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(iv) The location (building, room) from which the theft or loss occurred; and

(v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report, the theft or loss.

(2) A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

(b) An individual or entity must notify APHIS or CDC immediately upon discovery of a release of a select agent or toxin outside of the primary barriers of the biocontainment area.

(1) The release of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information);

(ii) An estimate of the quantity released;

(iii) The time and duration of the release;

(iv) The environment into which the release occurred (*e.g.*, in building or outside of building, waste system);

(v) The location (building, room) from which the release occurred; and

(vi) The number of individuals potentially exposed at the entity;

(vii) Actions taken to respond to the release; and

(viii) Hazards posed by the release.

(2) A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

§ 331.20 Administrative review.

An individual or entity may appeal a denial, revocation, or suspension of registration under this part. An individual may appeal a denial, limitation, or revocation of access approval under this part.[9] The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 30 calendar days of the decision. Where the denial, revocation, or suspension of registration or the denial, limitation, or revocation of an individual's access approval is based upon an identification by the Attorney General, the request for review will be forwarded to the Attorney General. The Administrator's decision constitutes final agency action.

[9] An entity may not appeal the denial or limitation of an individual's access to select agents or toxins.

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.
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340.8 Container requirements for the movement of regulated articles.
340.9 Cost and charges.

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

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]

[1] Part 340 regulates, among other things, the introduction of organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests. The introduction into the United States of such articles also may be subject to other regulations promulgated under the Plant Protection Act (7 U.S.C.

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(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; 66 FR 21058, Apr. 27, 2001]

§ 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.

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.

Person. Any individual, partnership, corporation, company, society, association, or other organized group.

Plant. Any living stage or form of any member of the plant kingdom[3] including, but not limited to, eukaryotic algae, mosses, club mosses, ferns, angiosperms, gymnosperms, and lichens (which contain algae) including any parts (e.g. pollen, seeds, cells, tubers, stems) thereof, and any cellular

7701–7772) and found in 7 CFR parts 319, 330, and 360. For example, under regulations promulgated in "Subpart-Nursery Stock, Plants, Roots, Bulbs, Seeds, and Other Plant Products" (7 CFR 319.37–3), a permit is required for the importation of certain classes of nursery stock whether such stock is genetically engineered or not. Accordingly, individuals should refer to those regulations before importing any nursery stock.

[2] An inspector may hold, seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of plants, plant pests, or other articles in accordance with sections 411, 412, 421, and 434 of the Plant Protection Act (7 U.S.C. 7711, 7712, 7731, and 7754).

[3] The taxonomic scheme for the plant kingdom is that found in Synopsis and Classification of Living Organisms by S.P. Parker, McGraw Hill (1984).

components (e.g. plasmids, ribosomes, etc.) thereof.

Plant pest. Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

Product. Anything made by or from, or derived from an organism, living or dead.

Recipient organism. The organism which receives genetic material from a donor organism.

Regulated article. Any organism which has been altered or produced through genetic engineering, 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. Excluded are recipient microorganisms which are not plant pests 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.

Release into the environment. The use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure.

Responsible person. The person who has control and will maintain control over the introduction of the regulated article and assure that all conditions contained in the permit and requirements in this part are complied with. A responsible person shall be a resident of the United States or designate an agent who is a resident of the United States.

Secretary. The Secretary of Agriculture, or any other officer or employee of the Department of Agriculture to whom authority to act in his/her stead has been or may hereafter be delegated.

Stably integrated. The cloned genetic material is contiguous with elements of the recipient genome and is replicated exclusively by mechanisms used by recipient genomic DNA.

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

State regulatory official. State official with responsibilities for plant health, or any other duly designated State official, in the State where the introduction is to take place.

United States. All of the States.

Vector or vector agent. Organisms or objects used to transfer genetic material from the donor organism to the recipient organism.

Well-characterized and contains only non-coding regulatory regions (e.g. operators, promoters, origins of replication, terminators, and ribosome binding regions). The genetic material added to a microorganism in which the following can be documented about such genetic material: (a) The exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides; (b) The regulatory region and any inserted flanking nucleotides do not code for protein or peptide; and (c) The regulatory region solely controls the activity of other sequences that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis.

