorized releases, and to respond to unauthorized releases if they occur. This information is used in part by APHIS to formulate the specific permit conditions. In cases where the permit is for environmental release, and would be in permit categories C or D according to the table in § 340.2(b)(3), a greater level of detail would be required for almost all aspects of the activity, including the recipient organism, the inserted gene(s), site location and management practices, and training and communication among the permit holder and agents involved in the activity covered under the permit. This information would also address the capability of the organism to persist or spread in the environment, or include details about how the engineered traits might be harmful.

5. Permit Conditions (§ 340.3)

Conditions are specific practices or requirements that an applicant must follow upon issuance of a permit. Under the current regulation, the permit conditions are described in the same section as the permit procedure itself. In the proposed revision, the permit conditions are enumerated in a separate section (§ 340.3) to accommodate the additional details to describe conditions for the three permit types as well as the categories of environmental release permits.

The use of permits and permit conditions gives APHIS and the responsible person a clearer understanding as to what actions must be taken for the permit holder to comply with the regulation. In the proposed regulation, APHIS has strived to provide as much transparency and predictability as possible about permit conditions while retaining sufficient flexibility so that the regulations will be adaptable in a broad range of cases.

Permits will be issued with the core permit conditions described in § 340.3(a), which are a minimum set of basic conditions for importation, interstate movement, and release. The Administrator may add to these conditions additional or expanded conditions when necessary to make it unlikely that actions under the permit would result in the introduction or dissemination of a plant pest or noxious weed.

The Administrator will assign the permit conditions in a manner that is commensurate with the risk of the individual proposed movement or release. Additional or expanded permit conditions may include, but are not limited to, specific requirements for: reproductive, cultural, spatial, temporal controls; monitoring; post-termination land use; site security or access restrictions; and management practices such as training of personnel involved in the release.

The proposed description of permit conditions elaborates on the ''standard'' permit conditions found in the current regulations, and the additional detail is designed to better communicate with potential applicants what the requirements are likely to be for their particular permit, and will better support administration of the program, including compliance and enforcement.

In the current regulation, only ''standard'' permit conditions are described, and APHIS has the authority to place other conditions upon the permit as deemed necessary by the

Administrator. The proposal for permit conditions will be more transparent to the public and this transparency will better facilitate planning by researchers, especially those who have not previously received permits from APHIS.

The proposed required core permit conditions consolidate six primary areas addressed in different parts of the current regulations to ensure compliance with the regulation and to make it unlikely that the permitted activity will result in the introduction and dissemination of a plant pest or noxious weed: Identity, shipment, unauthorized dissemination, communication and training, records, reports and notices. APHIS intends the list of specific condition areas we propose in § 340.3 to be used for all permits we issue as they apply to importation, interstate movement, and release into the environment. The required permit conditions listed in § 340.3 represent the permit conditions that we propose to apply for any type of permit. Listing them in the regulations should provide applicants with the ability to plan their activities with knowledge of the primary requirements for all activities that would have to be met to comply with the regulations.

For environmental release permits, proposed § 340.3(a)(4)(iii)(F) would also require the permit holder to notify APHIS seven days prior to initiation of the release if the release is Category C or D. For all Categories, permit holders are required to notify APHIS if they do not conduct the release.

The current regulations require environmental release permit holders to submit field test reports to APHIS within 6 months after termination of a field test. Under proposed § 340.3(a), the requirement simply states that the responsible person shall submit reports to APHIS at the times specified in the permit conditions and containing the information specified in the permit conditions.

APHIS is also proposing revision of the regulations to clarify the procedure it would use for amendment of permit conditions, transfer of a permit to a different responsible person, and revocation of an existing permit. Each of these additions to the regulations reflect current administrative practices and the incorporation of these into the regulations will make the overall system more transparent.

Currently, APHIS attaches conditions to permits at the moment the permit is issued to the applicant. Under the current regulations, the permitting procedure does not include a formal acknowledgement from the applicant prior to permit issuance that they are aware of and consent to the permit conditions. To verify that applicants are aware of and willing to abide by the conditions, APHIS proposes to add an additional administrative step in the permit procedure in § 340.2(d)(6) to support administration of the program. We are proposing to require that applicants agree prior to permit issuance that they will comply with all the permit conditions. Eventually, APHIS would build this feature into the existing ePermits system, and in the interim it would provide alternative mechanisms, such as e-mail communications, to implement this step of the permitting procedure.

APHIS is also proposing to clarify in § 340.2(h) of the regulations the procedure to be used when amendment of existing permit conditions is sought by the responsible person or required by APHIS, as well as the procedure for transfer of an existing permit to a different responsible person.

As with the current regulations, APHIS is retaining the flexibility to modify permit conditions as needed under individual circumstances. Proposed § 340.3 will increase transparency, yet still allow sufficient adaptability of the regulations for the full range of permit applications APHIS expects to receive today and in the future. APHIS recognizes that transparency and predictability for applicants must be balanced with maintaining Agency flexibility and adaptability for years to come under these regulations. APHIS encourages the public to comment on the choices we are proposing here, and we welcome suggestions for alternative approaches.

APHIS is proposing to revise the current sections of the regulations for container requirements for shipments of GE organisms (§ 340.8) and marking and identity requirements for imports of GE organisms (§ 340.7). Rather than the highly prescriptive approach in the current regulation, we will use an approach that is performance based and can be adapted to the activity that is being performed. This should provide greater efficiency for the public as well as APHIS, yet still achieve the necessary level of containment during shipments. We have reorganized this information in the regulations so that the requirements are associated with the related activity under the proposed regulation. For example, the shipping requirements for interstate movements under the conditional exemption have the requisite shipping conditions stipulated in the section for conditional exemptions. Likewise, the shipping conditions for import and interstate movement permits have been placed in the section for permit conditions, rather than retaining them in a separate section as in the current regulations. The performance-based standards we are proposing incorporates a simple performance standard in our proposed definition of secure shipment, discussed below: ''Shipment of a package of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.'' APHIS is also proposing to require applicants to provide their proposed methods of secure shipment, and APHIS will specify the methods of secure shipment as a permit condition.

APHIS proposes to eliminate the marking and identity requirements for imports of GE organisms as a separate section of the regulations (current § 340.7). As with the container standard issue discussed above, appropriate labeling and related requirements would be highly individual depending on the organism, type of permit, and other conditions.

APHIS is proposing to include relevant tribal officials when it provides copies of permit applications to state regulatory officials. The current regulations state that APHIS provides this information to state regulatory officials.

6. Elimination of Courtesy Permits

APHIS is also proposing to eliminate the issuance of courtesy permits. Courtesy permits have been part of the regulations since their inception in 1987, but in an effort to better allocate APHIS resources, APHIS is proposing to remove this regulatory feature. The current regulations provide the ability for APHIS to issue ''courtesy permits,'' in order to facilitate the movement of organisms which are outside the scope of these regulations, but whose movement might otherwise be hindered because of their similarity to organisms regulated under these regulations. The issuance of courtesy permits has generated confusion in the public and especially in the research community. The application form for courtesy permits is identical to the application for other types of permits, and the courtesy permit itself looks like other permits. This has led to the widespread misunderstanding by some researchers that courtesy permits are actually required for the movement of certain organisms, or that issuance of a courtesy permit removes the requirement for applicants to have other authorizations which may be required, under plant

pest regulations such as those found at 7 CFR part 330. APHIS commits significant resources to the issuance of these courtesy permits for the movement of organisms which are not subject to the provisions of part 340. APHIS will work with researchers and relevant government regulatory officials to facilitate the transition.

APHIS will also be available for consultation by persons who formerly used courtesy permits and other persons moving similar non-regulated articles, to discuss how to facilitate their movement. We also encourage the public to comment on the proposed elimination of courtesy permits and how APHIS should work with persons moving organisms for which we might formerly have issued courtesy permits.

C. Conditional Exemptions From Permit Requirement (§ 340.4)

The PPA allows the Secretary to create ''exceptions'' to the permit requirement when the Secretary deems that a permit is not necessary. That is, these regulated activities are allowed, under certain conditions, without seeking prior authorization via permit. The current APHIS regulations contain such PPA exceptions, but they are referred to as ''exemptions'' in the regulations. The current regulations include conditional exemptions from the requirement for interstate movement permits. These conditional exemptions were established in the regulations during the first few years after the regulations were first promulgated. The last conditional exemption was established in the regulations in 1990 for the interstate movement of GE plants of the species *Arabidopsis thaliana* as long as the conditions described in the regulations are met.

In its proposed revision to the regulations, APHIS is retaining the existing conditional exemptions from interstate movement. We are also proposing a new regulatory procedure that would enable APHIS to approve new conditional exemptions more efficiently than using the procedure of notice and comment rulemaking for each individual exemption. This can be a transparent and efficient way to provide regulatory relief. This new procedure for approving conditional exemptions is described in § 340.5, and it incorporates transparent steps including scientific review, public input, and adaptability when APHIS establishes the conditions relevant to the specific conditional exemption. Conditional exemptions, by their nature, will always include conditions and continued APHIS oversight to ensure that the conditions are met.

The current regulations provide for conditional exemptions from the requirement for permits for the interstate movement of certain GE strains of the microorganisms *Escherichia coli, Saccharomyces cerevisiae,* and *Bacillus subtilis,* and the plant *Arabidopsis thaliana* in § 340.2(b), and these conditional exemptions are being retained under the proposed regulations. Conditional exemptions from permit have been part of the regulations since the first exemption was established in 1988 (for the interstate movement of certain GE microorganisms), with the addition of another conditional exemption, through rulemaking, in 1990 for certain types of GE *Arabidopsis thaliana,* one of the most commonly used plants for scientific studies and which is frequently distributed among researchers. The essential conditions for each of these conditional exemptions address the following: (1) Species of the GE organism, (2) the types of genetic modifications that are allowed or prohibited for the GE organism, and (3) the manner in which the GE organism is shipped interstate. The existing conditional exemptions for the interstate movement of microorganisms were based on APHIS' conclusion that the exemption from the requirement for permits for interstate movement of these microorganisms would ''not present a risk of the introduction or dissemination of a plant pest'' (53 FR 12910, p.12910).

The existing conditional exemptions for *E. coli, Bacillus subtilis, Saccharomyces cerevisiae* and *Arabidopsis thaliana* are being retained in the proposed regulations. APHIS has no information that would indicate that such conditional exemption would be result in the introduction and dissemination of a plant pest or noxious weed. The text of the conditional exemption is being updated to place the shipping requirements with the other conditions associated with the exemption, instead of the current regulatory organization that has the shipping requirements in a separate section of the regulation.

In addition to the existing conditional exemptions, APHIS is proposing a transparent and efficient petition procedure in § 340.5 whereby the Administrator may approve additional conditional exemptions from permit without having to amend the regulations. This procedure would provide for a scientific review by APHIS as well as the opportunity for public review and comment on the scientific basis for the proposed exemption and the conditions associated with the exemption. The proposed procedure would provide an adaptable means of ensuring that the regulatory oversight is proportional to the risks posed by specific activities with GE organisms.

Proposed § 340.5 describes the procedure whereby a petitioner would seek a determination by the Administrator that the importation, interstate movement, and/or release into the environment of a GE organism is not subject to the requirement to have a permit under this part. We propose that the Administrator's decision to approve an exemption would be based upon a determination that the exemption from the requirement for a permit, when conducted with the associated conditions, is unlikely to result in the introduction or dissemination of a plant pest or noxious weed. APHIS anticipates that creating this new petition procedure to allow approval of additional conditional exemptions would enhance its ability to customize regulatory oversight to be proportional to any risks associated with importation, interstate movement, or release into the environment of a GE organism.

Under the proposed procedure, petitioners have the flexibility to propose various types of conditional exemptions from the requirement for a permit: The proposal can be for one or more permit types (importation, interstate movement, or release into the environment). In addition, the petitioner can propose the relevant conditions. The Administrator may approve the proposed conditional exemption as submitted in the petition, or the Administrator may impose alternatives to the requested exemption and conditions. The Administrator would review the scientific information and evaluate potential risks relevant to the proposal, then make the relevant documents (proposal and any supporting information) available to the public for review and comment prior to the Administrator's decision.

The information needed for a petition for conditional exemption would depend on the nature of the exemption requested and the proposed conditions for exemption. For example, conditional exemptions for the interstate movement of narrowly-defined groups of organisms with restrictive associated conditions might require considerably less information to justify than exemptions for broadly defined groups of organisms or less restrictive associated conditions. In making its determination, APHIS would consider all relevant information, including information in the scientific literature, copies of unpublished studies, and reviews by other regulatory agencies.

APHIS foresees many advantages to the proposed procedure, including scientific rigor, public involvement, and regulatory efficiency. APHIS would continue to provide to the public the relevant scientific information under consideration, its environmental analysis, and the rationale for its determination. The public would also retain its ability to provide comments to the agency prior to a decision approving a new exemption. APHIS decisions regarding these newly approved conditional exemptions would be published in the **Federal Register** and maintained on a list accessible to the public.

In evaluating whether to approve a new conditional exemption, APHIS would carefully consider issues related to enforceability of the conditional exemption when proposing to approve a conditional exemption. Unlike permit conditions, which are binding on the specific responsible person, the conditions associated with the exemption would apply to anyone who conducts the activity under the conditional exemption. Before granting such a conditional exemption, APHIS would take into consideration the likelihood that such conditions would be followed and the consequences if they are not.

Conditional exemptions could be used, for example, for the importation of certain GE commodities. A person could petition for an exemption from all permits for shipments of a particular GE commodity grain under the condition that the grain is not grown, but will only be moved for direct use as food, feed, or for processing. The proposed procedure to approve new exemptions would be sufficiently adaptable that it can consider approving exemptions for the shipment of certain GE commodities that would take into account any conditions necessary to make it unlikely to result in the introduction and dissemination of plant pests or noxious weeds.

APHIS considered proposing specific criteria in the regulations that the Agency would use when evaluating potential risks of imported GE commodities which are viable propagules such as grains like corn, wheat, etc. APHIS considered that such a criterion-based system in the regulations might allow APHIS to conduct expedited reviews of imports that met the specified criteria. APHIS considered criteria such as whether the GE plant had undergone a safety review in a foreign country, whether APHIS had granted nonregulated status to something similar, and the likelihood that the commodity could be propagated (seeds, fruit with seeds, nonviable products like flour, etc.).

However, at this time APHIS is not proposing such criteria in the regulation. APHIS does not rule out the possibility of developing such a criterion-based system in the future. We welcome comments from the public on this issue.

We are also proposing regulatory procedures whereby the Administrator may revoke any exemption under this part after it is approved. As proposed, the Administrator may revoke any exemption if the Administrator receives information subsequent to approving the exemption and makes a determination based upon this information that the circumstances have changed such that the exemption is likely to result in the introduction or dissemination of a plant pest or noxious weed. A revocation may not be appealed. However, any person may file a new petition in accordance with § 340.5 regarding the same or similar organisms covered by the exemption if new information relevant to the revocation becomes available.

In addition to this procedure for completely revoking an exemption so it would be unavailable for use by any person, we propose to add a provision in paragraph (e) of the conditional exemptions section, § 340.4, under which the Administrator may revoke the right of an individual person to use an exemption without revoking the exemption for other persons. The Administrator could revoke an individual's right to use an exemption after determining that the person or any agent of the person has failed to comply at any time with any provision of this part.

D. Petitions for Nonregulated Status (§ 340.5)

The current regulations include a procedure by which anyone may petition APHIS to grant ''nonregulated status'' to a GE organism, which means it would no longer be subject to the regulations in part 340. This nonregulated status is different from that of regulated articles that might be conditionally exempt from the requirement for a permit when moved interstate (following the conditions specified in the regulations).

Published APHIS decisions made under the current regulations have used different ways to express the basic standard ''unlikely to pose a plant pest risk'' in determining whether to grant nonregulated status to a specific GE organism. In its determinations, APHIS has conveyed the basic standard of ''unlikely to pose a plant pest risk'' by concluding that the GE organism ''poses no more of a plant pest risk than its non-genetically engineered counterpart,'' ''will not pose a plant pest risk''; or that there is ''no plant pest risk,'' or ''no direct or indirect plant pest effects.'' Regardless of the phrases used in its determination of nonregulated status to date, APHIS has applied the same basic evaluation criteria to each determination to conclude that the GE organism is unlikely to pose a plant pest risk and therefore is not subject to the part 340 regulations.

APHIS is proposing revisions to § 340.6 that will clarify the petition procedure, information requirements for petitions, and the standard upon which the Administrator will make a determination that a GE organism is approved for nonregulated status. Under the current regulations, the basic standard for a determination of nonregulated status of a GE organism has been related to plant pest risk. In § 340.6(b)(4) of this proposed rule, we are proposing to apply a similar basic standard derived from the proposed regulatory scope in § 340.0(a), namely, whether the GE organism is unlikely to be a plant pest or noxious weed.

The current regulations also have a provision at § 340.6 to extend a determination of nonregulated status and grant nonregulated status to a GE organism based on the similarity of the GE organism to an antecedent GE organism that has already granted nonregulated status (§ 340.6(e) ''Extensions to determinations of nonregulated status''). This provision has been in the APHIS regulations since 1997 and has been used fifteen times to grant nonregulated status to additional GE plants based on similarity to their antecedents. This existing ''extension procedure'' was designed for APHIS to take into account the previous evaluation conducted by APHIS and thereby afford the potential for expedited evaluations of a petition for extension. The extension procedure has some administrative aspects which are streamlined but in practice the APHIS scientific reviews for extensions are similar to those of the antecedent organism.

Some members of the public have misunderstood the nature of the extension procedure, believing that APHIS has not conducted a thorough scientific review. Some members of the public have misconstrued the term ''extension'' to conclude that an extension would extend the duration of nonregulated status (nonregulated status is not granted with an expiration date).

