

(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.

(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:

(i) One of the following plant species:
corn (*Zea mays* L.);
cotton (*Gossypium hirsutum* L.);
potato (*Solanum tuberosum* L.);
soybean (*Glycine max* [L.] Merr.);
tobacco (*Nicotiana tabacum* L.);
tomato (*Lycopersicon esculentum* L.);
or

(ii) Any additional plant species that BBEP has determined may be safely introduced in accordance with the eligibility criteria set forth in paragraph (b)(2) through (b)(6) of this section and the performance standards set forth in paragraph (c) of this section.

(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.

(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 use.

(5) To ensure the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, they must be:

(i) Noncoding regulatory sequences of known function, or

(ii) Sense or antisense genetic constructs derived from viral coat protein 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, or

(iii) Antisense genetic constructs derived from noncapsid 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.

(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, Biotechnology, Biologics, and Environmental Protection, 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 BBEP:

(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 the Director, BBEP, within 12 months after the start of the field test, and every 12 months through the duration of the field test. Final reports for those field tests lasting more than 12 months are due 6 months after the termination of the field test. Field test reports shall include:

(i) The APHIS reference number; and

(ii) Methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

(5) The Director, BBEP, 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) The Director, BBEP, will notify the appropriate State regulatory official(s) for notification and review within 5 business days of receipt of notification.

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

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

(4) The Director, BBEP, will provide acknowledgement within 30 days of receipt that the environmental release is appropriate under notification.

(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]

§ 340.4 Permits for the introduction of a regulated article.

(a) *Application for permit.* Two copies of a written application for a permit to introduce a regulated article shall be submitted by the responsible person on an application form obtained from Biotechnology, Biologics, and Environmental Protection to the Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, 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 Biotechnology, Biologics, and Environmental Protection 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.⁵ If the application is

⁵The 120 day review period would be extended if preparation of an environmental

not complete, the responsible individual will be advised what additional information must be submitted. Biotechnology, Biologics, and Environmental Protection shall commence the 120 day review period upon receipt of the additional information, assuming the additional information submitted is adequate. When it is determined that an application is complete, Biotechnology, Biologics, and Environmental Protection shall submit to the State department of agriculture of the State where the release is planned, a copy of the initial review and a copy of the application marked, "CBI Deleted", or "No CBI" for State notification and review. The application shall include the following information:⁶

(1) Name, title, address, telephone number, signature of the responsible person and type of permit requested (for importation, interstate movement, or release into the environment);

(2) All scientific, common, and trade names, and all designations necessary to identify the: Donor organism(s); recipient organism(s); vector or vector agent(s); constituent of each regulated article which is a product; and, regulated article;

(3) Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article;

(4) A description of the means of movement (e.g., mail, common carrier, baggage, or handcarried (and by whom));

(5) A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or

impact statement in addition to an environmental assessment was necessary.

⁶Application forms are available without charge from the Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Biotechnology Permits, 4700 River Road, Unit 147, Riverdale, Maryland 20737-1237, or from local offices which are listed in telephone directories. A person should specify in requesting the application that the permit is for the introduction of a regulated article subject to regulation under part 340.