[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; 62 FR 23956, May 2, 1997]

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

(a) *Groups of organisms which are or contain plant pests.* The organisms that are or contain plant pests are included

in the taxa or group of organisms contained in the following list. Within any taxonomic series included on the list, the lowest unit of classification actually listed is the taxon or group which may contain organisms which are regulated. Organisms belonging to all lower taxa contained within the group listed are included as organisms that may be or may contain plant pests, and are regulated *if they meet the definition of plant pest in § 340.1* [4]

NOTE: Any genetically engineered organism composed of DNA or RNA sequences, organelles, plasmids, parts, copies, and/or analogs, of or from any of the groups of organisms listed below shall be deemed a regulated article if it also meets the definition of plant pest in § 340.1.

GROUP

VIROIDS

Superkingdom Prokaryotae

Kingdom Virus

All members of groups containing plant viruses, and all other plant and insect viruses

Kingdom Monera

DIVISION BACTERIA

Family Pseudomonadaceae
  Genus Pseudomonas
  Genus Xanthomonas
Family Rhizobiaceae
  Genus Rhizobium
  Genus Bradyrhizobium
  Genus Agrobacterium
  Genus Phyllobacterium
Family Enterobacteriaceae
  Genus Erwinia
Family Streptomycetaceae
  Genus Streptomyces
Family Actinomycetaceae
  Genus Actinomyces

Coryneform group

  Genus Clavibacter
  Genus Arthrobacter
  Genus Curtobacterium
  Genus Corynebacteria
Gram-negative phloem-limited bacteria associated with plant diseases
Gram-negative xylem-limited bacteria associated with plant diseases
And all other bacteria associated with plant or insect diseases
Rickettsiaceae
  Rickettgial-like organisms associated with insect diseases

Class Mollicutes

Order Mycoplasmatales
Family Spiroplasmataceae
  Genus Spiroplasma
Mycoplasma-like organisms associated with plant diseases
Mycoplasma-like organisms associated with insect diseases

Superkingdom Eukaryotae

Kingdom Plantae

Subkingdom Thallobionta

Division Chlorophyta

  Genus Cephaleuros
  Genus Rhodochytrium
  Genus Phyllosiphon

Division Myxomycota

Class Plasmodiophoromycetes

Division Eumycota

Class Chytridiomycetes

Order Chytridiales

Class Oomycetes

Order Lagenidiales
Family Lagenidiaceae
Family Olpidiopsidaceae
Order Peronosporales
Family Albuginaceae
Family Peronosporaceae
Family Pythiaceae
Order Saprolegniales
Family Saprolegniaceae
Family Leptolegniellaceae

Class Zygomycetes

Order Mucorales
Family Choanephoraceae
Family Mucoraceae
Family Entomophthoraceae

[4] Any organism belonging to any taxa contained within any listed genera or taxa is only considered to be a plant pest if the organism "can directly or indirectly injure, or cause disease, or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants." Thus a particular unlisted species within a listed genus would be deemed a plant pest for purposes of § 340.2, if the scientific literature refers to the organism as a cause of direct or indirect injury, disease, or damage to any plants, plant parts or products of plants. (If there is any question concerning the plant pest status of an organism belonging to any listed genera or taxa, the person proposing to introduce the organism in question should consult with APHIS to determine if the organism is subject to regulation.)

Class Hemiascomycetes

Family Protomycetaceae
Family Taphrinaceae

Class Loculoascomycetes

Order Myriangiales
Family Elsinoeaceae
Family Myriangiaceae
Order Asterinales
Order Dothideales
Order Chaetothyriales
Order Hysteriales
Family Parmulariaceae
Family Phillipsiellaceae
Family Hysteriaceae
Order Pleosporales
Order Melanommatales

Class Plectomycetes

Order Eurotiales
Family Ophiostomataceae
Order Ascophaerales

Class Pyrenomycetes

Order Erysiphales
Order Meliolales
Order Xylariales
Order Diaporthales
Order Hypocreales
Order Clavicipitales

Class Discomycetes

Order Phacidiales
Order Helotiales
Family Ascocorticiceae
Family Hemiphacidiaceae
Family Dermataceae
Family Sclerotiniaceae
Order Cytarriales
Order Medeolariales
Order Pezziales
Family Sarcosomataceae
Family Sarcoscyphaceae