For these reasons, APHIS is proposing to eliminate the extension procedure in

the regulation. APHIS sees no advantage to retaining the distinction in the regulations between reviews for antecedents and reviews for subsequent petitions for extensions. Because the proposed revisions for petition for nonregulated status provide a high degree of flexibility, a separate extension procedure is not needed in the regulation. Review of petitions under the proposed regulations will rely on previous evaluations of similar GE organisms when they exist. APHIS foresees that some evaluations for nonregulated status may require less time if previous evaluations have addressed the issues relevant to a new petition for nonregulated status.

In § 340.6 we propose some revisions to the information that the Administrator may require a petitioner to submit in consideration of the particular petition. In the current regulation, the information needs are described largely with respect to evaluating GE plants, but APHIS foresees that other GE organisms may also be suitable candidates. This provision may become more important as new commercial applications of biotechnology emerge and new types of information are needed to properly assess the risks associated with new types of GE organisms. In all of the nonregulated status requests processed to date, the subject organisms and the alterations involved did not present unanticipated or completely novel approaches and APHIS was able to make a determination based on information in the petitions. When needed, APHIS obtained additional information from petitioners, in a consultation process similar to the one proposed.

We are also proposing a regulatory procedure whereby the Administrator may revoke a previous approval of nonregulated status. This is consistent with the existing regulations and policies that the Administrator may place a deregulated GE organism back under the regulations if the Administrator concludes that the GE organism poses a plant pest risk. As proposed, the Administrator may revoke any approval of nonregulated status if the Administrator receives information subsequent to approval that the GE organism is likely to be a plant pest or noxious weed. If the Administrator revokes an approval for nonregulated status, the Administrator may approve for the same GE organism an exemption from the requirement for permit in accordance with § 340.5. The revocation, its effective date, and the reasons for it will be published in the **Federal Register**. A revocation may not be appealed. However, any person may file a new petition in accordance with § 340.5 or § 340.6 regarding the same or similar organisms covered by the revocation if new information relevant to the revocation becomes available.

Treatment of GE Organisms That Have Been Granted Nonregulated Status

Although the APHIS evaluations of GE plants that would be conducted under the proposed regulatory changes will evaluate some additional factors because of consideration of noxious weed risks, APHIS nonetheless considers this proposed revision to be sufficiently consistent with the criteria evaluated in making determinations of nonregulated status to date under the current regulations. For this reason, APHIS is proposing that all previous determinations of nonregulated status made since the early 1990s under the part 340 regulations will be automatically approved for nonregulated status under the revisions proposed here. The history of safe use of these nonregulated GE plants in agriculture in the United States and other countries gives APHIS confidence that it is appropriate to retain nonregulated status under the revised regulations for all those GE plants which have been granted nonregulated status under the existing regulations. Many of these GE plants have been incorporated into plant breeding programs and been used to develop hundreds of crop varieties that have been widely and safely used in agriculture around the world.

We also note that although the addition of the term ''noxious weed'' is new to the proposed regulation, previous evaluations for determinations of nonregulated status considered the concept of plant pest risk in a broad context that included consideration of potential weediness. The evaluations considered, *inter alia,* whether the unmodified plant was a weed, whether the GE plant was a weed, and whether the interbreeding of the GE plant with sexually compatible plant species would result in offspring that would be weeds. In each case in which APHIS granted nonregulated status to date, APHIS reached the conclusion that in each instance that the potential for weediness was unlikely to occur. In the case of some petitions for nonregulated status in which the GE plants were engineered with sequences derived from plant viruses, APHIS also considered in its reviews whether the genetic modification was unlikely to result in a new plant pest, in this case a plant virus (through mechanisms such as recombination or transencapsidation).

E. Compliance, Enforcement, and Remedial Action (§ 340.7)

1. Ensuring Compliance With Permits and Exemption Activities

In recent years, APHIS has strengthened its program in order to improve permit holders' compliance with the regulations, to augment the approaches used to prevent or remediate potential risks to plant health, and to utilize appropriate enforcement strategies. This proposal provides an opportunity to set forth the compliance and enforcement requirements and the tools and administrative practices APHIS may employ as part of an integrated approach to prevent the introduction or dissemination of plant pests and noxious weeds, and to support overall administration of the program. These matters are addressed in proposed § 340.7, ''Compliance, enforcement, and remedial actions.'' These proposed regulatory changes also reflect certain provisions of the 2008 Farm Bill and align with recommendations of USDA's OIG.

APHIS seeks to clarify that it will use the full range of enforcement authorities and penalties granted under the PPA. As described above, APHIS issues permits with specific conditions or requirements placed upon the responsible person. Proposed § 340.7 clarifies the requirement for compliance with these conditions, as well as the approaches available to APHIS to verify compliance. Such conditions may include requirements for the responsible person to establish and maintain records related to the permit, as well as allowing APHIS to review those records. This section underscores APHIS' ability to conduct inspections and audit records related to the regulated activities.

In this proposed rule, the requirements for record retention are being increased. Records indicating that a GE organism that was imported or moved interstate reached its intended destination must be retained for at least 2 years after completion of importation or interstate movement, and all other records must be retained for at least 5 years after completion of all obligations required under a relevant permit or exemption. APHIS is also proposing changes to the nature of the records that are required, a topic discussed in greater detail in section E of this document, ''E. Paperwork Reduction Act.'' Changes include a requirement to maintain records for activities done under a conditional exemption, as well as contracts and other information related to agreements between the responsible person and all agents that conduct activities subject to this part.

In a previous section of this proposal we discussed the types of records proposed as core permit conditions in § 340.3. We also propose to add certain recordkeeping requirements to § 340.7 that would apply not just to responsible persons exercising permits, but to all responsible persons and their agents engaged in the importation, interstate movement, or release into the environment of any GE organism that is subject to this part, including persons utilizing the conditional exemptions from permits.

In recent years, APHIS has accrued a great deal of experience in enforcing the regulations and investigating possible violations of them. This experience has helped us identify specific types of records that may not be required by the current regulations, but that are necessary for effective enforcement of the proposed regulations.[2] For example, in investigations of field trials we have found that we could not always obtain detailed maps for each planting area used during each season of the trial. This information is important for the efficient enforcement of the regulations. We also found that sometimes records of actual field trial operations over time were not sufficient to confirm that the procedures, equipment, and safeguards APHIS approved for a field trial were actually employed. That is, while existing records could generally confirm plans to use, for example, certain cleaning equipment or procedures at certain intervals, or to conduct plantings on certain dates, the records did not confirm that plans were actually carried out on the approved dates. We also found that records for some field trials did not identify which staff members or contractors were responsible for performing which duties, either during a field test or in the event of an unauthorized release that triggered the field test contingency plan. When responsibilities cannot be linked to specific individuals, it makes it very difficult to investigate possible violations. Another gap in necessary records we discovered through experience was the absence of clear written records of the responsibilities of different organizations, when several different entities were involved in a field trial. During investigations we may need to review not only any written contracts, but also any written agreements among researchers, developers, or other parties that are sharing performance of tasks required by the permit for a field trial.

The proposed regulations would allow APHIS to require these types of records. As APHIS considered the types of records needed to support the regulations it became apparent that regulations could not specify in a ''one size fits all'' fashion all record requirements that might be needed. Therefore, we propose to add those detailed record requirements of truly general applicability in § 340.3 and § 340.7. However, we also propose in § 340.3 that we would continue to impose any necessary additional record requirements appropriate to each permit situation as individual permit conditions.

Proposed § 340.7 also outlines the possible consequences of failure to comply with the regulations, including denial of future permits; revocation of current permits; destruction, treatment, and removal of GE organisms; issuance of penalties; and a means to settle alleged civil violations prior to the issuance of an administrative complaint.

Under this proposal, every person whose activities are within the scope of the regulations must comply with all the requirements of this part. Moreover, a responsible person can be held liable for the violation of any requirement of this part by any agent working for the responsible person (including persons contracted to conduct or carry out the environmental release on their own or on leased properties).

We propose to address remediation authority and procedures to a greater degree of detail than the current regulations. In proposed §§ 340.7(e) and (g) we explicitly state that the APHIS Administrator has the authority to take remedial actions in the event that an incident requires such actions. We also specify that the APHIS Administrator has the authority to order remedial action by others. These orders could take the form of an Administrative Order, Emergency Action Notification, or similar regulatory instrument. Additional information about these types of orders and related procedures are provided in administrative guidance on the APHIS Web site. The consequence for failure to abide by the orders of the Administrator is also described in proposed § 340.7, linking remediation to enforcement.

Finally, APHIS has clarified in the proposed regulations that in the event of a permit revocation, it may act or order action of the responsible person in the handling of the organisms, articles, or means of conveyances.

2. Low Level Presence of Regulated GE Plants in Seed or Grain

On March 29, 2007, APHIS published a **Federal Register** notice titled ''Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Materials'' (72 FR 14649–14651; Docket No. APHIS–2006–0167. This notice described how APHIS responds when low levels of regulated GE plant materials occur in commercial seeds or grain that may be used for food or feed. This issue was also addressed in the DEIS in Issue 7. Both of these documents described how APHIS has addressed these occurrences in the past, and how the Agency intends to address them in the future. We are proposing to amend the current regulations to explicitly incorporate APHIS' low level presence policy.

As described in the DEIS, APHIS proposes to establish criteria under which the occurrence of a low level presence (LLP) of GE plant materials in seeds or grain may not be cause for agency remedial action. APHIS would still retain discretion to order corrective or remedial actions in situations that meet the non-actionable criteria, when the Administrator determines remedial action is needed to make the LLP unlikely to result in the introduction or dissemination of a plant pest or noxious weed. We propose to list criteria and describe possible enforcement actions in the regulations to improve transparency regarding how APHIS would respond to LLP in most instances. APHIS will not predetermine a specific level that is considered non-actionable as far as taking some remedial and/or enforcement action because this determination should always be made case-by-case. These criteria are intended to apply only to APHIS' decision to take or order remedial action in the event that LLP occurs. The proposed criteria are listed within the section describing the Administrator's ability to take or order remedial actions. Regardless of whether APHIS considers the LLP actionable with regard to remediation, any violations of the regulations or permit conditions could still result in any of the compliance and enforcement actions listed in the regulations, including imposing civil penalties.

APHIS is proposing a new provision in the regulations that would reflect the current policy cited above. The provision describes the criteria APHIS will use when determining that a LLP event would be non-actionable with regard to remediation, namely when the criteria support a conclusion that the

[2] Details of investigations that have led APHIS to propose expanded records requirements may be found in the ''Lessons Learned'' document cited above, and in investigation report documents on the APHIS Web site, e.g., ''2007 Report of LibertyLink Rice Incidents'' (*http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf*) and ''Transcript of Technical Briefing on Rice Investigation'' (*http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&contentid=2007/10/0285.xml*).

LLP is unlikely to result in the introduction or dissemination of a plant pest or noxious weed. Because the criteria are safety-based, they will be used for incidents of low level presence originating domestically (e.g., from field testing) as well as any low level presence that might be detected in import shipments that may contain organisms subject to regulation.

APHIS also considered two additional criteria, which we have not adopted in the proposed rule. First, we considered a criterion that would require that the genetic material be introduced into the plant using a method that has been demonstrated to result in integration of the new sequences into the plant genome, as defined in § 340.1. We did not include this criterion in our proposal because its relevance in the LLP context is unclear. A second criterion considered was that the genetic material engineered into the GE plant does not encode substances with whose function APHIS is unfamiliar. APHIS did not adopt this criterion since it is redundant with the proposed criteria that will be used, i.e., that the function of the introduced genetic sequences is known and that key food safety issues have been addressed.

The DEIS, in Issue 7, Alternative 3, proposed that APHIS would also consider the LLP safety criteria when deciding whether to issue a permit for environmental release, and what type and severity of permit conditions to assign to the release permit. In its evaluation of permit applications, APHIS does plan to refer to the LLP criteria, as described above.

F. Administrative Changes

1. Confidential Business Information

APHIS is proposing a new § 340.8 to provide further guidance on the manner in which confidential business information (CBI) will be addressed in the implementation of these regulations. This change will support the overall administration of the program. The proposed § 340.8 cites the relevance of the Freedom of Information Act (FOIA) and exemptions from releasing information pursuant to FOIA, namely, 5 U.S.C. 552(b)(4), and states that APHIS may exempt from disclosure to the public trade secrets and commercial or financial information obtained from a person that are privileged or confidential. Proposed § 340.8 also states how persons wishing to protect confidential business information should communicate with APHIS in permit applications, petitions, or other submissions to APHIS.

2. Time Frames for APHIS Action on Permit Applications and Petitions

Current regulations specify time frames within which APHIS must take certain actions, such as issuing permits, acknowledging notifications or issuing decisions on petitions to grant nonregulated status. APHIS experience in the last several years has shown that the time required to complete these actions has increased beyond the time frames originally stipulated in the regulations in 1987 (permits) and 1993 (petitions for nonregulated status). As stated in the current regulation, APHIS is obligated to give its reply in the stipulated time, even if required procedures are not yet complete. Therefore, APHIS proposes to include in § 340.2(d) of the regulations a statement that APHIS will generally respond in the time frames indicated. APHIS believes it is important to continue to meet the indicated time frames whenever possible, but the most important thing is to communicate the actual status of reviews and procedures with applicants rather than be obligated to reach a decision in a certain number of days despite the complexities involved with a review. APHIS is particularly seeking comment on this proposed change from persons with experience under the current time frames.

3. Duration Period for Permits

Under the current regulations, notifications for environmental release and interstate movement are valid for one year, and the duration period for a permit issued for an environmental release is not specified. Currently interstate movement permits are only valid for one year from the date of issuance, and a new import permit must be obtained for each imported shipment.

APHIS will continue to retain the flexibility of the permitting procedure to authorize environmental release permits that can be effective for any appropriate time period. In some cases, it may be most efficient to authorize environmental release permits that are valid for more than a single year. In such cases, APHIS can retain adequate oversight by performing periodic inspections and requiring periodic reports. Experience has revealed situations where field tests lasting more than one year are essential. For example, some environmental releases of GE fruit trees may take several years to evaluate the fruit production that often does not begin for several years after planting.

In order to provide greater flexibility and efficiency, APHIS is also proposing to eliminate the current restrictions in the regulation on the duration of permits for interstate movement and importation. The proposed regulations will remove the requirements that interstate movement permits are only valid for one year from the date of issuance, and that importation permits must be obtained for each individual importation. These changes should give APHIS the flexibility to issue these permits with suitable durations to meet the individual circumstances.

G. Definitions and Miscellaneous Changes

APHIS proposes to change certain definitions in § 340.1 of the regulations, to add certain new definitions, and to remove definitions for terms that are defined in the PPA or that no longer appear in the regulations.

Revised Definitions

APHIS proposes to change the definitions of the following terms in § 340.1:

Release into the environment would read ''Dispersal beyond the constraints of a contained facility or secure shipment. Synonymous with the term environmental release.''

Secure shipment is a new term defined below. By adding reference to secure shipment in this definition, we clarify the distinction between environmental release and shipments for importation and interstate movement; any such movements which are not done by secure shipment constitute an environmental release.

Responsible person would read ''The person who has control and will maintain control over a GE organism during its importation, interstate movement, or release into the environment and assures compliance with all conditions contained in any applicable permit or exemption as well as other requirements in this part. A responsible person shall be at least 18 years of age and be a legal resident of the United States or designate an agent who is at least 18 years of age and a legal resident of the United States.'' The change from the former definition is the addition of ''at least 18 years of age,'' added to prevent possible enforcement difficulties.

New Definitions

APHIS proposes to add definitions of the following new terms:

Confidential business information, CBI would read ''Information such as trade secrets or commercial or financial information that may be exempt from disclosure under Exemption 4 of the Freedom of Information Act (FOIA),

because disclosure could reasonably be expected to cause substantial competitive harm. USDA regulations on how the agency will handle CBI and how to determine what information may be exempt from disclosure under FOIA (5 U.S.C. 552) are found at 7 CFR § 1.12.'' We propose to add this definition because APHIS has often been asked to clarify what is and is not CBI, and how it is handled. The definition describes typical types of CBI, and the language in proposed § 340.8 describes how persons submitting documents to APHIS can request that identified information be treated as CBI. There is also additional guidance on CBI contained in administrative guidance on the APHIS Web site regarding document preparation for part 340 requests. However, it is important to realize that in actual situations where someone submits a FOIA request for particular information, the APHIS FOIA Officer makes the ultimate determination as to whether particular information shall be released, in accordance with the standards of FOIA, Executive Order 12600, and 7 CFR 1.12.

Contingency plan would read ''A written plan stating how the responsible person will respond in the event of the unauthorized environmental release of GE organisms.'' We propose to define this new term to describe a document mentioned in both the permit application information requirements section (§ 340.2(c)) and the permit conditions section (§ 340.3).

Exempt, exempted, exemption would read ''A determination by the Administrator that the importation, interstate movement, and/or release into the environment of an organism or class of organisms described in § 340.0(a) is not subject to the requirement to have a permit under this part. An exemption from one type of permit (e.g., interstate movement) does not remove remaining obligations to obtain other permits under this part.'' We propose to add this definition for the term *exemption* to refer to situations where a regulated movement is exempt from the requirement for a permit. The proposed definition is based on language in Sec. 411(b)(1) of the PPA (7 U.S.C. 7711(c)), titled ''Exception to permit requirement,'' which authorizes the Secretary to issue regulations to allow the movement of specified plant pests without further restriction if the Secretary finds that a permit is not necessary.

Noxious weed would read ''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.'' This is the definition for noxious weed found in the PPA.

