

Family Tephritidae  
 Family Tipulidae  
 Order Hymenoptera  
 Family Apidae  
 Family Caphidae  
 Family Chalcidae  
 Family Cynipidae  
 Family Eurytomidae  
 Family Formicidae  
 Family Psilidae  
 Family Siricidae  
 Family Tenthredinidae  
 Family Torymidae  
 Family Xylocopidae

Unclassified organisms and/or organisms whose classification is unknown.

(b) *Exemptions.* (1) A limited permit for interstate movement shall not be required for genetic material from any plant pest contained in *Escherichia coli* genotype K-12 (strain K-12 and its derivatives), sterile strains of *Saccharomyces cerevisiae*, or asporogenic strains of *Bacillus subtilis*, provided that all the following conditions are met:

(i) The microorganisms are shipped in a container that meets the requirements of § 340.8(b)(3);

(ii) The cloned genetic material is maintained on a nonconjugation proficient plasmid and the host does not contain other conjugation proficient plasmids or generalized transducing phages;

(iii) The cloned material does not include the complete infectious genome of a known plant pest;

(iv) The cloned genes 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 (*i.e.*, cell wall degrading enzymes); or

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

(2) A limited permit for interstate movement is not required for genetic material from any plant pest contained in the genome of the plant *Arabidopsis thaliana*, provided that all of the following conditions are met:

(i) The plants or plant materials are shipped in a container that meets the requirements of § 340.8(b) (1), (2), and (3);

(ii) The cloned genetic material is stably integrated into the plant genome;

(iii) The cloned material does not include the complete infectious genome of a known plant pest.

[52 FR 22908, June 16, 1987, as amended at 53 FR 12913, Apr. 20, 1988; 55 FR 53276, Dec. 28, 1990; 58 FR 17056, Mar. 31, 1993]

### § 340.3 Notification for the introduction of certain regulated articles.<sup>5</sup>

(a) *General.* Certain regulated articles may be introduced without a permit, provided that the introduction is in compliance with the requirements of this section. Any other introduction of regulated articles require a permit under § 340.4, with the exception of introductions that are conditionally exempt from permit requirements under § 340.2(b) of this part.

(b) *Regulated articles eligible for introduction under the notification procedure.* Regulated articles which meet all of the following six requirements and the performance standards set forth in paragraph (c) of this section are eligible for introduction under the notification procedure.

(1) The regulated article is any plant species that is not listed as a noxious weed in regulations at 7 CFR part 360 under the Plant Protection Act (7 U.S.C. 7712), and, when being considered for release into the environment, the regulated article is not considered by the Administrator to be a weed in the area of release into the environment.

(2) The introduced genetic material is "stably integrated" in the plant genome, as defined in § 340.1.

(3) The function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease.

<sup>5</sup>APHIS may issue guidelines regarding scientific procedures, practices, or protocols which it has found acceptable in making various determinations under the regulations. A person may follow an APHIS guideline or follow different procedures, practices, or protocols. When different procedures, practices, or protocols are followed, a person may, but is not required to, discuss the matter in advance with APHIS to help ensure that the procedures, practices, or protocols to be followed will be acceptable to APHIS.

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(4) The introduced genetic material does not:

- (i) Cause the production of an infectious entity, or
  - (ii) Encode substances that are known or likely to be toxic to nontarget organisms known or likely to feed or live on the plant species, or
  - (iii) Encode products intended for pharmaceutical or industrial use.
- (5) To ensure that the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, plant virus-derived sequences must be:

- (i) Noncoding regulatory sequences of known function, or
- (ii) Sense or antisense genetic constructs derived from viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species, and that do not encode a functional noncapsid gene product responsible for cell-to-cell movement of the virus.

(6) The plant has not been modified to contain the following genetic material from animal or human pathogens:

- (i) Any nucleic acid sequence derived from an animal or human virus, or
- (ii) Coding sequences whose products are known or likely causal agents of disease in animals or humans.

(c) *Performance standards for introductions under the notification procedure.* The following performance standards must be met for any introductions under the notification procedure.

(1) If the plants or plant materials are shipped, they must be shipped in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment.

(2) When the introduction is an environmental release, the regulated article must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release.

(3) The plants and plant parts must be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be

contained or devitalized when no longer in use.

(4) There must be no viable vector agent associated with the regulated article.