Class Teliomycetes

Class Phragmobasidiomycetes

Family Auriculariaceae
Family Ceratobasidiaceae

Class Hymenomycetes

Order Exobasidiales
Order Agaricales
Family Corticiaceae
Family Hymenochaetaceae
Family Echinodontiaceae
Family Fistulinaceae
Family Clavariaceae
Family Polyporaceae
Family Tricholomataceae

Class Hyphomycetes

Class Coelomycetes

And all other fungi associated with plant or insect diseases

Subkingdom Embryobionta

NOTE: *Organisms listed in the Code of Federal Regulations as noxious weeds are regulated under the Federal Noxious Weed Act*

Division Magnoliophyta

Family Balanophoraceae—parasitic species
Family Cuscutaceae—parasitic species
Family Hydnoraceae—parasitic species
Family Krameriaceae—parasitic species
Family Lauraceae—parasitic species
  Genus Cassytha
Family Lennoaceae—parasitic species
Family Loranthaceae—parasitic species
Family Myzodendraceae—parasitic species
Family Olacaceae—parasitic species
Family Orobanchaceae—parasitic species
Family Rafflesiaceae—parasitic species
Family Santalaceae—parasitic species
Family Scrophulariaceae—parasitic species
  Genus Alectra
  Genus Bartsia
  Genus Buchnera
  Genus Buttonia
  Genus Castilleja
  Genus Centranthera
  Genus Cordylanthus
  Genus Dasistoma
  Genus Euphrasia
  Genus Gerardia
  Genus Harveya
  Genus Hyobanche
  Genus Lathraea
  Genus Melampyrum
  Genus Melasma
  Genus Orthantha
  Genus Orthocarpus
  Genus Pedicularis
  Genus Rhamphicarpa
  Genus Rhinanthus
  Genus Schwalbea
  Genus Seymeria
  Genus Siphonostegia
  Genus Sopubia
  Genus Striga
  Genus Tozzia
Family Viscaceae—parasitic species

Kingdom Animalia

Subkingdom Protozoa

Genus Phytomonas

And all Protozoa associated with insect diseases

Subkingdom Eumetazoa

PHYLUM NEMATA

CLASS SECERNENTEA

Order Tylenchida
Family Anguinidae
Family Belonolaimidae
Family Caloosiidae
Family Criconematidae

Family Dolichodoridae
Family Fergusobiidae
Family Hemicycliophoridae
Family Heteroderidae
Family Hoplolaimidae
Family Meloidogynidae
Family Nacobbidae
Family Neotylenchidae
Family Nothotylenchidae
Family Paratylenchidae
Family Pratylenchidae
Family Tylenchidae
Family Tylenchulidae
Order Aphelenchida
Family Aphelenchoididae

CLASS ADENOPHOREA

Order Dorylaimida
Family Longidoridae
Family Trichodoridae

PHYLUM MOLLUSCA

CLASS GASTROPODA

Subclass Pulmonata
Order Basommatophora
  Superfamily Planorbacea
Order Stylommatophora
  Subfamily Strophocheilacea
Family Succineidae
  Superfamily Achatinacae
  Superfamily Arionacae
  Superfamily Limacacea
  Superfamily Helicacea
Order Systellommatophora
  Superfamily Veronicellacea

Phylum Arthropoda

Class Arachnida

Order Parasitiformes
  Suborder Mesostigmata
  Superfamily Ascoidea
  Superfamily Dermanyssoidea
Order Acariformes
  Suborder Prostigmata
  Superfamily Eriophyoidea
  Superfamily Tetranychoidea
  Superfamily Eupodoidea
  Superfamily Tydeoidea
  Superfamily Erythraenoidea
  Superfamily Trombidioidea
  Superfamily Hydryphantoidea
  Superfamily Tarsonemoidea
  Superfamily Pyemotoidea
Suborder Astigmata
  Superfamily Hemisarcoptoidea
  Superfamily Acaroidea