Recipient organism would read ''The organism that will receive the genetic material from a donor organism in the process of genetic engineering (once the organism is engineered it is referred to as the genetically engineered (GE) organism).'' This definition is needed to properly distinguish organisms and their traits in comparisons of GE organisms to the same organisms prior to transformation.

State or tribal regulatory official would read ''State or tribal official with responsibilities for plant health, or any other duly designated State or tribal official, in the State or on the tribal lands where the importation, interstate movement, or release into the environment is to take place.'' This term is used in reference to consultations with States and tribes under the regulations.

Secure shipment would read ''Shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.''

We propose to add the following two definitions to make it clear that, when the Administrator authorizes it, a signature required under the regulations may be an electronic signature and a written document required under the regulations (e.g., a permit application) may be an electronic document.

Signature, signed would read ''The discrete, verifiable symbol of an individual which, when affixed to a writing with the knowledge and consent of the individual, indicates a present intention to authenticate the writing. This includes electronic signatures when authorized by the Administrator.''

Write, writing, written would read ''Any document or communication required by this part to be in writing may also be provided by electronic communication when authorized by the Administrator.''

Deletion of Definitions

We propose to remove the following definitions from the regulations: *courtesy permit, expression vector, introduce or introduction, regulated article, stably integrated, vector or vector agent,* and *well-characterized and contains only non-coding regulatory regions.*

These definitions would be removed because the terms would no longer be used in the regulations. We propose to eliminate the term *regulated article* partly because the use of the term ''article'' in current part 340 is not consistent with usage in the PPA, which uses the term article to mean ''any material or tangible object that could harbor plant pests or noxious weeds''—that is, things like packing materials, shipping containers, commodities, etc.—and not a plant pest or noxious weed itself. Under the current regulation, however, *regulated article* refers exclusively to certain GE organisms. Furthermore, under both the PPA and part 340, ''articles'' are not regulated, but rather their importation, interstate movement or environmental release is regulated. For these reasons, the term ''regulated article'' in the current regulations is both inconsistent with the terminology of the PPA and difficult for the public to comprehend.

We also propose to remove the definition for introduction. APHIS currently uses the term in part 340 to denote certain kinds of activities that fall within the scope of the regulation, namely importation, interstate movement, and release into the environment. The PPA, however, does not specifically define the term introduction. Therefore, to avoid confusion, instead of using the term introduction to define the different types of regulated activities, APHIS will instead refer to these specific activities themselves in the regulations, namely, the importation, interstate movement and release into the environment.

Miscellaneous Changes

We also propose to make minor miscellaneous changes to the regulations to improve their clarity and remove redundancies. For example, in addition to adding the definition for CBI discussed above, we are consolidating requirements concerning CBI, formerly contained in several sections of the regulations, into proposed § 340.8.

IV. Required Analyses

A. National Environmental Policy Act

On January 23, 2004 (69 FR 3271), APHIS published a notice of intent to prepare a draft environmental impact statement (DEIS) in accordance with the National Environmental Policy Act in connection with the regulations at 7 CFR part 340 and potential changes to those regulations. This notice identified potential issues and alternatives to be studied and requested public comment to shape the scope of the DEIS.

On July 17, 2007, APHIS published the DEIS evaluating regulatory alternatives under consideration and solicited public comment on the DEIS

(72 FR 39021–39025). The Environmental Protection Agency published a separate notice on July 13, 2007, soliciting public comment on the DEIS (72 FR 38576–38577). The notices sought comments on the quality of our analysis of potential environmental effects of the alternatives under consideration, and also sought views on how each alternative would affect areas such as the overall effectiveness of our biotechnology program, its operational efficiency, industry compliance issues, or other issues that would be associated with the implementation of an alternative.

The major elements of this proposed rule were accurately described in the alternatives contained in the DEIS and their potential environmental effects were analyzed in the DEIS. Table 4 below provides a comparison between the proposed changes to part 340 and the DEIS. We received numerous comments on the DEIS, which will be discussed fully when we publish a final environmental impact statement (FEIS). The DEIS and the comments on it were used by APHIS to inform decision makers and aid the design of this proposal. Information from the DEIS comments, along with information from many other sources, including certain provisions of the 2008 Farm Bill and recommendations from USDA's OIG, was used to inform the drafters of this proposed rule about the issues perceived to be involved in and addressed by the rulemaking. We will respond to all DEIS comments in detail in the FEIS since the agency action (revising the regulations in part 340) is still subject to change based on comments and information received on this proposed rule, and thus we cannot provide definitive and final comment responses until we issue the FEIS and the final rule.

Consideration of the DEIS comments led APHIS to refine and reorganize some of the regulatory alternatives it considered. Therefore, the presentation and discussion of the alternatives proposed in this proposal do not exactly match those described in the DEIS. The differences are primarily a matter of reorganizing and realigning some material and their corresponding regulatory alternatives, using more descriptive terms in some criteria listed in the alternatives, and choosing between regulatory alternatives that fall within the analysis of the DEIS. Accordingly, the DEIS is still consistent and applicable as an analysis of the potential environmental effects of the proposed action. However, we are interested in receiving comments on whether any of the proposed regulatory alternatives in this document do not appear to have been adequately addressed within the DEIS.

TABLE 4—SUMMARY OF PROPOSED CHANGES TO THE REGULATIONS AND RELATIONSHIP TO DEIS

Summary of proposed substantive changes to the regulation	DEIS issue	DEIS alternative
Redescription of which GE organisms are subject to the regulations.	1	2 (DEIS preferred alternative) or 3.
Deletion of the list of plant pest taxa in the regulations and the petition procedure to amend the list.		
Clarification that APHIS has the authority to regulate nonliving materials through permit conditions in cases where such materials may pose a risk as a noxious weed.	5	2 (DEIS preferred alternative).
Revision of the application information requirements and permit conditions for all permit types.		
Elimination of the current notification procedure for importation, interstate movement, and release into the environment of certain types of GE plants (permitting procedure will be used instead).	2	4 (DEIS preferred alternative).
Revision of the permitting system for environmental releases:	2	4 (DEIS preferred alternative).
• Subdivision into 5 categories of permits for environmental releases (4 for GE plants, 1 for other GE organisms).	4	2 (DEIS preferred alternative).
• Continue strict permit conditions for environmental releases of GE plants engineered to produce compounds intended for pharmaceutical or industrial uses.	6	1 (No action alternative).
Continued use of permits with appropriate conditions for single or multiple year releases.		
Creation of new administrative procedures in permitting: (1) The explicit agreement of the responsible person to comply with regulatory requirements of the permit, (2) amendment of existing permit conditions, (3) transfer of permits to a different responsible person, and (4) revocation of a permit.		
Elimination of the prescribed shipping container provisions in favor of a performance based approach specified as permit conditions for importation and interstate movement.	10	2 (DEIS preferred alternative).
Revision of the existing conditional exemptions for interstate movement such that the shipping standard is part of the exemption. Addition of a recordkeeping requirement for persons using the existing conditional exemptions.		
Elimination of the option for APHIS to issue courtesy permits for importation, interstate movement, and environmental release of GE organisms which are not subject to the regulation.		
Creation of a petition procedure for the Administrator to approve additional conditional exemptions from the requirement for a permit. This also includes a description of administrative steps if Administrator revokes an exemption, amends the conditions of an exemption, or prohibits a person from using a conditional exemption.	3 8	2 (DEIS preferred alternative). 1 (DEIS No Action alternative).
Clarification and revision of the existing petition procedure for determining nonregulated status, including elimination of the procedure to extend a previous determination of nonregulated status, and a description of the administrative steps if Administrator revokes nonregulated status.		
Clarification of the actions the Administrator may take related to compliance, enforcement, and remediation.		
Clarification of APHIS approach to the low level presence of regulated GE plants in seed or grain.	7	3 (DEIS preferred alternative).
Definition of Confidential Business Information (CBI) and description of administrative practices for CBI.		

We received approximately 23,000 comments on the DEIS, of which more than 22,000 were variations of several form letters. There were also several lengthy and detailed evaluations of environmental, scientific, legal, cultural, and economic issues raised by the DEIS. APHIS took all comments related to regulatory changes under consideration as we developed the content of this proposed rule, and altered a number of preliminary ideas for the proposal based on comments. We will fully summarize and address the comments received on the DEIS in a Final Environmental Impact Statement to be prepared in conjunction with the publication of a final rule. In addition to specific DEIS issues that were discussed above in the Preamble, the following section summarizes and discusses those comments on the DEIS that were most directly related to the regulatory alternatives discussed in this proposed rule and the ways in which these comments affected development of the proposal.

Many DEIS commenters addressed how the regulations should use the PPA authorities regarding noxious weeds, plant pests, and biological control organisms. Most comments on the DEIS that addressed this issue stated that APHIS should expand the scope of its regulatory program beyond plant pests to include both noxious weeds and certain biological control organisms, consistent with all of the regulatory authorities of the PPA. The following opinions were expressed regarding PPA authority regarding noxious weeds and the meaning of the PPA definition of noxious weed.

Very few commenters suggested that APHIS biotechnology regulations should implement the PPA's noxious weed definition in its broadest possible sense. One commenter suggested that APHIS broadly interpret the phrase ''other interests of agriculture,'' in the PPA definition of noxious weed such that APHIS would consider a plant to be a noxious weed if it poses solely economic harm, i.e., in the absence of physical harm. As explained previously in this proposal, such an interpretation is not consistent with the PPA, nor with the manner in which APHIS–PPQ has implemented the noxious weed program pursuant to the PPA. Many commenters suggested that APHIS needed clear regulations or policies to describe how it will be evaluating whether GE plants pose threats as noxious weeds. APHIS agrees and has framed this proposal to clarify the issue for the public.

Some commenters stated that APHIS should acknowledge limits to its consideration of potential damage to public health in APHIS regulations, and the noxious weed definition should not be interpreted so broadly as to provide APHIS with the legal responsibility or authority to determine the food safety of GE crops or to prevent GE crops from entering the food supply. The commenters stated that Congress clearly intended the FDA to be responsible in this area.

We agree, and this proposal acknowledges FDA authority in the food safety area. However, it is important that the regulatory procedures in each agency dovetail and support each other where agency mission areas come in contact. This proposal recognizes this need for mutual agency support. When a permit for environmental release, importation, or interstate movement of a new GE organism is submitted to APHIS, we would evaluate whether there are any signs that the environmental release, importation, or interstate movement of the organism could present risks to the public health. If APHIS is concerned that there may be food safety risks associated with the GE organism, we would contact FDA. The decision on whether or how to regulate food and feed from the GE organism to address food and feed safety risks would then be FDA's. On the other hand, it is also likely that existing food safety evaluations will prove to be useful and relevant to APHIS evaluations of a GE organism. Food safety concerns are one of several factors APHIS would take into account when considering, for example, what types of permit conditions are needed for the environmental release of a GE organism, or whether activities associated with the organism should qualify for an exemption from the permit requirement.

Several commenters stated that under the current regulations APHIS has always considered noxious weed risk, or at least ''weediness.'' We agree that in practice, when APHIS assesses a GE plant it has always evaluated the potential weediness of the GE plant in relation to its plant pest potential. In the context of the PPA, ''weediness'' is more properly a noxious weed risk characteristic than a plant pest one, and the proposed revision of the regulations will more clearly align the regulations with the plant pest and noxious weed risk pursuant to the PPA. Current APHIS regulations and guidance directly address the importance of including weediness when evaluating risks associated with GE organisms. For example, when the petition procedure to grant nonregulated status was added to part 340 in 1993, the traits APHIS listed for evaluation explicitly included ''weediness of the regulated article'' (see current § 340.6(c)(4)).

Several DEIS commenters addressed what characteristics should trigger regulation of a GE organism, or put another way, how to set the scope of organisms subject to regulation. In the DEIS, APHIS explored many options including continuing to make its decisions primarily based upon the transformation event (also sometimes referred to as the individual transformed line, transgenic line or GE line). Some members of the public refer to this as an event-by-event approach. It is sometimes contrasted with a ''trait-based'' approach that focuses more on the resulting trait or phenotype of the GE organism. In a trait-based approach, a regulatory decision for an organism engineered for one phenotype would apply equally to other GE organisms if they had the same phenotype or trait, regardless of whether they were engineered with the same genes. APHIS invited comment on the relative merits of the event-by-event approach and the trait-based approach. The current regulations do not limit APHIS to one approach or the other. Many readers equated ''event-by-event'' with a ''process-based'' system and likewise equated ''trait-based'' regulation with a ''product-based'' system. Thus many comments focused on the relative merits of a product-based system versus a process-based system.

Some suggested that the trigger be ''process-based'', i.e., the process of modifying the organism by recombinant DNA techniques would be the determinant. Others suggested the trigger be ''product-based'', i.e., the nature of the resulting product (organism) would be the determinant for whether the organism would be subject to the regulation. Many of the comments were not actually related to the basis for the trigger, but rather to the focus of the risk assessment, with most stating that the risk assessments should be based on the biology of the organism (product-based), not the technique by which it was made (process-based). One commenter believes that the process of genetic engineering is a useful trigger, but once regulated, the characteristics of the GE organism should dominate APHIS considerations of safety.

Those supporting a process-based approach for identifying which organisms should be subject to regulation stated that each GE organism can have unintended as well as intended changes, and that these unintended changes to the organism would require that each individual resulting from genetic engineering must be assessed on a case-by-case basis.

Some commenters also suggested that this approach of APHIS assessment of each individual GE organism better protects the environment and human health than an approach that focuses primarily on the trait(s) of the GE organism.

Some commenters against process-based approach stated that this approach is illogical, on the one hand, to regulate a plant species with no known risks only because GE techniques were used to modify it, whereas on the other hand the same plant species modified by other techniques faces no additional regulatory requirements from APHIS.

Those supporting a product-based regulatory approach stated that it would be aligned with the preponderance of scientific opinion on the issue, that the characteristics of the organism should take precedence over the technique of genetic modification in the APHIS assessment of the organism. APHIS agrees that any evaluation of risk should be based on the biology of the product.

Several commenters suggested that the definition of *regulated article* would have to be reexamined and possibly redefined to reflect changes in the PPA. Commenters also stated that the term *regulated article* was problematic whether linked to specific taxa in § 340.2, under the current regulations, or linked to plants produced by particular technologies. These commenters emphasized that actions under the regulations usually amount to an investigation of whether an article (GE organism) needs to be regulated, and that predefining the subject of the investigation as a regulated article strongly implies that a decision has been made to require some regulatory oversight.

The proposed elimination of the term ''regulated article'' would facilitate a clearer understanding that it is not the GE organism that is regulated, but rather the importation, interstate movement, or release into the environment of the GE organism.

APHIS determined that eliminating ''introduction'' as a defined term would facilitate clearer understanding that the activities subject to the regulations are in fact importation, interstate movement, and release into the environment.

In the DEIS, APHIS discussed the need to regulate nonliving products of GE organisms. The preferred alternative was to have a procedure to regulate non-viable material only in certain rare circumstances when it might pose a risk. Most of the DEIS comments addressing this issue agreed that APHIS should regulate nonviable GE plant material only in certain circumstances, based on the risks posed. The few comments that provided greater detail identified toxicity risks and possible persistence in the environment of toxic nonviable plant parts or debris as the most significant risk associated with nonliving GE products. A few commenters also stated that adding a clear definition of ''nonliving'' or ''nonviable'' would aid the regulations.

APHIS has responded to these comments in this proposal by not usually regulating nonliving GE products, and by providing that when any control is needed over such a product that is associated with a living GE organism which is covered by a permit, due to toxicity or other risks, such controls would be included as permit conditions in permits issued for the associated living GE organism. We propose to provide for this by adding the following sentence to paragraph (b) of § 340.3, *Permit conditions:* ''The Administrator may also assign permit conditions addressing nonliving materials associated with or derived from GE plants when such conditions are needed to make it unlikely that the nonliving materials would pose a noxious weed risk.''

We received one DEIS comment directly addressing the issuance of courtesy permits. This comment supported retaining use of courtesy permits, and stated that courtesy permits facilitate the importation of GE *Drosophila melanogaster* strains by the research community and also ease the workload for APHIS. The continued issuance of courtesy permits diverts Agency resources unnecessarily from organisms that are within the scope of the regulations. We intend to help develop informational materials for the research community and other agencies that are aware of courtesy permits to clarify that such permits are not required, and to explain this to any persons who contact us requesting courtesy permits in the future.

Several DEIS comments addressed the notification procedure and supported eliminating it. Some comments suggested that the types of organisms formerly eligible for the notification process should instead be handled through a two-tiered permitting process, with experimental permits for field trials and commercial permits for GE crops that are to be sold in commerce. Other comments suggested that while some organisms might require permits with minimal conditions rather than notifications, others with even lower risks could be exempted from permit requirements. These latter comments also generally suggested that some of the criteria in the current regulations used to determine eligibility for the notification process could be preserved in the new regulations as criteria to identify organisms that should be exempted from the requirement for a permit. One commenter stated that since the current ''notification'' process involves acknowledgment by APHIS and conditions as well as notification, changing to a system of low risk permits would be a *de facto* acknowledgment of the current process. To address these issues, APHIS is proposing to eliminate notifications and to handle regulated GE organisms that previously would have been eligible for notifications through a permitting procedure.

We received a few comments on the DEIS generally related to procedures for reviewing permit applications. Comments stated that the role of States in reviewing or approving permit applications for GE crops has been very important and useful under the current regulations, and should continue in future regulations. Comments also stated the importance of scientific integrity in the review process, and emphasized the importance of coordinating with other agencies (particularly FDA and EPA review) when issues within their mission area arise during APHIS review of applications.

The proposed changes to the permit application procedure address these concerns. States would have a continuing role in application review that is very similar to their existing role, and we have been increasing interactions with the relevant tribal authorities in recent years.

