

handling or disposal of regulated garbage occurs;

(iii) Remove regulated garbage from a means of conveyance only in tight, leak-proof receptacles;

(iv) Move the receptacles of regulated garbage only to a facility approved in accordance with § 330.400(g)(2); and

(v) At the approved facility, dispose of the regulated garbage only through incineration, sterilization, grinding into a sewage system approved in accordance with § 330.400(g)(2), or in any other manner approved by the Administrator and described in the compliance agreement.

(3) Approval for a compliance agreement may be denied at any time if the Administrator determines that the requirements set forth in this subpart are not met, after notice of, and the reasons for, the proposed denial of the approval, and an opportunity to demonstrate or achieve compliance with such requirements, has been afforded to the compliance agreement applicant.

(4) Any compliance agreement may be canceled in writing by the Administrator whenever it is found that the person who has entered into the compliance agreement has failed to comply with this subpart. Any person whose compliance agreement has been cancelled may appeal the decision, in writing, within 10 days after receiving written notification of the cancellation. The appeal must state all of the facts and reasons upon which the person relies to show that the compliance agreement was wrongfully cancelled. As promptly as circumstances allow, the Administrator will grant or deny the appeal, in writing, stating the reasons for the decision. A hearing will be held to resolve any conflict as to any material fact. Rules of practice concerning a hearing will be adopted by the Administrator. This administrative remedy must be exhausted before a person can file suit in court challenging the cancellation of a compliance agreement.

(5) Where a compliance agreement is denied or cancelled, regulated garbage may continue to be unloaded from a means of conveyance and disposed of at

an approved facility in accordance with § 330.400(g)(1).

(Approved by the Office of Management and Budget under control number 0579-0054.)

[39 FR 32320, Sept. 6, 1974, as amended at 43 FR 39954, Sept. 8, 1978; 45 FR 80268, Dec. 4, 1980; 48 FR 57466, Dec. 30, 1983; 58 FR 66248, Dec. 20, 1993; 62 FR 19903, Apr. 24, 1997]

PART 331—PLANT PEST REGULATIONS GOVERNING INTERSTATE MOVEMENT OF CERTAIN PRODUCTS AND ARTICLES [RESERVED]

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

Sec.

340.0 Restrictions on the introduction of regulated articles.

340.1 Definitions.

340.2 Groups of organisms which are or contain plant pests and exemptions.

340.3 Notification for the introduction of certain regulated articles.

340.4 Permits for the introduction of a regulated article.

340.5 Petition to amend the list of organisms.

340.6 Petition for determination of nonregulated status.

340.7 Marking and identity.

340.8 Container requirements for the movement of regulated articles.

340.9 Cost and charges.

AUTHORITY: 7 U.S.C. 150aa-150jj, 151-167, and 1622n; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(c).

SOURCE: 52 FR 22908, June 16, 1987, unless otherwise noted.

§ 340.0 Restrictions on the introduction of regulated articles.

(a) No person shall introduce any regulated article unless the Administrator is:

(1) Notified of the introduction in accordance with § 340.3, or such introduction is authorized by permit in accordance with § 340.4, or such introduction is conditionally exempt from permit requirements under § 340.2(b); and

(2) Such introduction is in conformity with all other applicable restrictions in this part.¹

(b) Any regulated article introduced not in compliance with the requirements of this part shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary to prevent the introduction of such plant pests.²

[52 FR 22908, June 16, 1987, as amended at 58 FR 17056, Mar. 31, 1993; 62 FR 23956, May 2, 1997]

§ 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

¹Part 340 regulates, among other things, the 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. The introduction into the United States of such articles may be subject to other regulations promulgated under the Federal Plant Pest Act (7 U.S.C. 150aa *et seq.*), the Plant Quarantine Act (7 U.S.C. 151 *et seq.*) and the Federal Noxious Weed Act (7 U.S.C. 2801 *et seq.*) and found in 7 CFR parts 319, 321, 330, and 360. For example under regulations promulgated in 7 CFR "Subpart-Nursery Stock" (7 CFR 319.37) a permit is required for the importation of certain classes of nursery stock whether genetically engineered or not. Thus, a person should consult those regulations prior to the importation of any nursery stock.

²Pursuant to section 105 of the Federal Plant Pest Act (7 U.S.C. 150dd) the Secretary of Agriculture is authorized to order prompt removal from the United States or to seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of, in such manner as the Secretary deems appropriate, certain regulated articles which are believed to be infested or infected by or contain a plant pest.

United States Department of Agriculture.

Antecedent organism. An organism that has already been the subject of a determination of nonregulated status by APHIS under § 340.6, and that is used as a reference for comparison to the regulated article under consideration under these regulations.

Courtesy permit. A written permit issued by the Administrator, in accordance with § 340.4(h).

Donor organism. The organism from which genetic material is obtained for transfer to the recipient organism.

Environment. All the land, air, and water; and all living organisms in association with land, air and water.

Expression vector. A cloning vector designed so that a coding sequence inserted at a particular site will be transcribed and translated into protein.

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

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. From any State into or through any other State.

Introduce or introduction. To move into or through the United States, to release into the environment, to move interstate, or any attempt thereat.

Move (moving, movement). To ship, offer for shipment, offer for entry, import, receive for transportation, carry, or otherwise transport or move, or allow to be moved into, through, or within the United States.

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 permit issued by the Administrator, for the introduction of a regulated article under conditions determined by the Administrator, not to present a risk of plant pest introduction.