Class Diplopoda

Order Polydesmida

Class Insecta

Order Collembola
Family Sminthoridae
Order Isoptera
Order Thysanoptera
Order Orthoptera
Family Acrididae
Family Gryllidae
Family Gryllacrididae
Family Gryllotalpidae
Family Phasmatidae
Family Ronaleidae
Family Tettigoniidae
Family Tetrigidae
Order Hemiptera
Family Thaumastocoridae
Family Aradidae
  Superfamily Piesmatoidea
  Superfamily Lygaeoidea
  Superfamily Idiostoloidea
  Superfamily Coreoidea
  Superfamily Pentatomoidea
  Superfamily Pyrrhocoroidea
  Superfamily Tingoidea
  Superfamily Miroidea
Order Homoptera
Order Coleoptera
Family Anobiidae
Family Apionidae
Family Anthribidae
Family Bostrichidae
Family Brentidae
Family Bruchidae
Family Buprestidae
Family Byturidae
Family Cantharidae
Family Carabidae
Family Cerambycidae
Family Chrysomelidae
Family Coccinellidae
  Subfamily Epilachninae
Family Curculionidae
Family Dermestidae
Family Elateridae
Family Hydrophilidae
  Genus Helophorus
Family Lyctidae
Family Meloidae
Family Mordellidae
Family Platypodidae
Family Scarabaeidae
  Subfamily Melolonthinae
  Subfamily Rutelinae
  Subfamily Cetoniinae
  Subfamily Dynastinae
Family Scolytidae
Family Selbytidae
Family Tenebrionidae
Order Lepidoptera
Order Diptera
Family Agromyzidae
Family Anthomyiidae
Family Cecidomyiidae
Family Chloropidae
Family Ephydridae
Family Lonchaeidae
Family Muscidae
  Genus Atherigona
Family Otitidae
  Genus Euxeta
Family Syrphidae

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 *Arabiodopsis 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.[5]

(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.

[5] 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.

(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 submission 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.[6]

(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.[7] If the application is not complete, the responsible individual will be

[6] See footnote 5 in § 340.3.

[7] The 120 day review period would be extended if preparation of an environmental

Continued

advised what additional information must be submitted. APHIS 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, APHIS 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:[8]

(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 structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics);

(6) A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article;

(7) Country and locality where the donor organism, recipient organism, vector or vector agent, and regulated article were collected, developed, and produced;

(8) A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design;

(9) The quantity of the regulated article to be introduced and proposed schedule and number of introductions;

(10) A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: Donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and regulated article;

(11) A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location; pilot project location; production, propagation, and manufacture location; proposed sale and distribution location);

(12) A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations;

(13) A detailed description of any biological material (e.g., culture medium, or host material) accompanying the regulated article during movement; and

(14) A detailed description of the proposed method of final disposition of the regulated article.

(c) *Limited permits for interstate movement or importation of a regulated article.*

impact statement in addition to an environmental assessment was necessary.

[8] Application forms are available without charge from 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, 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.

An application for the interstate movement or importation of a regulated article shall be submitted at least 60 days in advance of the first proposed interstate movement and at least 60 days prior to each importation. An initial review shall be completed by APHIS within 15 days of the receipt of the application. If the application is complete, the responsible person shall be notified of the date of receipt of the application for purposes of advising the applicant when the 60 day review period commenced. If the application is not complete, the responsible person will be advised what additional information must be submitted. APHIS shall commence the 60 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, APHIS shall submit to the State department of agriculture of the State of destination of the regulated article a copy of the initial review and the application marked, "CBI Deleted", or "No CBI" for State notification and review.

(1) *Limited permit for interstate movement.* The responsible person may apply for a single limited permit for the interstate movement of multiple regulated articles in lieu of submitting an application for each individual interstate movement. Each limited permit issued shall be numbered and shall be valid for one year from the date of issuance. If a permit is sought for multiple interstate movements between contained facilities the responsible individual shall specify in the permit application all the regulated articles to be moved interstate; the origins and destinations of all proposed shipments; a detailed description of all the contained facilities where regulated articles will be utilized at destination; and a description of the containers that will be used to transport the regulated articles. A limited permit for interstate movement of a regulated article shall only be valid for the movement of those regulated articles moving between those locations specified in the application. If a person seeks to move regulated articles other than those specified in the application, or to a location other than those listed in the application, a supplemental application shall be submitted to APHIS. No person shall move a regulated article interstate unless the number of the limited permit appears on the outside of the shipping container. The responsible person shipping a regulated article interstate shall keep records for one year demonstrating that the regulated article arrived at its intended destination. The responsible person seeking a limited permit for interstate movement shall submit on an application form obtained from APHIS, the data required by paragraphs (b) (1), (2), (4), (6), (7), (9), and (11) through (14) of this section.