Several comments were peripherally related to the DEIS issue of whether APHIS should establish standard or general permit conditions or what they should require. These comments emphasized that the purpose of permit conditions is to control risks not otherwise controlled, and that permit conditions must be developed in response to careful consideration of the risks presented by the particular permitted activity. One comment stated that APHIS should not require permit conditions that have the primary purpose of preventing crops from entering the food supply, because APHIS does not have the legal authority or scientific expertise to set them.

We have taken these views into account in designing this proposed rule. Proposed § 340.3 describes the core list of general conditions that APHIS would impose on all permits as well as additional conditions for specific types of permits. APHIS is also making it clear that APHIS may also add other specific

conditions to a permit upon its issuance. Conditions are specific practices or requirements that an applicant must follow upon issuance of a permit. Conditions are added as a consequence of the APHIS evaluation in order to make it unlikely that actions under the permit would result in the introduction or dissemination of a plant pest or noxious weed.

Several DEIS comments stressed that APHIS needs to do more to ensure that the permit conditions it sets are actually followed and enforced. The changes to permit procedures proposed for § 340.2 contribute to that goal by obtaining written agreement from the responsible person that he or she, and all of their agents, must comply with all of the permit conditions before issuance of the permit.

Almost all DEIS comments on containers or marking and identity for regulated articles supported performance standards for containers. Most of these commenters made the point that performance criteria are generally more adaptable and efficient than prescriptive criteria. Some stated that shipping research organisms interstate in enclosed containers is a low-risk activity that is very unlikely to result in release, establishment or harm.

Some commenters stated that the type of container indicated by performance standards must be appropriate to the level of risk in the tiered permit system for the shipped GE organism. One commenter requested that APHIS make its container standards consistent with the International Air Transporters Association (IATA) requirements for shipping.

The way this proposed rule deals with container standards is consistent with the above DEIS comments.

Most of the commenters addressing tiered or categorized permit systems supported APHIS establishing a tiered permitting system for plants based on criteria that included risk and other GE organism characteristics. However, commenters also stressed that risk categories should be based on a trait by species approach, not on the basis of individual transformed plant line (referred to as ''event-by-event'' in some of the comments). Some commenters advised against using limited broad based categories that include many different species with different biologies and different risk factors. Several stated the importance of evaluating permit applications on a case-by-case basis, to avoid the risk that categorizing permit types could result in approval of risky releases that were inadvertently seen as ''routine categories.''

Several commenters stated that a tiered permitting system should be flexible and allow consideration of any factors that seem relevant, or allow reclassification of a GE plant from one tier to another based on additional characterization information and agency familiarity with the GE plant. Some commenters opposed the development of a tiered risk-based permitting system because each transformation event can have unintended effects that must be assessed on a case-by-case basis, rather than through predefined categories. We have addressed these views in this proposed rule by changing the permit tier system described in the DEIS to a proposed permit application categorization system that is more flexible than the system described in the DEIS.

In the DEIS, APHIS considered whether to continue to issue environmental release permits for GE plants engineered to produce pharmaceutical and industrial compounds if the GE plant species is the same as, or sexually compatible with, a species commonly used for food or feed. APHIS concludes that the permitting procedure with its stringent permit conditions can continue to effectively minimize the risks that may be associated with the environmental release of such GE plants. APHIS will continue to impose appropriate permit conditions that take into account the issues related to the public safety of proteins or other substances that these plants have been engineered to produce.

Numerous commenters supported banning the outdoor production of pharmaceuticals and industrial substances in food and feed crops. Some stated that food crops should not be used for the production of pharmaceuticals and industrial substances.

Some commenters stated that GE plants used for the production of pharmaceuticals and industrial substances should be evaluated by criteria that are different from those used to evaluate crops intended for food. Other commenters stated that if such GE industrial plants were made from food crop species, or could spread genes to food crop species, they should be evaluated based on food safety risk, not the industrial product's function, and approved only if they pose no food safety risks. However, with regard to evaluating food safety, several commenters also stated that FDA should be the agency evaluating these risks.

We have not seen evidence suggesting that these types of organisms present unique or uncontrollable risks, or risks higher than those that may be associated with many other uses for GE plants. Our approach in this proposed rule addresses the other concerns cited by DEIS commenters.

Many commenters were concerned that the outdoor cultivation of GE plants producing pharmaceutical and industrial compounds could be a source of gene flow to nearby non-GE plants or result in the co-mingling of grain with related crop species intended for food or feed. Risks associated with this scenario may be abated by either of two means: (1) Preventing such gene flow or co-mingling from occurring, or (2) establishing that if such gene flow or co-mingling to other plants does occur, it does not present an unacceptable risk of introducing or disseminating a noxious weed.

Such gene flow can be minimized or substantially prevented through permit conditions developed for environmental releases of GE pharmaceutical or industrial plants. In many cases the genetic and phenotypic characteristics of the organism also serves to discourage survivability of the plant away from the intended site as well as gene flow to other plants. During the review prior to permit issuance, APHIS would also always consider the effects if the GE plant were likely to spread widely, or if large-scale gene flow to other plants occurred. A permit for an environmental release would not be approved if APHIS concluded there was a likelihood of such events causing any of the types of harm as described in the noxious weed definition.

One DEIS comment on the issue of multiple-year permits stated that compliance agreements should be used instead of actual multiple-year permits. Another suggested that multiple-year permits should be limited to trait/crop combinations not intended for feed or food use. In contrast, another comment stated that APHIS should consider allowing multi-year permits for any product, not just GE pharmaceutical or industrial plants.

Several commenters stated a risk-based opposition to multi-year permits and stated that crops engineered to produce pharmaceuticals or industrial compounds should always be regulated under an annually-reviewed permit system.

This proposed rule addresses the risk-based concerns cited by commenters in the proposed processes for issuing permits and granting exemptions, discussed elsewhere in this document. We propose to allow multi-year permits for any type of regulated activity, when we determine that appropriate risk-related conditions can be prescribed for those activities. We have not seen any

convincing evidence, in DEIS comments or elsewhere, that limiting use of multi-year permits to certain types of organisms would reduce risk or otherwise serve the purpose of the regulations.

Of the approximately 67 comments received by APHIS on the interstate movement exemptions discussion in the DEIS, 30 comments appear to support APHIS' preferred Alternative 2, under which APHIS would exempt from permit requirements for interstate movement a class of GE plants or organisms that are well-studied and present little or no environmental risk, as is currently done for *Arabidopsis.* However, many of these commenters suggested that APHIS choose an approach that combined this with one or more of the other Alternatives. Several commenters stated that the regulations should provide a procedure for APHIS to consider additional exemptions from interstate movement restrictions on a case-by-case basis.

APHIS has concluded that the most appropriate proposal for the regulations at this time is to provide a clear and adaptable procedure whereby it would use a case-by-case approach to consider the merits of new exemptions from the requirement for a permit. The procedure, described in proposed § 340.5, would allow for a transparent procedure in which APHIS would evaluate the proposed exemption, and the public would have an opportunity to review APHIS' evaluation and provide comments prior to APHIS decisions on individual cases. The proposed procedure should provide the benefit of transparency and scientific rigor while affording a more streamlined and cost-efficient procedure that would not require formal amendment of the regulations when each new exemption is approved.

Several DEIS comments addressed what criteria in the regulations the Agency could use to determine the level of risk assessment applied to imported GE commodities which are viable propagules. They fell into two general groups. Both groups stated that any expedited review or exemption for GE commodity imports needed to be granted based on a review of risk and a determination that the importation presented no significant risks. Beyond that, one group emphasized that commodity imports were in general inherently safe, and such an expedited system would be appropriate and would also greatly facilitate international trade. The other group was skeptical about inherent safety of GE commodities and suggested that exemptions should only be offered when there are procedures ensuring that the commodities are made non-viable or safeguards are in place to ensure that propagation will not occur. Some comments in this group also stated that such exemptions should not be granted for a GE commodity from any country until APHIS has confidence that the country has robust regulatory guidelines and assessment standards with strong, reliable science and trustworthy regulatory oversight, equivalent in effectiveness to the U.S. system.

One comment included a general statement that it was important that a petitioner for deregulation or exemption should work closely with APHIS to develop and evaluate the management plan under which the subject GE organism would be grown if deregulated or exempted. APHIS agrees that its regulatory approach should include working closely with petitioners on their proposals for exemption, especially if management plans are part of the requisite conditions. APHIS would retain some degree of oversight and could restrict movements of a GE organism such that the exemption and its conditions are unlikely to result in the introduction or dissemination of a plant pest or noxious weed. The proposed procedure to approve additional conditional exemptions is sufficiently adaptable even when the exemption is for all forms of movement (i.e., importation, interstate movement, and environmental release).

Very few DEIS comments directly addressed enforcement and compliance. A few comments stated that APHIS regulatory oversight and enforcement of its regulations in the past have been insufficient and have provided inadequate containment of GE crops. This proposed rule would strengthen enforcement and compliance and enhance the effectiveness of the regulations.

Comments on the discussion in the DEIS of low level presence ranged from suggestions that APHIS should completely prevent such incidents by banning all outdoor growth of GE plants to suggestions that LLP is a minor problem needing only minimal controls, and does not warrant an increased regulatory burden to control a minor risk. Some commenters stated that the preferred alternative in the DEIS accepted too high a level of risk. These commenters generally preferred DEIS alternative 4, which would impose very strict permit conditions on all environmental releases to reduce the likelihood of LLP events. Most commenters agreed that APHIS should adopt an LLP policy that recognizes the wide variety of risk levels associated with such incidents, and that beyond applying general criteria APHIS should investigate each unauthorized release individually and determine actions based on the facts surrounding each incident. Some commenters stated that any LLP policy should clearly state that even if an incident was found to be non-actionable (i.e., not requiring remedial action), persons involved would still be subject to enforcement actions such as civil penalties if violations of the regulations occurred.

APHIS has considered all these views in the development of this proposed rule and has attempted to find a reasonable balance. It is not warranted, or practical, to implement a ''zero tolerance'' LLP policy. Instead, we propose a policy that each LLP incident would be individually investigated, and APHIS would then make a decision on whether, or what kind of, remedial action is needed. In making this determination APHIS would use established criteria to rate the risks involved in the LLP incident. However, these criteria would not fully determine the APHIS response. In addition to considering the criteria, APHIS would evaluate any other relevant information regarding the LLP incident and order remedial action if it appears necessary.

Also, we propose to clearly state that regardless of whether APHIS considers the LLP actionable with regard to remediation, any violations of the regulations or permit conditions can still result in compliance and enforcement actions for failure to comply with the regulations.

One DEIS comment directly addressed timelines for APHIS to perform permit- and petition-related activities and urged APHIS to continue to define specific timelines for regulatory reviews to allow for a predictable regulatory review system. The comment stated that time frames are especially critical for field trial permitting activities since planting occurs during a narrow window each year and a delay of a month or two in a regulatory decision can result in a year delay due to the inability to timely plant a field trial.

We understand the concerns, and have decided to keep the time frames in the text of the regulations. However, as discussed above, APHIS will view them as performance goals and will generally respond in the time frames indicated, rather than be obligated to respond at those times. In recent years, there has been an increase in the time required for APHIS review due to the increasing complexity of issues related to environmental effects, new traits, and unfamiliar species. In addition to

retaining general time frames in the regulations, APHIS intends to discuss time frames with each applicant early in the application process, and to the extent possible give the applicant reliable time estimates based on the nature and complexity of the particular application and current APHIS activities and resources that are expected to affect the application review.

B. 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.

We have prepared an economic analysis for this proposed rule, which is summarized below. Copies of the full economic analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov). The analysis provides a cost-benefit analysis, as required by Executive Order 12866, and an analysis of the potential economic effects of this final rule on small entities, as required by the Regulatory Flexibility Act.

Background

The adoption of genetically engineered (GE) crops by farmers worldwide has become increasingly widespread. The United States, Argentina, Brazil, Canada, and China are the major GE crop adopters. In 2008, 92 percent of soybean, 80 percent of corn, and 86 percent of cotton acreages planted in the United States were genetically engineered (USDA NASS, 2008). In addition to the major field crops, GE varieties of papaya, yellow squash, and zucchini were available for commercial production in 2008.

Worldwide plantings of transgenic crops grew by 12 percent in 2007, reaching 282.4 million acres in 23 countries growing biotech crops in 2007, including 12 developing countries. Over the next decade, use of these ''first-generation'' GE crops, which carry traits such as insect resistance and herbicide tolerance, should continue to grow while a second generation of crops promises new applications and traits such as improved drought tolerance, biofuel-related enhancements, and quality and nutritional traits.[3]

[3] Global Status of Commercialized Biotech/GM Crops, ISAAA Briefs 37–2007, 35–2006, The International Service for the Acquisition of Agri-Biotech Applications, Cornell University.

The benefits associated with the use of some GE crops already in production include higher yields, lower pesticide costs, and overall savings in management time. There are also environmental benefits from reduced pesticide use. Attempts have been made to quantify the benefits that have occurred as a result of the adoption of GE crops and, according to a recent survey, farm-level net economic benefits worldwide from the adoption of GE crops were estimated to be $7 billion in 2006 (Brookes and Barfoot 2008). Total net benefits, 1996–2006, were estimated to be $34 billion. Of this total estimated net welfare gains, the United States experienced the largest benefit, with $15.8 billion; followed by Argentina, $6.6 billion; China, $5.8 billion; and Brazil, $1.9 billion (Brookes and Barfoot 2008). U.S. farmers' welfare gains from the adoption of biotechnology ranged from 29 to 42 percent of total net welfare gains (Price *et al.* 2005; Falck-Zepeda, Traxler, and Nelson 2000).

The high rate of GE crop adoption by farmers has been driven by an increase in consumption of product developed with the use of GE techniques. However, studies that quantify consumers' benefits from the use of biotechnology are limited, as most studies tend to focus on the direct adopters of biotechnology, i.e., the producers. Price *et al.* (2006) found consumers do benefit from the adoption of Bt cotton.

Overall, consumers' gains from the adoption of various GE crops have been estimated to range from 4 to 17 percent of total net welfare gains (Price *et al.* 2005; Falck-Zepeda, Traxler, and Nelson 2000).

Crop producers and consumers are not the only beneficiaries of recent advances in biotechnology. The providers of biotechnology have also benefited from the increased adoption of GE products. Intellectual property right laws have offered incentives for the private sector to invest in research and development of GE products, and as a result, plant breeding expenditures have largely shifted from the public to the private sector (Fuglie 2006). As private research spending has increased, so has the number of firms engaged in this type of research. However, consolidation and mergers during the 1990's resulted in an industry dominated by large companies. Currently, 80 percent of biotech traits that have been approved are owned or co-owned by four firms (Bayer Crop Science, DuPont, Monsanto, and Syngenta) or their subsidiaries (Kalaitzandonakes, Alston, and Bradford 2007).

With regard to the beneficial effects for the environment of GE plants in commercial production, their production has resulted since 1996 in decreases in the use of pesticides by 286 million kg and in the use of herbicides by 51 million kg (Brookes and Barfoot 2008). These declines represent 7.9 percent reductions. In terms of greenhouse gases, one study estimated cultivation using no-tillage systems associated with GE crops modified for herbicide tolerance to reduce fuel use by 32.52 liters/ha (89 percent) compared to conventional methods, and 14.7 liters/ha (76 percent) compared to reduced tillage methods (Jasa 2002). An American Soybean Association survey[4] showed significant reductions in tillage, and therefore in fuel use, by growers of glyphosate-tolerant soybeans. The fuel reductions were estimated as 1.26 gallons per acre, or, for the 56 million acres of glyphosate-tolerant soybeans planted in 2001, 70 million gallons of fuel saved and associated greenhouse gas emissions avoided. These fuel-use reductions translate into reductions of carbon dioxide emissions of 89.44 kg/ha and 40.43 kg/ha, respectively. Overall in 2006, the total carbon dioxide savings associated with the use of GE crops were 1.2 billion kg. This is equivalent to removing 540,000 cars from the streets for a year.

Benefits of the Proposed Rule

The proposed rule would provide benefits by establishing more efficient regulation of GE organisms and activities subject to part 340 and by continuing to provide a high level of protection against risks associated with these organisms and activities. Benefits would also include improved public understanding of and confidence in APHIS' biotechnology regulatory responsibilities, and improved clarity and transparency of the regulatory process. Several amendments of the proposed rule would improve the efficiency of APHIS' biotech regulatory process. Particular proposed changes that should improve the efficiency of the regulations include the elimination of courtesy permits and the establishment of a procedure to evaluate and grant requests for new exemptions from the requirement that GE organisms have a permit to be imported, moved interstate, or released into the environment.

Approving new exemptions could be done without amending the regulations, resulting in considerable time savings

[4] Cited in Fawcett, Richard and Towery, Dan. Conservation Tillage and Plant Biotechnology: How New Technologies Can Improve the Environment By Reducing the Need to Plow. Conservation Technology Information Center, West Lafayette, Indiana.

for regulated parties and reducing APHIS' rulemaking costs. Persons using an exemption would also avoid the costs and delays associated with obtaining a permit for each new planned movement or release of a GE organism covered by the exemption.

APHIS commits considerable resources to issuing courtesy permits not actually required by or needed to implement the part 340 regulations. These courtesy permits have been issued to facilitate the movement of GE organisms that are but whose movement may be hindered due to their similarity to organisms that are subject to part 340. By improving public awareness that such organisms do not need a permit and eliminating the courtesy permit process APHIS would improve efficiency and reduce its regulatory workload, and save time for regulated entities who would no longer make unnecessary courtesy permit requests.