(5) 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.

(6) Upon termination of the field test:

- (i) No viable material shall remain which is likely to volunteer in subsequent seasons, or
- (ii) Volunteers shall be managed to prevent persistence in the environment.

(d) *Procedural requirements for notifying APHIS.* The following procedures shall be followed for any introductions under the notification procedure:

(1) Notification should be directed to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biotechnology and Scientific Services, Biotechnology Permits, 4700 River Road, Unit 147, Riverdale, Maryland 20737-1237.

(2) The notification shall include the following:

(i) Name, title, address, telephone number, and signature of the responsible person;

(ii) Information necessary to identify the regulated article(s), including:

(A) The scientific, common, or trade names, and phenotype of regulated article,

(B) The designations for the genetic loci, the encoded proteins or functions, and donor organisms for all genes from which introduced genetic material was derived, and

(C) The method by which the recipient was transformed;

(iii) The names and locations of the origination and destination facilities for movement or the field site location for the environmental release; and the size of the introduction,

(iv) The date and, in the case of environmental release, the expected duration of the introduction (release); and

(v) A statement that certifies that introduction of the regulated article will be in accordance with the provisions of this section.

(3) Notification must be submitted to APHIS:

(i) At least 10 days prior to the day of introduction, if the introduction is interstate movement.

(ii) At least 30 days prior to the day of introduction, if the introduction is an importation.

(iii) At least 30 days prior to the day of introduction, if the introduction is an environmental release.

(4) Field test reports must be submitted to APHIS within 6 months after termination of the field test. Field test reports shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

(5) The Administrator, shall be notified of any unusual occurrence within the time periods and in the manner specified in §340.4(f)(10).

(6) Access shall be allowed for APHIS and State regulatory officials to inspect facilities and/or the field test site and any records necessary to evaluate compliance with the provisions of paragraphs (b) and (c) of this section.

(e) *Administrative action in response to notification.* (1) APHIS will provide copies of all notifications to appropriate State regulatory official(s) for review within 5 business days of receipt. Comments to APHIS from appropriate State regulatory officials in response to notifications for interstate movement of regulated articles will not be required by APHIS prior to acknowledgment, although States may provide their reviews to APHIS at their discretion.

(2) The Administrator, will provide acknowledgement within 10 days of receipt that the interstate movement is appropriate under notification.

(3) The Administrator, will provide acknowledgement within 30 days of receipt that the importation is appropriate under notification.

(4) APHIS will provide acknowledgment within 30 days of receipt that the environmental release is appropriate under notification. Such acknowledgment will apply to field testing for 1 year from the date of introduction, and may be renewed annually by submis-

sion of an additional notification to APHIS.

(5) A person denied permission for introduction of a regulated article under notification may apply for a permit for introduction of that regulated article without prejudice.

[58 FR 17056, Mar. 31, 1993, as amended at 59 FR 67610, Dec. 30, 1994; 62 FR 23956, May 2, 1997; 66 FR 21058, Apr. 27, 2001; 68 FR 46436, Aug. 6, 2003]

#### §340.4 Permits for the introduction of a regulated article.<sup>6</sup>

(a) *Application for permit.* Two copies of a written application for a permit to introduce a regulated article, which may be obtained from APHIS, shall be submitted by the responsible person to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biotechnology and Scientific Services, Biotechnology Permits, 4700 River Road, Unit 147, Riverdale, Maryland 20737-1237. If there are portions of the application deemed to contain trade secret or confidential business information (CBI), each page of the application containing such information should be marked "CBI Copy". In addition, those portions of the application which are deemed "CBI" shall be so designated. The second copy shall have all such CBI deleted and shall be marked on each page of the application where CBI was deleted, "CBI Deleted". If an application does not contain CBI then the first page of both copies shall be marked "No CBI".

(b) *Permit for release into the environment.* An application for the release into the environment of a regulated article shall be submitted at least 120 days in advance of the proposed release into the environment. An initial review shall be completed by APHIS within 30 days of the receipt of the application. If the application is complete, the responsible individual shall be notified of the date of receipt of the application for purposes of advising the applicant when the 120 day review period commenced.<sup>7</sup> If the application is not complete, the responsible individual will be

<sup>6</sup>See footnote 5 in §340.3.

<sup>7</sup>The 120 day review period would be extended if preparation of an environmental

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