(2) *Limited permit for importation.* The responsible person seeking a permit for the importation of a regulated article shall submit an application for a permit prior to the importation of *each* shipment of regulated articles. The responsible person importing a regulated article shall keep records for one year demonstrating that the regulated article arrived at its intended destination. The responsible person seeking a limited permit for importation shall submit on an application form obtained from APHIS data required by paragraphs (b) (1), (2), (4), (6), (7), (9), and (11) through (14) of this section.[9]

(d) *Premises inspection.* An inspector may inspect the site or facility where regulated articles are proposed, pursuant to a permit, to be released into the environment or contained after their interstate movement or importation. Failure to allow the inspection of a premises prior to the issuance of a permit or limited permit shall be grounds for the denial of the permit.

(e) *Administrative action on applications.* After receipt and review by APHIS of the application and the data submitted pursuant to paragraph (a) of this section, including any additional information requested by APHIS, a permit shall be granted or denied. If a

[9] Renewals may receive shorter review. In the case of a renewal for a limited permit for importation that has been issued less than one year earlier, APHIS will notify the responsible person within 15 days that either: (1) The renewal permit is approved or (2) that a 60 day review period is necessary because the conditions of the original permit have changed.

permit is denied, the applicant shall be promptly informed of the reasons why the permit was denied and given the opportunity to appeal the denial in accordance with the provisions of paragraph (g) of this section. If a permit is granted, the permit will specify the applicable conditions for introduction of the regulated article under this part.

(f) *Permit conditions.* A person who is issued a permit and his/her employees or agents shall comply with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Administrator to be necessary to prevent the dissemination and establishment of plant pests:

(1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests.

(2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of plant pests.

(3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit;

(4) The regulated article shall be maintained only in areas and premises specified in the permit;

(5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article;

(6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation;

(7) The regulated article shall be subject to the application of measures determined by the Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article;

(8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the Administrator to be necessary to prevent the spread of plant pests;

(9) A person who has been issued a permit shall submit to APHIS a field test report within 6 months after the termination of the field test. A field test report shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

(10) APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences:

(i) Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article;

(ii) In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms);

(11) A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:

(i) Import or offer the regulated article for entry only through any USDA plant inspection station listed in §319.37–14 of this chapter;

(ii) Notify APHIS promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

(iii) Mark and identify the regulated article in accordance with §340.5 of this part.

(g) *Withdrawal or denial of a permit.* Any permit which has been issued may be withdrawn by an inspector or the Administrator if he/she determines that the holder thereof has not complied with one or more of the conditions listed on the permit. APHIS will confirm the reasons for the withdrawal of the permit in writing within ten (10) days. Any person whose permit has been withdrawn or any person who has been denied a permit may appeal the decision in writing to the Administrator within ten (10) days after receiving the written notification of the

withdrawal or denial. The appeal shall state all of the facts and reasons upon which the person relies to show that the permit was wrongfully withdrawn or denied. The Administrator shall grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator.

(h) *Courtesy permit*—(1) *Issuance.* The Administrator may issue a courtesy permit for the introduction of organisms modified through genetic engineering which are not subject to regulation under this part to facilitate movement when the movement might otherwise be impeded because of the similarity of the organism to other organisms regulated under this part.

(2) *Application.* A person seeking a courtesy permit shall submit on an application form obtained from APHIS data required by paragraphs (b) (1), (2), and (5) of this section and shall indicate such data is being submitted as a request for a courtesy permit. A person should also include a statement explaining why he or she believes the organism or product does not come within the definition of a regulated article. The application shall be submitted at least 60 days prior to the time the courtesy permit is sought.

(3) *Administrative action.* APHIS shall complete an initial review within 15 days of the date of 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 60 day review period commenced. If the application is not complete, the responsible individual will be advised what additional information must be submitted, and shall commence the 60 day review period upon receipt of the additional information, assuming the additional information submitted is adequate. Within 60 days from the date of receipt of a complete application, APHIS will either issue a courtesy permit or advise the responsible individual that a permit is required under paragraph (b) or (c) of this section.