The Agency currently issues environmental release permits, including permits that are used for production of pharmaceutical and industrial compounds sold in commerce. In general, permits for releases of plants producing pharmaceutical or industrial compounds have been limited to a one-year duration. However, the proposed regulations provide a more useful and efficient approach to setting appropriate risk-related conditions in multi-year environmental release permits. Under the proposed system, APHIS would likely increase issuance of multi-year environmental release permits, thereby reducing the time the regulated entities need to spend submitting applications as well as the time APHIS spends reviewing the permit applications.

APHIS' biotechnology operations would be aided by more clarity in terms of required data submissions and administrative procedures. More detail is provided regarding what applicant information is required for each permit application type, and how application information relates to the proposed new permit categories for environmental release permits. These changes, along with more clearly defined categories for the environmental release permits, would potentially reduce the time some entities, large or small, spend on an application or petition process. Increased efficiency benefits may be most helpful to smaller companies and public sector entities, where GE research is generally conducted on a much smaller scale than that of large agri-business enterprises.

The proposal includes provisions to require necessary recordkeeping and reporting but to fine-tune this burden through particularized permit conditions to require only what is needed to ensure regulatory compliance based on individual cases. This should contribute to greater efficiency.

The proposed rule's greater clarity and transparency is expected to enhance the general public's perception of APHIS regulation in this area, with associated benefits from increased support of and compliance with the regulations.

In addition to the information provided in the regulations, APHIS proposes to develop new guidance documents to assist in the preparation and submission of applications.

Costs of the Proposed Rule

There are several cost areas associated with the proposed rule. Costs associated with the proposed rule that regulated entities would incur include costs of learning and adapting procedures to changed requirements, providing more or different information in permit applications, and additional recordkeeping for some entities. The additional recordkeeping burden is discussed below in the Paperwork Reduction Act section. Annual costs resulting from the additional recordkeeping may be estimated as the salary and associated costs for 640 additional hours of recordkeeping divided among 160 respondents.

Many provisions of the proposed regulations are revisions of the current regulations, and it is not expected that familiarization costs would be substantial. However, estimates of these costs are not available and therefore APHIS invites public comment on the costs the regulated community may incur with respect to rule familiarization and changes to their application systems.

Costs to APHIS are currently incurred in the regulatory assessment and review of submitted materials. Because the new permit process is largely similar to the current process, it is expected that ongoing permit processing costs to APHIS would remain essentially unchanged. As a start-up cost to change the permit system to accommodate requirements of the proposed rule, APHIS may potentially incur a one-time additional cost of $500,000. However the current system is adaptable to the new regulations and it is not anticipated that there would be any efficiency loss during the transitional period. APHIS would also potentially incur incremental costs conducting outreach activities for the proposed rule, developing guidance documents to ensure that the regulated community is familiar with the requirements of the rule, and providing staff training that may be necessary. Because of the new definition of the scope of the regulations, APHIS may devote more resources to consultations with regulated parties if they request consultation to determine whether particular GE organisms are or are not subject to the regulations. Such consultation should decrease after the first year or two of implementation, as such determinations of regulated status accumulate and become the basis for guidance of general applicability.

Initial Regulatory Flexibility Analysis

In accordance with the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), this analysis considers the economic impact of the proposed rule on small businesses, small organizations, and small governmental jurisdictions. Section 603 of the Act requires that the initial regulatory flexibility analysis (IRFA) be made available for public comments. This section addresses the IRFA requirements, as stated in Sections 603(b) and 603(c) of the Act.

Reasons Action Is Being Considered

APHIS is taking action to amend 7 CFR part 340, which was promulgated in 1987 under the authority of the Federal Plant Pest Act of 1957 and the Plant Quarantine Act of 1912. These acts were subsequently subsumed within the Plant Protection Act (PPA) of 2000, and the proposed revisions would bring part 340 in alignment with this Act. Advances in biotechnology and accumulation of oversight experience by APHIS have also made it necessary to revise and update the regulations, and in addition, the 2008 Farm Bill (The Food, Conservation, and Energy Act of 2008) enacted most recently contains provisions that need to be incorporated into the proposed rule. The proposed changes would improve the regulatory process by providing greater transparency, flexibility, and efficiency.

Objective and Legal Basis for the Rule

The objectives of this rule are to amend part 340 to provide consistency with the PPA authorities and to incorporate updates and improvements to provide a more efficient regulatory process while controlling potential risk to plant health and the environment. The PPA authorizes the Secretary of Agriculture to implement programs and policies designed to prevent the introduction and spread of plant pests and diseases. Specifically, the Secretary of Agriculture is given the authority under the PPA to prevent the importation or dissemination of plant pests and noxious weeds. To do so, the

Secretary may regulate the importation, interstate movement, and release into the environment of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance that could potentially spread plant pests or noxious weeds.

Description and Estimate of the Number of Small Entities Regulated

The proposed rule may affect a wide range of public and private biotechnology research facilities, GE crop and seed production, food processors, grain processors, and paper producers that fall into various categories of the North American Industry Classification System (NAICS). For the purpose of this analysis and following the Small Business Administration (SBA) guidelines, the potentially affected entities are classified within the following sectors: Agriculture, Forestry, Fishing and Hunting (Sector 11), Manufacturing (Sectors 31–33), Wholesale Trade (Sector 42), Retail Trade (Sector 44 and 45), Transportation (Sectors 48 and 49), and Professional, Scientific and Technical Services (Sector 54).

For the Agriculture, Forestry, Fishing and Hunting sector, the subsectors of Crop Production, Animal Production, Forestry and Logging, and Support Activities for Agriculture and Forestry are potentially affected by this rule. The proposed rule may affect a wide range of establishments in the Crop Production category. Establishments in this category are considered small by SBA standards if annual sales are not more than $0.75 million. According to the 2002 Census of Agriculture, 97 percent of the farming businesses are considered small. Potentially affected crop-producing industries, with their NAICS codes in parentheses, are as follows: Soybean Farming (111110); Oilseed Farming (except soybean) (111120); Dry Pea and Bean Farming (111130); Wheat Farming (111140); Corn Farming (111150); Rice Farming (111160); Oilseed and Grain Combination Farming (111191); All Other Grain Farming (111199); Potato Farming (111211); Other Vegetable (except potato) and Melon Farming (111219); Orange Groves (111310); Citrus (except orange) Groves (111320); Apple Orchards (111331); Grape Vineyards (111332); Strawberry Farming (111333); Berry (except Strawberry) Farming (111334); Tree Nut Farming (111335); Fruit and Tree Nut Combination Farming (111336); Other Noncitrus Fruit Farming (111337); Mushroom Production (111411); Other Food Crops Grown Under Cover (111419); Nursery and Tree Production (111421); Floriculture Production (111422); Tobacco Farming (111910); Cotton Farming (111920); Sugarcane Farming (111930); Hay Farming (111940); Sugar Beet Farming (111950); Peanut Farming (111960); and All other Miscellaneous Crop Farming (111970).

Some aspects of animal production may be affected because some GE plants are used for animal feeds and may have enhanced nutritional value or other benefits. In terms of animal production, potentially affected entities include ones within the following industries: Beef Cattle Ranching and Farming (NAICS 112111); Cattle Feedlots (NAICS 112112); Hog and Pig Farming (NAICS 112210); Sheep Farming (NAICS 112410); Goat Farming (NAICS 112420); and Apiculture (NAICS 112910). Except for Cattle Feedlots, entities in all of these industries are considered small by SBA standards if annual sales are not more than $0.75 million. Cattle Feedlot establishments are considered small by SBA standards if annual sales are not more than $2 million. According to the 2002 Census of Agriculture, 93 percent of Cattle Feedlot businesses, 99 percent of Beef Cattle Ranching and Farming businesses, 81 percent of Hog and Pig Farming businesses, 99 percent of Sheep and Goat farming businesses, and 99 percent of Apiculture businesses are considered small.

For the Forestry and Logging subsector the potentially affected establishments are classified within Timber Tract Operations (NAICS 113110); Forest Nursery and Gathering of Forest Products (NAICS 113210); and Logging (NAICS 113310). Establishments in the category of Timber Tract Operations and Forest Nursery and Gathering of Forest Products are considered small by SBA standards if annual sales are not more than $6.5 million and establishments in the category of Logging are considered small if employment is not more than 500. According to the 2002 Survey of Business Owners, 99 percent of establishments in the Logging category are considered small. Neither the Census of Agriculture nor the Economic Census tracks revenue for establishments classified within Timber Tract Operations and Forest Nursery and Gathering of Forest Products.

In terms of Support Activities for Agriculture and Forestry, the potentially affected establishments are classified within Cotton Ginning (NAICS 11511); Soil Preparation, Planting, and Cultivating (NAICS 115112); Crop Harvesting (NAICS 115113); Postharvest Crop Activities (NAICS 115114); Farm Management Services (115116) Support Activities for Animal Production (NAICS 115210); and Support Activities for Forestry (NAICS 115310). Establishments in these categories are considered small by SBA standards if annual sales are not more than $6.5 million. However, neither the Census of Agriculture nor the Economic Census reports revenue for these establishments.

Entities that may be directly affected by the proposed rule in the Manufacturing Sector are classified within Ethyl Alcohol Manufacturing (NAICS 325193); Pesticide and Other Agricultural Chemical Manufacturing (NAICS 325320); Pharmaceutical Preparation Manufacturing (NAICS 325412); and Medicinal and Botanical Manufacturing (NAICS 325411). Establishments in the Ethyl Alcohol Manufacturing category are considered small if they employ not more than 1,000 persons and those in the category of Pesticide and Other Agricultural Chemical Manufacturing (NAICS 325320) are considered small if they employ not more than 500 persons. For both the Pharmaceutical Preparation Manufacturing (NAICS 325412); and Medicinal and Botanical Manufacturing (NAICS 325411) categories, establishments are considered small if they employ not more than 750 persons. According to the 2002 Economic Census, 98 percent of the establishments in the Chemical Manufacturing Sector had fewer than 500 employees and 99 percent had fewer than 1000. Therefore, businesses in the chemical manufacturing are predominantly small by SBA standards.

In terms of Wholesale Trade, entities that would be potentially affected may be found in the following categories: Fresh Fruit and Vegetable Merchant Wholesalers (NAICS 424480); Other Grocery and Related Products Merchant Wholesalers (NAICS 424490); Grain and Field Bean Merchant Wholesalers (NAICS 424510); Other Farm Product Raw Material Merchant Wholesalers (NAICS 424590); Farm Supplies and Merchant Wholesalers (NAICS 424910); and Flower, Nursery Stock, and Florists' Supplies Merchant Wholesalers (NAICS 424930). Establishments in the above categories are considered small by SBA standards if they employ not more than 100 persons. According to the 2002 Survey of Business Owners, 97 percent of the establishments in this category employed fewer than 100 people and are considered small by SBA standards.

Retail Trade, establishments that would be affected by the rules are in the following categories: Nursery and Garden Centers (NAICS 444220); Supermarkets and Other Grocery Stores (NAICS 445110); Fruit and Vegetable

Markets (NAICS 445230); All Other Specialty Food Stores (NAICS 445299); Food (Health) Supplement Stores (NAICS 446191); Warehouse Clubs and Superstores (NAICS 452910); and Florist (NAICS 453110). Establishments in the Nursery and Garden Center, Fruit and Vegetable Markets, All other Specialty Food Stores, Food (Health) Supplement Stores; and Florist categories are considered small by SBA standards if annual sales are not more than $6.5 million. Supermarkets and Other Grocery Stores are considered small by SBA standards if annual sales are not more than $25 million. While the Economic Census reports total annual sales, the Census does not provide a breakdown of these establishments by revenue categories.

In terms of the Transportation sector, the potentially affected entities are in the category Farm Product Warehousing and Storage (NAICS 493130). Establishments in this category are considered small by SBA standards if annual sales are not more than $23.5 million. However, the Economic Census reports only total revenue for all establishments in this category.

In terms of Professional, Scientific and Technical Services, establishments in the category of Research and Development in the Physical, Engineering, and Life Sciences (NAICS 54170) may be affected. Establishments in this category are considered small by SBA standards if they employ not more than 500 persons. According to 2002 Economic Census, 82 percent of the establishments in this category are considered small.

Although information was not available on the business sizes for all potentially affected establishments, based on the foregoing information we can assume that the majority of the entities that may be affected by the proposed rule are small by SBA standards.

Given the aforementioned, a review of entities that have made application requests to APHIS shows that of the 420 applicants for the last 6 years, 263 were universities and colleges and public and private research institutions. The remainder of the applicants fall under various NAICS classification codes specified above but given time constraints their business size could not be readily determined. We were able to ascertain that the 263 institutions (63 percent) are large by SBA standards as they fall under NAICS code 54170 Research and Development in Physical Science. Establishments in this category are considered small by SBA standards if they employ not more than 500 persons. Even though the 2002 Economic Census suggests that 82 percent of the establishments in this category are considered small, the majority of applicants to APHIS are large by SBA standards.[5]

Description and Estimate of Compliance Requirement

The proposed rule would require additional and modified information collections through recordkeeping, reporting, and notifications to APHIS when certain events occur. The proposed application process requires certain new information. The current and proposed rules both require submission of reports following an environmental release or field test, but the proposed requirement is more specific about the contents of such reports. Both the current and proposed rules require APHIS to be notified if an unauthorized release occurs or if during release the GE organism is found to have characteristics substantially different from those anticipated by the permit. The proposed rule is more specific about the types of records that must be kept for importations, interstate movements, and environmental releases, where the current regulations left more of these details to be specified only in permit conditions. In terms of record retention requirements, the proposed rule spells out a 2-year retention for records indicating that a GE organism imported or moved interstate reached its intended destination, and a 5-year retention for all other required records. By providing more specific information on what records are required, the proposed rule should alleviate some current burden that may result from persons keeping unnecessary records. In addition, APHIS has established the Biotechnology Quality Management System (BQMS), which is a voluntary compliance assistance unit within USDA APHIS. BQMS would facilitate the regulatory efforts of USDA APHIS by conducting outreach activities and providing compliance assistance to the regulated community. This would lessen any burden of the proposed rule to the regulated community.

Duplication, Overlap, and Conflict With Existing Rules and Regulations

APHIS has identified areas where the proposed rule will need to be closely coordinated with other Federal rules and statutory authorities. Coordination has been an important aspect of the daily implementation of the current regulation, and APHIS foresees additional areas for coordination under the proposed rule. In particular, APHIS will coordinate with the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA). FDA regulates GE organisms under the authority of the Federal Food, Drug and Cosmetic Act and the Public Health Service Act (42 U.S.C. 262 *et seq.*), as appropriate. The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain biological control organisms under the Toxic Substances Control Act (TSCA). As examples of areas that need coordination, some of the plant-incorporated protectants regulated by EPA are also subject to APHIS requirements under the PPA. Also, FDA is the primary U.S. agency responsible for ensuring the safety of commercial food and food additives, and FDA authority extends to any nonpesticidal substance that may be introduced into a new GE plant and that is expected to become a component of food. The proposed regulations would clarify the regulatory scope and procedures used by APHIS relative to these other agencies and improve the coordination process.

Significant Alternatives to the Rule

APHIS considered several significant alternatives during development of this proposed rule. We have compared the selected alternatives to others that were not selected to evaluate their feasibility and to consider whether any alternatives provide ways to minimize significant economic impacts on small entities. We have not identified any selected alternative that imposes disproportionate costs on small businesses, or any non-selected alternative that would both achieve the regulatory purposes and reduce costs for small businesses.

The selected alternative regarding the scope of the regulatory oversight was to add considerations of noxious weed risk in addition to evaluating plant pest risks, and to use genetic transformation, coupled with a determination by the Administrator as to whether a GE organism met certain risk-based criteria, as the trigger for regulation. Other alternatives considered included continuing to base the scope of regulation only on plant pest risks, or trying to develop a set of solely trait-based criteria that could be used to predict what articles would be regulated without the need for determinations by the Administrator. The first of these alternatives could have resulted in costs from damages caused by a GE plant with

[5] The size determination was made using public information about these entities. This information was primarily obtained from the entities' Web sites.

noxious weed aspects that was not regulated under the plant pest risks standard. The second alternative was not considered technically feasible, and could also have resulted in costs for persons who erroneously decide their GE plant is not within the scope of the regulations, but are overruled by a later determination by the Administrator that the GE plant is regulated.

The selected alternative for providing transparency and predictability to the permitting system was to establish permit categories for environmental releases of plants based on newly devised criteria. We also considered evaluating all requests for environmental release permits on a case-by-case basis, without categories. This alternative would have resulted in less predictability for applicants, and likely would have increased their costs for information collection because applications known to be in a particular category can contain less information about non-relevant areas.

The selected alternative regarding the duration period for permits was to make multi-year permits for interstate movement and importation more feasible by removing the one-year limit for interstate movement permits and the requirement to obtain a new importation permit for each imported shipment. We also considered alternatives to maintain either the current or alternative specific time limits for such permits. These alternatives would have resulted in additional costs for applicants who would have to reapply for permits, rather than having the original permit issued with an appropriate duration.

C. Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

D. Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) No State or local laws or regulations would be preempted by this rule; (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.

E. 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). The information collection or recordkeeping requirements in current 7 CFR part 340 have been approved under OMB Control No. 0579–0085. 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. APHIS–2008–0023. Please send a copy of your comments to: (1) Docket No. APHIS–2008–0023, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 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.

This proposed rule contains certain information collection and recordkeeping requirements that would apply to persons and their agents engaged in the importation, interstate movement, or release into the environment of any GE organism that is subject to the regulations. The majority of the requirements would apply to persons moving GE organisms under a permit issued by APHIS, but some requirements also apply to persons engaged in regulatory activities with GE organisms even when no permit is required, e.g., when they are exempted from the interstate movement permit requirement.

The proposed information and recordkeeping requirements are found in § 340.3, *Permit conditions,* and in § 340.7, *Compliance, enforcement, and remedial action.* Permit conditions for individual permits issued under the regulations may also require that certain records relevant to the particular movement must be kept.

The proposed permit conditions for shipments imported or moved interstate include maintaining records of the same types of information that the current regulations require to be on the package labeling of such shipments (nature and quantity, sender, destination, permit number, etc.) We believe that most persons shipping or importing GE organisms already maintain such records as part of normal business practices.

The proposed permit conditions for environmental releases include keeping records of all protocols or guidelines used to direct any environmental release. The current regulations already require persons conducting an environmental release under permit or notification to create and submit to APHIS a field test report, and in many cases the protocol or guidelines would normally be included in these field reports. This proposed change would require that the protocols or guidelines be kept in all cases as distinctly identifiable records, which may cause some increase in recordkeeping burden.

In some particular environmental release cases where higher risk levels make it necessary, the proposed rule would allow APHIS to add a special permit condition requiring the permit holder to maintain and make available to APHIS written manuals or protocols describing how specified permit conditions will be met, such as management practices used for the environmental release, training, communications, and identity preservation systems. This would be used in cases where it is deemed necessary to provide specific guidance in addition to the proposed general condition for all permits (i.e., that the holder must keep records related to permitted activities of sufficient quality and completeness to demonstrate compliance with all permit conditions and requirements under this part). Another proposed permit condition would require permit holders to develop and keep a written contingency plan to respond to any unauthorized environmental release. Both of these recordkeeping requirements would be added because some researchers or developers were found to be unclear about what management and communications practices were needed to prevent unauthorized releases, and also about their responsibilities and the measures they must take in the event of an unauthorized release.

The proposed procedure to apply for an environmental release permit requires applicants to submit a great deal of information characterizing the nature of the GE organism, the type of movement and release planned, plans and methods used to prevent unauthorized releases, and other matters. Most of the same information is obtained through the current application process, which allows the Administrator to require an applicant to submit any additional information that is needed for adequate evaluation of the application. The proposed application procedure is more specific in describing what information is required, and may result in a slight increase in the amount of information submitted with the average application.

The reporting burden for permit holders under the proposed rule would be similar to the burden under the

current regulations. In both cases they must submit reports of all field tests to APHIS, report any unauthorized releases, and submit any additional reports required as individual permit conditions in their permits.

The current regulations do not specify record retention periods, although some permits APHIS issued included specific retention requirements as permit conditions. This proposal would require that records associated with an importation or interstate shipment must be retained for at least 2 years after completion of the movement, and all other records (e.g., regarding environmental releases) must be retained for at least 5 years after completion of all obligations required under a relevant permit or exemption.

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 2 hours per response.

Respondents: Public and private biotechnology research facilities, GE crop and seed producers, food processors, grain processors, and paper producers that fall into various categories of the North American Industry Classification System.

Estimated annual number of respondents: 160.

Estimated annual number of responses per respondent: 2.

Estimated annual number of responses: 320.

Estimated total annual burden on respondents: 640 hours.

Copies of this information collection can be obtained from Celeste Sickles, the Agency Information Management Specialist, at (301) 851–2908.

F. E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Mrs. Celeste Sickles, the Agency Information Management Specialist, at (301) 851–2908.

List of Subjects in 7 CFR Part 340

Administrative practice and procedure, Biotechnology, Genetic engineering, Imports, Packaging and containers, Permits, Plant diseases and pests, Noxious weeds, Transportation.

Accordingly, we propose to revise 7 CFR part 340 to read as follows:

PART 340—IMPORTATION, INTERSTATE MOVEMENT, AND RELEASE INTO THE ENVIRONMENT OF CERTAIN GENETICALLY ENGINEERED ORGANISMS

Sec.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

§ 340.0 Scope and general restrictions.

(a) In order to prevent the unauthorized introduction or dissemination of a plant pest or noxious weed, no person shall import, move interstate, or release into the environment genetically engineered organisms described in paragraph (b) of this section, unless the importation, interstate movement, or release into the environment:

(1) Is authorized under a permit issued by the Administrator in accordance with § 340.2, or

(2) Is exempt from the requirements for a permit in accordance with § 340.4 or § 340.5, or

(3) Is approved for nonregulated status in accordance with § 340.6 or has previously been approved for nonregulated status pursuant to former regulations under this part, or

(4) Is excluded in accordance with paragraph (d) of this section.

(b) Genetically engineered organisms whose importation, interstate movement, or release into the environment is subject to the regulations in this part are:

(1) Genetically engineered plants if:

(i) The unmodified parent plant from which the GE plant was derived is a plant pest or noxious weed, or

(ii) The trait introduced by genetic engineering could increase the potential for the GE plant to be a plant pest or noxious weed, or

(iii) The risk that the GE plant poses as a plant pest or noxious weed is unknown, or

(iv) The Administrator determines that the GE plant poses a plant pest or noxious weed risk.

(2) Genetically engineered non-plant, non-vertebrate organisms if:

(i) The recipient organism can directly or indirectly injure, cause damage to, or cause disease in plants or plant products; or

(ii) The GE organism has been engineered in such a way that it may increase the potential for it to be a plant pest: or

(iii) The risk that the GE organism poses as a plant pest is unknown, or

(iv) The Administrator determines that the GE organism poses a plant pest risk.

(3) *Opportunity to consult APHIS.* Any person may contact APHIS to discuss how the criteria of this paragraph apply in the case of a particular GE organism or group of organisms.

(c) The Administrator may issue permits for the importation, interstate movement, or release into the environment of certain genetically engineered organisms described in paragraph (a) of this section. These permits may include such requirements or conditions as the Administrator deems necessary to prevent the unauthorized introduction or dissemination of a plant pest or noxious weed. The Administrator may also designate certain exemptions from the requirement to obtain permits. The Administrator may also approve for nonregulated status a genetically engineered organism described in paragraph (a) of this section for which a determination has been made by the Administrator that the organism is unlikely to be a plant pest or noxious weed.

(d) Genetically engineered microorganisms that are regulated as biological control organisms under the Federal Insecticide, Fungicide, and Rodenticide Act are not subject to the regulations in this part. Genetically engineered microorganisms where the recipient microorganism is not a plant pest and which has resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions are not subject to the regulations in this part.

§ 340.1 Definitions.

Terms used in the singular form in this part shall be construed as the plural, and vice versa, as the case may demand. The following terms, when used in this part, shall be construed, respectively, to mean:

Administrator. The Administrator of the Animal and Plant Health Inspection Service (APHIS) or any other employee of APHIS to whom authority has been, or may be, delegated to act in the Administrator's stead.

Animal and Plant Health Inspection Service (APHIS). An agency of the United States Department of Agriculture.

Confidential business information, CBI. Information such as trade secrets or commercial or financial information that may be exempt from disclosure under Exemption 4 of the Freedom of Information Act (FOIA), because disclosure could reasonably be expected to cause substantial competitive harm. USDA regulations on how the agency will handle CBI and how to determine what information may be exempt from disclosure under FOIA (5 U.S.C. 552) are found at 7 CFR 1.12.

Contained facility, contained structure. A physical structure designed to minimize release into the outdoor environment. Examples of contained structures include, but are not limited to, laboratories, containment greenhouses, bioreactors, and fermenters.

Contingency plan. A written plan stating how the responsible person will respond in the event of the unauthorized environmental release of GE organisms.

Donor organism. The organism from which genetic material is obtained for transfer to the recipient organism in the process of genetic engineering.

Environmental release. See definition of *Release into the environment.*

Exempt, exempted, exemption from permit. A determination by the Administrator that the importation, interstate movement, and/or release into the environment of an organism or class of organisms described in § 340.0(a) is not subject to the requirement to have a permit under this part. An exemption from one type of permit (e.g., interstate movement) does not remove remaining obligations to obtain other permits under this part.

Genetic engineering. The genetic modification of organisms by recombinant DNA techniques.

Genetically engineered, GE. A term applied to organisms that have been produced by genetic engineering, e.g., GE organisms, GE plants.

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

Inspector. Any employee of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or other person, authorized by the Administrator, in accordance with law to enforce the provisions of this part.

Interstate movement. Movement from any State into or through any other State.

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

Nonregulated status. A determination by the Administrator that an organism described in § 340.0(a) is not subject to any of the regulatory requirements of this part.

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.

Organism. Any active, infective, or dormant stage or life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.

Permit. A written authorization by the Administrator for the importation, interstate movement, and/or release into the environment of a GE organism under this part.

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

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

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

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.

Recipient organism. The organism that will receive the genetic material from a donor organism in the process of genetic engineering (once the organism is engineered it is referred to as the genetically engineered (GE) organism).

Release into the environment. Dispersal beyond the constraints of a contained facility or secure shipment. Synonymous with the term environmental release.

Responsible person. The person who has control and will maintain control over a GE organism during its importation, interstate movement, or release into the environment and assures compliance with all conditions contained in any applicable permit or exemption as well as other requirements in this part. A responsible person shall be at least 18 years of age and be a legal resident of the United States or designate an agent who is at least 18 years of age and a legal resident of the United States.

Secure shipment. Shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

Signature, signed. The discrete, verifiable symbol of an individual which, when affixed to a writing with the knowledge and consent of the individual, indicates a present intention to authenticate the writing. This includes electronic signatures when authorized by the Administrator.

State. Any State of the United States, the District of Columbia, American Samoa, Guam, Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and any other Territories, Possessions, or Districts of the United States.

State or tribal regulatory official. State or tribal official with responsibilities for plant health, or any other duly designated State or tribal official, in the

State or on the tribal lands where the importation, interstate movement, or release into the environment is to take place.

United States. All of the States.

Write, writing, written. Any document or communication required by this part to be in writing may also be provided by electronic communication when authorized by the Administrator.

§ 340.2 Procedure for permits.

(a) *General.* A permit is required for the importation, interstate movement, or release into the environment of any GE organism that is subject to this part, as described in § 340.0, The responsible person seeking a permit for the importation, interstate movement, or release into the environment of such organisms shall submit a written application for a permit to APHIS in accordance with paragraph (c) of this section and obtain the permit prior to the importation, interstate movement, or release into the environment.

(b) *Types of permits.* The Administrator may issue the following three types of permits under this part.

(1) *Import permit.* Import permits are for secure shipment via any means of conveyance from outside the United States into contained facilities within the United States.

(2) *Interstate movement permit.* Interstate movement permits are for secure shipment via any means of conveyance from a contained facility in any State into or through any other State to another contained facility.

(3) *Environmental release permit.* Environmental release permits are for the environmental release of GE organisms. In cases in which importation and interstate movements will occur incidental to an environmental release, the importation and interstate movements will also be authorized under the environmental release permit.

(c) *Permit application information requirements.* Applicants must submit to APHIS sufficient information about the specific nature of the GE organism and the particular proposed permit conditions, so that the Administrator is able to consider whether the proposed importation, interstate movement, or release into the environment is likely to result in the introduction or dissemination of a plant pest or noxious weed. The basic information required in permit applications is described in this paragraph. The type and level of detail needed for the Administrator to issue a permit may vary by type of permit. For environmental releases, application information will be used to sort proposed releases of GE organisms into administrative categories described in paragraph (d) of this section. Applicants should consult with APHIS prior to applying for permits in order to obtain further guidance as to what additional information the Administrator may require to be submitted with the application.

(1) *Information required in all permit applications.* Each application must include all of the following information, and any other information specified for individual types of permits as described in this paragraph:

(i) The name, title, and contact information (e.g., mailing address, e-mail, telephone and fax numbers) of the responsible person;

(ii) The type of permit sought (importation, interstate movement, or environmental release, and if the permit is for environmental release, which category);

(iii) Information necessary to identify and characterize the GE organism(s) for which a permit is sought, including:

(A) The scientific names of all donor and recipient species plus any designations used for the GE organism(s) (e.g., strain, line, variety);

(B) The form of the GE organism (e.g., seeds, rootstocks, tubers, spores, larvae, eggs) and the amount (e.g., numbers, total weight or volume); and a description of any biological material accompanying the GE organism under permit (e.g., culture medium, or host organisms, etc.);

(C) The anticipated phenotype of the GE organism and the nature of the inserted sequences or other genetic modification intended to confer the phenotype;

(D) Intended uses of the GE organism after the termination of the importation, interstate movement, or environmental release (e.g., contained research in laboratories or containment greenhouses, culturing, propagation, breeding, processing for analysis or manufacture, sale and distribution for consumption); and

(E) Description of how the GE organism will be marked, labeled, or otherwise identified during the importation, interstate movement, or environmental release;

(iv) The proposed time frame (estimated start and duration) within which the importation(s), interstate movement(s) or environmental release(s) will occur;

(v) Description of how permit requirements will be communicated to persons having contact with the GE organism under permit;

(vi) Description of any training given to persons having contact with the GE organism under permit, including but not limited to detailed information on how this training will facilitate compliance with conditions imposed under the permit and any other regulatory requirements under this part; and

(vii) A certification statement signed by the responsible person that certifies that the application information is correct.

(2) *Additional information required in all applications for importation permits, interstate movement permits, and all environmental release permits that include importation or interstate movement.*

(i) The location(s) of the origin(s) and destination(s), including information on the addresses, and contact details of the sender(s) and recipient(s), if different from the responsible person.

(ii) A description of the method of secure shipment.

(iii) A description of the manner in which packaging material, shipping containers, and any other material accompanying the GE organism will be disposed.

(3) *Additional information required in all environmental release permit applications.* Information should address the persistence risk and potential harm of the GE organism in the environment, including but not limited to:

(i) A description of how the phenotype of the GE organism differs from the phenotype of the recipient organism, particularly with respect to potential interactions with and its likelihood of persistence in the environment.

(ii) The location and size of all proposed release sites, including area, geographic coordinates, addresses, and contact information of a person at each release site, if different from the responsible person. Include information about the ecology and agronomy of each site, including but not limited to:

(A) Presence of any wild or cultivated species that are sexually compatible with the GE organism;

(B) Presence of any Federally-listed threatened or endangered species that could interact with the GE organism during the release;

(C) Presence of any designated critical habitat, or habitat proposed for designation, in the area of the release site; and

(D) Land use history of the site and adjacent areas.

(iii) A description of the site management practices and control procedures designed to make it unlikely that there will be unauthorized introduction or dissemination of the GE organism beyond the proposed area and

the permit time frame of release. Each of the descriptions shall include:

(A) Description of the methods and stages of transport of the GE organism from a contained facility to the environmental release site, and any storage methods used at the site;

(B) Description of methods of planting, inoculation, or release; any reproductive or cultural controls; methods of treatment and harvest used for the GE organism; and a proposed plan for monitoring the site for pests, diseases, and effects on other organisms during the time the GE organism is released;

(C) Description of the methods and stages of transport of the GE organism from release site back into contained facilities, or methods of devitalization at the site(s) of the environmental release;

(D) Description of the cleaning, disinfection, or other methods used to make it unlikely that unauthorized dissemination of the GE organism into the environment could occur via means of conveyance and other articles (e.g., planters, harvesters, containers);

(E) Description of any post-release land use practices, including any monitoring plans to ensure that the GE organism or its progeny are unlikely to reproduce and disseminate in the environment after the termination of the release (e.g., managing volunteer plants); and

(F) Description of the contingency plans associated with the release.

(d) *Administrator action on permit applications.* An initial review should generally be completed by APHIS within 15 days of the receipt of the application for importation or interstate movement permits, and within 30 days for environmental release permits. An application will be considered complete when the Administrator determines that it includes all information required by this section and any additional information that the Administrator determines is needed for review. If necessary after its initial evaluation of an application, APHIS will notify the applicant in writing if the submitted application information is incomplete, and the applicant will be provided the opportunity, without prejudice, to revise the application information to meet the needs for administrative processing and scientific review. Once the Administrator has determined that an application is complete, the Administrator will commence review. The APHIS review should generally be completed within 60 days after it is determined to be complete for importation and interstate movement permits, and within 120 days after it is determined to be complete for environmental release permits.

(1) *Administrative categories for environmental releases.* The Administrator will use the following categories to efficiently administer the program and tailor regulatory oversight in a manner that is commensurate with risk. Environmental releases of GE plants are assigned to one of four categories (A–D), using the factors described in (i–iv). A fifth category (E) is for environmental releases of all non-plant organisms; applications in this category will be reviewed on a case-by-case basis.

(i) *Initial sorting into categories.* The Administrator will use the following factors to initially sort environmental releases into administrative categories.

(A) Persistence of the nonmodified plant, ranked as follows:

(*1*) *Low:* Populations of the recipient plant are unlikely to persist in the environment without human intervention, and the recipient plant has no interfertile wild relatives in the United States.

(*2*) *Moderate:* Populations of the recipient plant are known to be weakly persistent in the environment without human intervention, or the recipient plant has interfertile wild relatives in the United States.

(*3*) *High:* Populations of the recipient plant are known to be strongly persistent in the environment without human intervention, or the recipient plant has interfertile wild relatives in the United States which are aggressive colonizers.

(*4*) *Severe:* The recipient plant is a Federally-listed noxious weed or is known to be similarly aggressive in its ability to colonize and persist in the environment without human intervention.

(B) Potential harm or damage of the engineered traits, ranked as follows:

(*1*) *Low:* Any new proteins or substances produced are unlikely to be toxic or otherwise cause serious harm to humans, vertebrate animals, or invertebrate organisms upon consumption of or contact with the plant or plant parts; and

(*i*) No morphological changes which could cause mechanical injury or damage; and

(*ii*) Introduced sequences are known not to result in plant disease, and confers no or very low increased disease susceptibility.