(Approved by the Office of Management and Budget under control number 0579–0216)

[52 FR 22908, June 16, 1987. Redesignated at 58 FR 17056, Mar. 31, 1993, as amended at 58 FR 17058, Mar. 31, 1993; 59 FR 67610, Dec. 30, 1994; 62 FR 23956, 23957, May 2, 1997; 68 FR 46436, Aug. 6, 2003; 72 FR 43523, Aug. 6, 2007]

§ 340.5 Petition to amend the list of organisms.[10]

(a) *General.* Any person may submit to the Administrator a petition to amend the list of organisms in § 340.2 of this part by adding or deleting any genus, species, or subspecies. A petitioner may supplement, amend, or withdraw a petition in writing without prior approval of the Administrator and without prejudice to resubmission at any time until the Administrator rules on the petition. A petition to amend the list of organisms shall be submitted in accordance with the procedures and format specified by this section.

(b) *Submission procedures and format.* A person shall submit two copies of a petition to the Animal and Plant Health Inspection Service, Biotechnology and Scientific Services, PPQ, Biotechnology Permits, 4700 River Road, Unit 147, Riverdale, Maryland 20737–1237. The petition should be dated, and structured as follows:

PETITION TO AMEND 7 CFR 340.2

The undersigned submits this petition under 7 CFR 340.4 to request that the Administrator [add the following genus, species, or subspecies to the list of organisms in 7 CFR 340.2] or [to remove the following genus, species, or subspecies from the list of organisms in § 340.2].

A. Statement of Grounds

(A person must present a full statement explaining the factual grounds why the genus, species, or subspecies to be added to § 340.2 of this part is a plant pest or why there is reason to believe the genus, species, or subspecies is a plant pest or why the genus, species, or subspecies sought to be removed is not a plant pest or why there is reason to believe the genus, species, or subspecies is not a plant pest. The petition should include copies of scientific literature which the petitioner is relying upon, copies

[10] See footnote 5 in § 340.3.

of unpublished studies, or data from tests performed. *The petition should not include trade secret or confidential business information.*

A person should also include representative information known to the petitioner which would be unfavorable to a petition for listing or delisting. (If a person is not aware of any unfavorable information the petition should state, Unfavorable Information: NONE).

B. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petitioner relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) _____

(Name of petitioner) _____

(Mailing address) _____

(Telephone number) _____

(c) *Administrative action on a petition.* (1) A petition to amend the list of organisms which meets the requirements of paragraph (b) of this section will be filed by the APHIS, stamped with the date of filing, and assigned a docket number. The docket number shall identify the file established for all submissions relating to the petition. APHIS, will promptly notify the petitioner in writing of the filing and docket number of a petition. If a petition does not meet the requirements of paragraph (b) of this section, the petitioner shall be sent a notice indicating how the petition is deficient.

(2) After the filing of a petition to amend the list of organisms USDA shall publish a proposal in the FEDERAL REGISTER to amend §340.2 and solicit comments thereon from the public. An interested person may submit written comments to the APHIS on a filed petition, which shall become part of the docket file.

(3) The Administrator shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either: (i) Approve the petition in whole or in part in which case the Administrator shall concurrently take appropriate action (publication of a document in the FEDERAL REGISTER amending §340.2 of this part; or (ii) deny the petition in whole or in part. The petitioner shall be notified in writing of the Administrator's decision. The decision shall be placed in the public docket file in the offices of APHIS, and in the form of a notice published in the FEDERAL REGISTER.

[52 FR 22908, June 16, 1987. Redesignated at 58 FR 17056, Mar. 31, 1993, as amended at 58 FR 17059, Mar. 31, 1993; 59 FR 67611, Dec. 30, 1994; 62 FR 23957, May 2, 1997]

§340.6 Petition for determination of nonregulated status.[11]

(a) *General.* Any person may submit to the Administrator, a petition to seek a determination that an article should not be regulated under this part. A petitioner may supplement, amend, or withdraw a petition in writing without prior approval of the Administrator, and without affecting resubmission at any time until the Administrator, rules on the petition. A petition for determination of nonregulated status shall be submitted in accordance with the procedure and format specified in this section.

(b) *Submission procedures and format.* A person shall submit two copies of a petition to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biotechnology and Scientific Services, Biotechnology Coordination and Technical Assistance, 4700 River Road, Unit 146, Riverdale, Maryland 20737–1237. The petition shall be dated and structured as follows:

PETITION FOR DETERMINATION OF NONREGULATED STATUS

The undersigned submits this petition under 7 CFR 340.6 to request that the Administrator, make a determination that the article should not be regulated under 7 CFR part 340.