(*2*) *Moderate:* Any new proteins or substances produced are unlikely to be toxic or otherwise cause serious harm to humans or vertebrate animals upon consumption of or contact with the plant or plant; or

(*i*) Novel resistance to the application of an herbicide; or

(*ii*) Novel ability to cause mechanical injury or damage; or

(*iii*) Produces proteins or substances that are associated with plant disease that are not prevalent or endemic in the area of release, or that confer an increased susceptibility to disease.

(*3*) *High:* Any new proteins or substances produced may be toxic or to otherwise cause serious harm to humans or vertebrate animals, upon consumption of or contact with the plant or plant parts; or

(*i*) Produces an infectious entity which can cause disease in plants.

(*4*) *Severe:* Any new proteins or substances produced are known or likely to be highly toxic or fatal to humans or vertebrate animals, upon consumption of or contact with the plant or plant parts.

(C) Environmental releases will be initially sorted into administrative categories A–D as shown in Table 1, based upon the persistence risk and potential harm described in paragraphs (d)(1)(i)(A) and (B) of this section.

TABLE 1 TO § 340.2(d)(1)—INITIAL SORTING INTO PERMIT ADMINISTRATIVE CATEGORIES (A, B, C, AND D) FOR ENVIRONMENTAL RELEASES OF GE PLANTS, BASED UPON PERSISTENCE RISK OF THE RECIPIENT PLANT SPECIES AND POTENTIAL HARM OR DAMAGE OF THE ENGINEERED TRAIT

Persistence *	Potential harm or damage of engineered trait			
	Low	Moderate	High	Severe
Low	A	A	C	D
Moderate	A	B	C	D
High	B	B	C	D

TABLE 1 TO § 340.2(d)(1)—INITIAL SORTING INTO PERMIT ADMINISTRATIVE CATEGORIES (A, B, C, AND D) FOR ENVIRONMENTAL RELEASES OF GE PLANTS, BASED UPON PERSISTENCE RISK OF THE RECIPIENT PLANT SPECIES AND POTENTIAL HARM OR DAMAGE OF THE ENGINEERED TRAIT—Continued

Persistence *	Potential harm or damage of engineered trait			
	Low	Moderate	High	Severe
Severe	D	D	D	D

* Persistence risk of the recipient plant species.

(2) *Modification of initial sorting based upon additional considerations.* Following initial sorting using the factors described in paragraph (1)(i) of this section, the Administrator may reassign the environmental release to a different category based upon one or more of the following factors:

(i) How the recipient plant is used;

(ii) Whether the added trait significantly alters the persistence risk of the GE plant;

(iii) Whether the gene function is known and based upon empirical observation of the added trait in the same species; and

(iv) Any other information the Administrator deems relevant to the risk of introduction or dissemination of a plant pest or noxious weed.

(3) *APHIS review and assignment of permit conditions.* The Administrator will conduct a review and assign appropriate permit conditions so that the proposed activity will be conducted in a manner that makes it unlikely to result in the introduction and dissemination of a plant pest or noxious weed.

(4) *State or tribal review and comment.* The Administrator will submit for notice and review a copy of the permit application and any permit conditions to the appropriate state or tribal regulatory official. Comments received from the state or tribal regulatory official may be considered by the Administrator prior to permit issuance.

(5) *Site inspection.* Prior to and after permit issuance, an inspector may inspect the sites or the means of conveyance associated with the proposed importation, interstate movement, or release into the environment. The responsible person must allow any such inspections.

(6) *Issuance of a permit.* The Administrator may issue a permit if the Administrator concludes that the actions allowed under the permit are unlikely to result in the introduction or dissemination of a plant pest or noxious weed.

(i) Prior to the issuance of a permit, the responsible person must agree in writing, in a manner prescribed by the Administrator, that the responsible person and all agents of the responsible person will comply with the permit conditions. The Administrator will deny the permit application if the responsible person does not agree that both the responsible person and all of his or her agents will comply with all of the permit conditions.

(ii) If a permit is issued, the permit will include specific permit conditions required by the Administrator in accordance with § 340.3. If a permit is denied, within a reasonable time thereafter the applicant will be informed in writing of the reasons why the permit was denied and will be given the opportunity to appeal the denial in accordance with the provisions of paragraph (g) of this section.

(e) *Denial or revocation of a permit.* Permits may be denied or revoked in accordance with this paragraph.

(1) *Denial.* The Administrator may deny an application for a permit if:

(i) The Administrator cannot conclude based on the application that the actions proposed under the permit are unlikely to result in introduction or dissemination of a plant pest or noxious weed; or

(ii) The Administrator receives information apart from the application that precludes a conclusion by the Administrator that the actions proposed under the permit would be unlikely to result in the introduction or dissemination of a plant pest or noxious weed; or

(iii) The Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with any provision of this part. This would include failure to comply with the conditions of any permit issued.

(2) *Revocation.* The Administrator may revoke a permit if:

(i) The Administrator receives information subsequent to issuing a permit and makes a determination based upon this information that the circumstances have changed such that actions under the permit would be likely to result in the introduction or dissemination of a plant pest or noxious weed; or

(ii) The Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with any provision of this part. This would include failure to comply with the conditions of any permit issued.

(f) *Notice of revocation.* The Administrator may revoke, either orally or in writing, any permit which has been issued. If the revocation is oral, the Administrator will communicate the revocation and the reasons for it in writing as promptly as circumstances allow.

(g) *Appeal of denial or revocation of permit.* Any person who has been denied a permit or had a permit revoked may appeal the decision in writing to the Administrator within ten days after receiving the written notification of the revocation or denial. The appeal shall state all of the facts and reasons upon which the person relies to assert that the permit was wrongfully revoked or denied. The Administrator will grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. Upon request of the applicant, a hearing may be held to resolve any conflict as to any material fact. Rules of practice concerning such a hearing will be adopted by the Administrator. This administrative remedy must be exhausted before a person can file suit in court challenging the denial or revocation of a permit.

(h) *Amendment or transfer of permits.* Permits issued under this part may only be amended or transferred in accordance with this section.

(1) *Amendment at responsible person's request.* Where circumstances have changed so that a responsible person desires to have the permit amended, such responsible person must submit a written justification and provide supporting information to APHIS. The Administrator will review the amendment request, and may amend the permit. Prior to issuance of an amended permit, the responsible person must agree in writing that he or she and all of his or her agents will comply with the amended permit and conditions.

(2) *Amendment initiated by APHIS.* The Administrator may amend any

permit and its conditions at any time, upon determining that the amendment is needed to make it unlikely that actions under the permit would result in the introduction or dissemination of a plant pest or noxious weed, or to ensure that the permit is in compliance with all of the requirements of this part. As soon as circumstances allow, the Administrator will notify the responsible person in writing of the amendment to the permit and the reason(s) for it. The responsible person must agree in writing to comply with the permit and conditions as amended before the Administrator will issue the amended permit. If the responsible person does not agree in writing to comply with the amended permit and conditions, the existing permit will be revoked.

(3) *Transfer of permits.* Permits issued through this part may only be transferred by the Administrator in response to a request by both the responsible person and the proposed transferee, or in the case of a deceased responsible person, the deceased responsible person's legal representative and the proposed transferee. Such transfer may occur if the Administrator determines that:

(i) The proposed transferee meets all of the qualifications of a responsible person under this part;

(ii) The proposed transferee has provided adequate written assurances to the Administrator that the proposed transferee and all of his or her agents will meet the terms and conditions of the permit, including any outstanding mitigation requirements or commitments under this part, and that the proposed transferee agrees to assume all responsibility and liability associated with permit activities and responsibilities; and

(iii) The proposed transferee has provided such other information as the Administrator determines is necessary to the processing of the request for transfer of permit.

§ 340.3 Permit conditions.

(a) *Core permit conditions.* Permits will be issued with the permit conditions below, which are a minimum set of basic conditions. The Administrator may add additional or expanded conditions when necessary to make it unlikely that actions under the permit would result in the introduction or dissemination of a plant pest or noxious weed.

(1) *Permit conditions for all permit types.*

(i) *Identity.* The identity of the GE organism shall be maintained at all times, in order to maintain control of the GE organism, keep it distinct from other organisms, and minimize unintended mixing of the GE organism with other organisms. Conditions for maintaining the identity of the GE organism include, but are not limited to:

(A) Marking, labeling, or otherwise identifying all GE organisms during the course of the permit; and

(B) Having the ability to account for all GE materials associated with the permit.

(ii) *Communication and training.* The responsible person shall effectively communicate any and all conditions, activities, actions, and contingency plans associated with the permit to all his or her agents and any other persons participating in permit-related activities, in order to ensure all persons comply with all requirements under this part. Conditions for communicating and training include, but are not limited to:

(A) Establishing, implementing, and maintaining the means to effectively communicate to all his or her agents and any other persons participating in permit-related activities;

(B) Providing a copy of the permit and conditions to all agents involved in a permit; and

(C) Training all agents and any other persons participating in permit-related activities to effectively conduct tasks required under the permit.

(iii) *Records.* In addition to any other records required by this section or § 340.7(b), records, related to permitted activities of sufficient quality and completeness to demonstrate compliance with all permit conditions and requirements under this part, must be maintained.

(iv) *Notice.* The responsible person shall notify APHIS orally within 24 hours of discovery, and subsequently in writing within 5 business days of discovery, in the event of an unauthorized importation, interstate movement, or release into the environment of a GE organism regulated under this part.

(2) Additional permit conditions for interstate movement permits, importation permits, and environmental release permits which include either an interstate movement or importation.

(i) *Shipment.* The GE organism must be transported in such a way as to minimize the likelihood of the unauthorized release of the GE organism. Conditions include, but are not limited to:

(A) Ensuring that the GE organism is transported in such a way that it is a secure shipment, as defined in § 340.1; and

(B) Treating or disposing of all packaging material, shipping containers, and any other material accompanying the GE organism in such a manner as to make it unlikely to result in the organism's unauthorized importation, interstate movement, or release into the environment.

(ii) *Records.* In addition to any other records required by this section or § 340.7(b), the following records shall be maintained:

(A) Information identifying the general nature and quantity of the organism being shipped;

(B) Name and address of sender, owner, or person shipping the organism;

(C) Name, address, and telephone number of recipient;

(D) Any invoices, packing lists, or bills of lading used for the shipment;

(E) The shipper's name and identifying shipper's mark and number; and

(F) A description of any containers that were used to transport the GE organisms, and a copy of any label used on these containers during transport.

(3) *Additional permit conditions for import permits, and environmental release permits which include importation.*

(i) *Port(s) of Entry.* The GE organism shall be presented for entry only at a port(s) specified in the permit.

(ii) *Records.* In addition to any other records required by this section or § 340.7(b), the responsible person shall maintain records that identify the country and locality where the GE organism was collected, developed, manufactured, reared, cultivated or cultured.

(4) *Additional permit conditions for environmental release permits.*

(i) *Environmental release controls.* Sufficient controls shall be applied during the environmental release of the GE organism to make it unlikely to result in the unauthorized release of the GE organism into the environment. Conditions include, but are not limited to:

(A) Taking adequate precautions as described in the permit to ensure that the GE organism is not inadvertently released in transit between contained facilities and the location of environmental release;

(B) Developing and being prepared to implement a written contingency plan to respond to any unauthorized environmental release;

(C) Following any and all required reproductive, cultural, spatial, and temporal controls, such as isolation distances, buffer zones, and flower removal, as described in the permit, and monitor to ensure that the controls are maintained throughout the duration of the release;

(D) Cleaning equipment used in the environmental release in order to remove or devitalize any viable GE organism the equipment may carry, as described in the permit;

(E) Devitalizing or moving into a contained facility any viable GE material remaining at the termination of the environmental release, when applicable, as described in the permit; and

(F) Managing and monitoring the area of release after the termination of the environmental release and removing or devitalizing any GE organisms which persist after the release, as required in the permit.

(ii) *Records*. In addition to any other records required by this section or § 340.7(b), the following records shall be maintained for each release:

(A) All protocols or guidelines used to direct any environmental release of the GE organism; and

(B) All environmental release reports for the organism. At a minimum such reports must include the APHIS reference number for the environmental release, methods of observation used during the environmental release, resulting information, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment, and any notices sent to APHIS of any unusual occurrence during the environmental release.

(iii) *Reports and Notices*. In order for the Administrator to monitor the progress of the environmental release, and to evaluate compliance with required permit conditions, permit conditions will include, but are not limited to:

(A) The responsible person shall submit periodic reports and notices to APHIS at the times specified in the permit and containing the information specified within the permit; and

(B) The responsible person shall notify APHIS orally within 24 hours of discovery, and subsequently in writing within 5 business days of discovery, in the event that the GE organism is found to have characteristics substantially different from those listed in the permit or if any circumstances occur which may increase the risk of disseminating a plant pest or noxious weed.

(C) The responsible person shall notify APHIS in writing if the authorized release will not be conducted.

(D) Within 28 days after the initiation of the release, the responsible person shall report to APHIS in writing the final release site coordinates; number of GE organisms actually released; any information related to the expected date(s) and quantities of GE organisms for subsequent planned releases to be done under this permit.

(E) The responsible person shall provide APHIS with a final report that includes information related to any occurrences during the release that might result in the dissemination of a plant pest or noxious weed.

(F) For categories C and D, permit holders shall provide APHIS with written notice no less than seven days prior to the planned initiation of the release.

(G) For categories C and D, permit holders shall provide APHIS with a report no less than 21 days prior to release termination (e.g., harvest of GE plants) that describes the anticipated date(s) of termination.

(b) *Standard for additional permit conditions assigned by Administrator*. The Administrator will assign the permit conditions described above in a manner that is commensurate with the risk of the individual proposed release. Additional or expanded permit conditions may include, but are not limited to specific requirements for: Reproductive, cultural, spatial, temporal controls; monitoring; post-termination land use; site security or access restrictions; and management practices such as training of personnel involved in the release. The Administrator may also assign permit conditions addressing nonliving materials associated with or derived from GE plants when such conditions are needed to make it unlikely that the nonliving materials would pose a noxious weed risk.

§ 340.4 Conditional exemptions from the requirement for a permit for interstate movement.

(a) *General*. Certain GE organisms described in paragraph (b) of this section may be moved interstate without a permit under this part, if they meet the shipping conditions enumerated in paragraph (c).

(b) *Conditional exemptions from the requirement for a permit for interstate movement of certain organisms*. A permit for interstate movement will not be required for the following genetically engineered organisms provided that they meet the requirements of this paragraph and paragraph (c).

(1) *Escherichia coli* genotype K–12 (strain K–12 and its derivatives), sterile strains of *Saccharomyces cerevisiae*, or asporogenic strains of *Bacillus subtilis,* provided that the introduced genetic sequences:

(i) Are maintained on a nonconjugation proficient plasmid, and the organism does not contain other conjugation proficient plasmids or generalized transducing phages;

(ii) Do not cause the production of an infectious entity;

(iii) Are not carried on an expression vector if the cloned genes code for:

(*A*) A toxin to plants or plant products, or a toxin to organisms beneficial to plants; or

(*B*) Other factors directly involved in eliciting plant disease (e.g., cell wall degrading enzymes; or

(*C*) Substances acting as, or inhibitory to, plant growth regulators.

(2) *Arabidopsis thaliana* provided that the introduced genetic sequences:

(i) Do not cause the production of an infectious entity;

(*ii*) Are not derived from an animal or human pathogen;

(*iii*) Do not encode products that are toxic to vertebrates;

(*iv*) Do not encode products known to or likely to be causal agents of disease in vertebrates; and

(*v*) Do not encode products intended for pharmaceutical or industrial use.

(c) *Shipping conditions*. Organisms that meet the criteria described in paragraph (b) of this section must be shipped as follows:

(i) The container and means of conveyance must provide secure shipment to make it unlikely that the introduction or dissemination of the organisms will occur while in transit.

(ii) The container must contain a document which includes the following written information:

(A) Names and contact details for the sender and recipient, and

(B) A statement that the contents are genetically engineered and are eligible for interstate movement without permit under this part, but are not exempt from permit requirements under this part if the organism is imported or released into the environment;

(iii) The responsible person shall notify APHIS orally within 24 hours of discovery, and subsequently in writing within 5 business days of discovery, in the event of an unauthorized release into the environment of a GE organism regulated under this part.

(d) *Revocation of an exemption from requirement for permit*. The Administrator may revoke any existing conditional exemption. The Administrator may revoke a conditional exemption if the Administrator receives information subsequent to approving the conditional exemption and makes a determination based upon this information that the circumstances have changed such that the conditional exemption is likely to result in the introduction or dissemination of a plant pest or noxious weed. The revocation, its effective date, and the reasons for it will be published in the **Federal**

Register. A revocation may not be appealed. However, any person may file a new petition in accordance with § 340.5 regarding the same or similar organisms covered by the revocation if new information relevant to the revocation becomes available.

(e) *Revocation of a person's use of a conditional exemption from requirement for permit.* The Administrator may revoke the right of any person to use a conditional exemption from the requirement for a permit under this part after determining that the person or any agent of the person has failed to comply at any time with any provision of this part. This would include failure to comply with the conditions of any permit or exemption.

(1) *Appeal of revocation of a person's use of a conditional exemption.* Any person who has had the right to use a conditional exemption revoked may appeal the decision in writing to the Administrator within ten days after receiving the written notification of the revocation. The appeal shall state all of the facts and reasons upon which the person relies to assert that the use of the conditional exemption was wrongfully revoked. The Administrator will grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. Upon request of the applicant, a hearing may be held to resolve any conflict as to any material fact. Rules of practice concerning such a hearing will be adopted by the Administrator. This administrative remedy must be exhausted before a person can file suit in court challenging the revocation.

§ 340.5 Petition for new conditional exemptions from the requirement for a permit.

(a) *General.* Any person may petition to initiate the procedure for establishing a new conditional exemption from the requirement for a permit under § 340.0(b)(1) of this part. The Administrator may initiate the procedure without filing a petition. All petitions and all actions by the Administrator to establish a new conditional exemption will be evaluated according to the standards for petition approval or denial contained in paragraph (b)(4) of this section.

(b) *Petition submission and evaluation procedure.* To petition for a new conditional exemption from the requirement for a permit under this part, a petitioner must submit a written petition to the Administrator.

(1) The petition must contain information that supports a conclusion that use of the conditional exemption is unlikely to result in the introduction or dissemination of a plant pest or noxious weed. The information shall include the following:

(i) Description of the biology of the organism prior to genetic engineering.

(ii) Detailed description of the genetic changes made to the organism.

(iii) Detailed description of the phenotype of the GE organism, including known and potential differences from the recipient organism that could change the likelihood that the GE organism will pose a risk as a plant pest or noxious weed. Examples of relevant information include, but are not limited to:

(A) Growth habit and reproduction of the GE organism;

(B) Potential host range or geographic area of distribution;

(C) Potential for other organisms to pose risks as plant pests or noxious weeds if they acquire the trait from the GE organism (e.g. via sexual reproduction, horizontal gene transfer);

(D) Susceptibility of the GE organism to disease or damage by pests;

(E) Pathogenicity of the GE organism and/or ability of the GE organism to cause damage or injury to plants or plant parts;

(F) Toxicity, allergenicity, and/or ability of the GE organism to damage or injure other organisms;

(iv) A detailed description of proposed condition(s) to be associated with the exemption and how the conditions would make the exemption unlikely to result in the introduction or dissemination of a plant pest or noxious weed.

(v) Any relevant experimental information, published references, or scientific information which support the conclusions of the petition;

(vi) All reports required under § 340.3;

(vi) Any information known to the petitioner that the GE organism may pose a risk as a plant pest or noxious weed;

(vii) Any other information that the Administrator believes to be relevant to a determination that the proposed conditional exemption from the requirement for a permit for the importation, interstate movement, or release into the environment of the GE organism is unlikely to result in the introduction or dissemination of a plant pest or noxious weed.

(viii) A signed certification by the petitioner that, to the best knowledge and belief of the petitioner, the petition includes all information on which to base a determination, and that it includes all information known to the petitioner which is unfavorable to the petition.

(2) *Insufficient information.* If, upon initial review of the petition, the Administrator concludes that there is insufficient information upon which to make a determination on the petition, the petitioner will be sent a written notice indicating what additional information may be required.

(3) *Public notice.* The Administrator should generally complete the review of the complete petition within 180 days, then publish a notice in the **Federal Register** of the availability of documents related to APHIS' assessment of the proposed conditional exemption. This notice will specify that comments will be accepted from the public on the proposal.

(4) *Petition approval or denial standard.* The Administrator will assess the GE organism and the conditions of the requested exemption to determine whether the requested exemption from a permit for importation, interstate movement, or release into the environment would be unlikely to result in the introduction or dissemination of a plant pest or noxious weed. The Administrator will also consider whether any conditions not contained in the petition would be needed to ensure that the requested exemption would be unlikely to result in the introduction or dissemination of a plant pest or noxious weed. After completing review of the available information and any public comments received on it, the Administrator will furnish to the petitioner and publish in the **Federal Register** one of the following responses:

(i) *Approve a conditional exemption from requirement for a permit.* The approval of a conditional exemption from the requirement for a permit will state which GE organism(s) may be imported, moved interstate, and/or environmentally released without a permit under this part, as well as the conditions relevant to the exemption. The Administrator may also add additional conditions not proposed in the petition, if the Administrator concludes that additional conditions are needed to ensure that the conditional exemption would be unlikely to result in the introduction or dissemination of a plant pest or noxious weed.

(ii) *Deny a conditional exemption from requirement for a permit.* The Administrator will deny a petition if the Administrator cannot conclude that the proposed exemption would be unlikely to result in the introduction or dissemination of a plant pest or noxious weed. The Administrator's written decision will set forth the reason for the denial.

(c) *Appeal of decision.* Any person whose petition under § 340.5 has been denied may appeal the decision in writing to the Administrator within ten days after receiving the written notification of the decision. The appeal shall state all of the facts and reasons upon which the person relies to show that the decision should be changed. The Administrator will grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. Upon request of the applicant, a hearing may be held to resolve any conflict as to any material fact. Rules of practice concerning such a hearing will be adopted by the Administrator. This administrative remedy must be exhausted before a person can file suit in court challenging the decision.

(d) *Amending an exemption after approval.* The Administrator may amend conditions to any conditional exemption approved under this section. The Administrator may amend a conditional exemption if the Administrator determines based on information received subsequent to the approval of the exemption that the exemption needs to be amended to ensure that the exemption would be unlikely to result in the introduction or dissemination of a plant pest or noxious weed, and that additional conditions can successfully mitigate that risk. The Administrator may also amend a conditional exemption if needed to ensure that the exemption is in compliance with all of the requirements of this part. The amended conditional exemption and the reasons for it will be published in the **Federal Register**. The addition of conditions may not be appealed. However, any person may file a new petition in accordance with paragraph (a) of this section regarding the same or similar organisms covered by the amended exemption if new information relevant to the amended exemption becomes available.

(e) *Revocation of an exemption from requirement for permit.* The Administrator may revoke any conditional exemption under this section. The Administrator may revoke a conditional exemption if the Administrator receives information subsequent to approving the exemption and makes a determination based upon this information that the circumstances have changed such that the conditional exemption is likely to result in the introduction or dissemination of a plant pest or noxious weed. The revocation, its effective date, and the reasons for it will be published in the **Federal Register**. A revocation may not be appealed. However, any person may file a new petition in accordance with this section regarding the same or similar organisms covered by the revocation if new information relevant to the revocation becomes available.

(f) *Revocation of a person's use of a conditional exemption from requirement for permit.* The Administrator may revoke the right of any person to use a conditional exemption from the requirement for a permit under this part after determining that the person or any agent of the person has failed to comply at any time with any provision of this part. This would include failure to comply with the conditions of any permit or exemption.

(1) *Appeal of revocation of a person's use of a conditional exemption.* Any person who has had the right to use a conditional exemption revoked may appeal the decision in writing to the Administrator within ten days after receiving the written notification of the revocation. The appeal shall state all of the facts and reasons upon which the person relies to assert that the use of the exemption was wrongfully revoked. The Administrator will grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. Upon request of the applicant, a hearing may be held to resolve any conflict as to any material fact. Rules of practice concerning such a hearing will be adopted by the Administrator. This administrative remedy must be exhausted before a person can file suit in court challenging the revocation.

(2) [Reserved]

§ 340.6 Petition for nonregulated status.

(a) *General.* Any person may petition to initiate the procedure for approving nonregulated status under this part for a GE organism. The Administrator may initiate the procedure without filing a petition. All petitions and all actions by the Administrator to initiate the procedure for approving nonregulated status will be evaluated according to the standards for petition approval or denial contained in paragraph (b)(4) of this section.

(b) *Petition submission and evaluation procedure.* To petition for approval of nonregulated status, a petitioner must submit a written petition to the Administrator.

(1) The petition must contain information that supports a conclusion that the GE organism is unlikely to be a plant pest or noxious weed. The information shall include the following:

(i) Description of the biology of the organism prior to genetic engineering.

(ii) Detailed description of the genetic changes made to the organism.

(iii) Detailed description of the phenotype of the GE organism, including known and potential differences from the recipient organism that could change the likelihood that the GE organism is unlikely to be a plant pest or noxious weed. Examples of relevant information include, but are not limited to:

(A) Growth habit and reproduction of the GE organism;

(B) Potential host range or geographic area of distribution;

(C) Potential for other organisms to pose risks as plant pests or noxious weeds if they acquire the trait from the GE organism (e.g. via sexual reproduction, horizontal gene transfer);

(D) Susceptibility of the GE organism to disease or damage by pests;

(E) Pathogenicity of the GE organism and/or ability of the GE organism to cause damage or injury to plants or plant parts;

(F) Toxicity, allergenicity, and/or ability of the GE organism to damage or injure other organisms;

(iv) Any relevant experimental information, published references, or scientific information which support the conclusions of the petition;

(v) All reports required under § 340.3;

(vi) Any information known to the petitioner that the GE organism may pose risk as a plant pest or noxious weed;

(vii) Any other information that the Administrator believes to be relevant to a determination that the GE organism is unlikely to be a plant pest or noxious weed.

(viii) A signed certification by the petitioner that, to the best knowledge and belief of the petitioner, the petition includes all information on which to base a determination, and that it includes all information known to the petitioner which is unfavorable to the petition.

(2) *Insufficient information.* If, upon initial review of the petition, the Administrator concludes that there is insufficient information upon which to make a determination on the petition, the petitioner will be sent a written notice indicating what additional information may be required.

(3) *Public notice.* The Administrator should generally complete the review of the complete petition within 180 days, then publish a notice in the **Federal Register** of the availability of documents related to APHIS' assessment of the proposal for nonregulated status. This notice will specify that comments will be accepted from the public on the proposal.

(4) *Petition approval or denial standard.* The Administrator will assess the GE organism to determine whether the GE organism is unlikely to be a plant pest or noxious weed. After completing review of the available information and any public comments received on it, the Administrator will furnish to the petitioner and publish in the **Federal Register** one of the following responses:

(i) *Approve nonregulated status.* The approval of nonregulated status will state which GE organism(s) have been determined to have nonregulated status.

(ii) *Deny nonregulated status.* The Administrator will deny a petition if the Administrator cannot conclude that the GE organism is unlikely to be a plant pest or noxious weed. The Administrator's written decision will set forth the reason for the denial.

(c) *Appeal of decision.* Any person whose petition under § 340.6 has been denied may appeal the decision in writing to the Administrator within ten days after receiving the written notification of the decision. The appeal shall state all of the facts and reasons upon which the person relies to show that the decision should be changed. The Administrator will grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. Upon request of the applicant, a hearing may be held to resolve any conflict as to any material fact. Rules of practice concerning such a hearing will be adopted by the Administrator. This administrative remedy must be exhausted before a person can file suit in court challenging the decision.

(d) *Revocation of nonregulated status.* The Administrator may revoke any approval of nonregulated status of a GE organism. The Administrator may revoke an approval of nonregulated status if the Administrator receives information subsequent to approving the nonregulated status and makes a determination based upon this information that the circumstances have changed such that the GE organism is likely to be a plant pest or noxious weed. If the Administrator revokes an approval for nonregulated status, the Administrator may approve for the same GE organism an exemption from the requirement for permit in accordance with § 340.5. The revocation, its effective date, and the reasons for it will be published in the **Federal Register**. A revocation may not be appealed. However, any person may file a new petition in accordance with this section regarding the same or similar organisms covered by the revocation if new information relevant to the revocation becomes available.

§ 340.7 Compliance, enforcement, and remedial action.

(a) *Access for inspection.* Inspectors shall have access to inspect any relevant premises, facility, location, storage area, waypoint, materials, equipment, means of conveyance, and other articles related to importation, interstate movement, and environmental releases of GE organisms regulated under this part.

(b) *Access to audit and review records.* Inspectors shall have access to audit and review all records required to be maintained under this part.

(c) *Required records.* Responsible persons and their agents engaged in the importation, interstate movement, or release into the environment of a GE organism subject to the regulations of this part are required to establish and keep the following records.

(1) All records required as a condition of a permit or a conditional exemption approved under the procedure described in § 340.5.

(2) Address and any other information needed to identify all contained facilities where the GE organism was stored or utilized, and all locations where the GE organism was released into the environment;

(3) A record identifying which APHIS permit, if any, authorized the importation, interstate movement, or release into the environment;

(4) A record identifying which exemption under this part, if any, authorized the importation, interstate movement, or release into the environment; and

(5) Copies of contracts between the responsible person and all agents that conduct activities subject to this part for the responsible person, and copies of other records (e.g., e-mails, telephone records) for such agreements made without a written contract.

(d) *Record retention.* Records indicating that such a GE organism that was imported or moved interstate reached its intended destination must be retained for at least 2 years after completion of importation or interstate movement, and all other records must be retained for at least 5 years after completion of all obligations required under a relevant permit or exemption.

(e) *Enforcement.* (1) Failure of any person to comply with any of the requirements of this part may result in any or all of the following:

(i) Denial of a permit request by that person;

(ii) After the issuance of a permit, revocation of a permit and destruction, treatment, or removal of the GE organism, or other measures as deemed appropriate or necessary by the Administrator;

(iii) Criminal and/or civil penalties, and

(iv) Remedial or other measures as determined appropriate and necessary by the Administrator.

(2) The Administrator may seek a civil penalty as well as impose and require corrective action plans, remedial measures or other measures as determined appropriate and necessary by the Administrator.

(3) Prior to the issuance of a complaint seeking a civil penalty, the Administrator may enter into a stipulation in which the responsible person agrees to take certain remedial actions or other measures in addition to or in lieu of a stipulated civil penalty, in accordance with 7 CFR § 380.10.

(f) *Liability for acts of an agent.* For purposes of enforcing this part, the act, omission, or failure of any agent for a responsible person as defined in § 340.1 of this part may be deemed also to be the act, omission, or failure of the responsible person.

(g) *Remedial action.* The Administrator may hold, seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of any GE organisms subject to this part, in order to ensure the GE organisms are unlikely to result in the dissemination of a plant pest or noxious weed. Accordingly, the Administrator may order the responsible person for an active or revoked permit or any other person, through an Emergency Action Notification or other administrative order, to apply remedial measures to a GE organism or means of conveyance carrying a GE organism subject to regulation by this part. The Administrator's determination of whether or not to require or order corrective and/or remedial action in a given situation does not affect, influence, restrict, or in any other way limit the Administrator's determination on whether or not to seek criminal or civil penalties or order other compliance or enforcement requirements as deemed necessary or appropriate by the Administrator to the given situation.

(1) Failure of a person to comply with the Administrator's order for corrective and/or remedial action authorizes the Administrator to take corrective and/or remedial action and recover from the person the costs of any care, handling, application of remedial measures, devitalization, or disposal incurred by APHIS in connection with the corrective and/or remedial actions taken.

(2) *Low level presence (LLP) remedial action.* The Administrator may order remedial action for any unauthorized release into the environment of GE

organisms, including situations involving a low-level mixing of GE plants and materials subject to regulation [1] under this part with commercial seed and grain. In some LLP situations the Administrator may determine not to order remedial action, if the Administrator determines that the low-level mixing is unlikely to result in the introduction or dissemination of a plant pest or noxious weed. These determinations will be made in the same way, based on the same factors, regardless of whether the LLP originates domestically or is found in import shipments that may contain organisms subject to regulation. The factors the Administrator will consider that would support a decision not to order LLP remedial action include, but are not limited to, determinations that:

(i) A GE plant of the same species expressing nearly identical proteins or substances has already been approved for nonregulated status under this part; or

(ii) All of the following statements are true with regard to the GE plant or plants subject to the regulations under this part.

(A) The function of the introduced genetic sequences is known and its expression in the GE plant is unlikely to pose plant pest or noxious weed risk;

(B) Introduced genetic sequences do not cause the production of an infectious entity;

(C) Any genetic sequences derived from plant viruses are non-coding regulatory sequences of known function; or, if sense or antisense genetic sequences, they are derived from viruses prevalent and endemic in the United States that infect plants of the same host species and do not encode a functional noncapsid gene product responsible for cell-to-cell movement of the virus.

(D) The GE plant is not expected to establish outside of a managed ecosystem, and has no sexually-compatible, wild relatives in the United States;

(E) The GE plant does not produce new substances that are known or likely to be toxic to non-target organisms, does not contain genetic sequences from animal or human pathogens, and does not encode products known or likely to be causal agents of disease in animals or humans.

(F) If the GE plant is a food or feed crop, then at least one of the following must be true:

(*1*) The U.S. Environmental Protection Agency has established a tolerance or an exemption from tolerance for any plant-incorporated protectant expressed by the GE plant, or

(*2*) Key food safety issues of the new protein or other substance have been addressed, or,

(*3*) No new protein or substance is produced.

§ 340.8 Confidential business information.

In accordance with the Freedom of Information Act (FOIA) and exemptions from releasing information pursuant to FOIA, namely, 5 U.S.C. 552(b)(4), APHIS may exempt from disclosure to the public trade secrets and commercial or financial information obtained from a person that are privileged or confidential. Persons wishing to protect confidential business information in permit applications, petitions, or other submissions to APHIS under this part should do so in the following manner. If there are portions of a document deemed to contain trade secret or confidential business information, each page containing such information must be marked ''CBI Copy.'' A second copy of each such document must be submitted with all such CBI deleted and marked on each page where the CBI was deleted: ''CBI Deleted.'' In addition, those portions of the document which are deemed ''CBI'' must be identified in an attachment to the document, which also must justify how each piece of information requested to be treated as CBI is a trade secret or is commercial or financial information and are privileged or confidential.

§ 340.9 Costs and charges.

The services of the inspector related to carrying out this part and provided during regularly assigned hours of duty and at the usual places of duty will be furnished without cost.[2] The U.S. Department of Agriculture will not be responsible for any costs or charges incident to inspections or compliance with the provisions of this part, other than for the services of the inspector.

Done in Washington, DC, this 1st day of October 2008.

Charles D. Lambert,

Acting Under Secretary for Marketing and Regulatory Programs.

[FR Doc. E8–23584 Filed 10–6–08; 9:30 am]

BILLING CODE 3410–34–P

[1] ''Subject to regulation'' may include situations where a GE organism granted nonregulated status subsequently had that status revoked in accordance with § 340.6(d).

[2] The Department's provisions relating to overtime charges for an inspector's services are set forth in 7 CFR part 354.0.