(Signature) _____

A. Statement of Grounds

A person must present a full statement explaining the factual grounds why the organism should not be regulated under 7 CFR part 340. The petitioner shall include copies of scientific literature, copies of unpublished studies, when available, and data from tests performed upon which to base a determination. The petition shall include all information set forth in paragraph (c) of 7 CFR 340.6. If there are portions of the petition deemed to contain trade secret or confidential business information (CBI), each page of the petition containing such information should be

[11] See footnote 5 in §340.3.

marked "CBI Copy". In addition, those portions of the petition which are deemed "CBI" shall be so designated. The second copy shall have all such CBI deleted and shall have marked on each page where the CBI was deleted: "CBI Deleted." If a petition does not contain CBI, the first page of both copies shall be marked: "No CBI."

A person shall also include information known to the petitioner which would be unfavorable to a petition. If a person is not aware of any unfavorable information, the petition should state, "Unfavorable information: NONE."

B. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which to base a determination, and that it includes relevant data and information known to the petitioner which are unfavorable to the petition.

(Signature) _____

(Name of Petitioner) _____

(Mailing Address) _____

(Telephone Number) _____

(c) *Required data and information.* The petition shall include the following information:

(1) Description of the biology of the nonmodified recipient plant and information necessary to identify the recipient plant in the narrowest taxonomic grouping applicable.

(2) Relevant experimental data and publications.

(3) A detailed description of the differences in genotype between the regulated article and the nonmodified recipient organism. Include all scientific, common, or trade names, and all designations necessary to identify: the donor organism(s), the nature of the transformation system (vector or vector agent(s)), the inserted genetic material and its product(s), and the regulated article. Include country and locality where the donor, the recipient, and the vector organisms and the regulated articles are collected, developed, and produced.

(4) A detailed description of the phenotype of the regulated article. Describe known and potential differences from the unmodified recipient organism that would substantiate that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived, including but not limited to: Plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the regulated article on nontarget organisms, indirect plant pest effects on other agricultural products, transfer of genetic information to organisms with which it cannot interbreed, and any other information which the Administrator believes to be relevant to a determination. Any information known to the petitioner that indicates that a regulated article may pose a greater plant pest risk than the unmodified recipient organism shall also be included.

(5) Field test reports for all trials conducted under permit or notification procedures, involving the regulated article, that were submitted prior to submission of a petition for determination of nonregulated status or prior to submission of a request for extension of a determination of nonregulated status under paragraph (e) of this part. 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.

(d) *Administrative action on a petition.* (1) A petition for determination of nonregulated status under this part which meets the requirements of paragraphs (b) and (c) of this section will be filed by the Administrator, stamped with the date of filing, and assigned a petition number. The petition number shall identify the file established for all submissions relating to the petition. APHIS will promptly notify the petitioner in writing of the filing and the assigned petition number. If a petition does not meet the requirements specified in this section, the petitioner shall be sent a notice indicating how the petition is deficient.

(2) After the filing of a completed petition, APHIS shall publish a notice in the FEDERAL REGISTER. This notice

shall specify that comments will be accepted from the public on the filed petition during a 60 day period commencing with the date of the notice. During the comment period, any interested person may submit to the Administrator, written comments, regarding the filed petition, which shall become part of the petition file.

(3) The Administrator shall, based upon available information, furnish a response to each petitioner within 180 days of receipt of a completed petition. The response will either:

(i) Approve the petition in whole or in part; or

(ii) deny the petition.

The petitioner shall be notified in writing of the Administrator's decision. The decision shall be placed in the public petition file in the offices of APHIS and notice of availability published in the FEDERAL REGISTER.

(e) *Extensions to determinations of nonregulated status.* (1) The Administrator may determine that a regulated article does not pose a potential for plant pest risk, and should therefore not be regulated under this part, based on the similarity of that organism to an antecedent organism.

(2) A person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request shall include information to establish the similarity of the antecedent organism and the regulated articles in question.

(3) APHIS will announce in the FEDERAL REGISTER all preliminary decisions to extend determinations of nonregulated status 30 days before the decisions become final and effective. If additional information becomes available that APHIS believes justifies changing its decision, it will issue a revised decision.

(4) If a request to APHIS to extend a determination of nonregulated status under this part is denied, APHIS will inform the submitter of that request of the reasons for denial. The submitter may submit a modified request or a separate petition for determination of nonregulated status without prejudice.

(f) *Denial of a petition; appeal.* (1) The Administrator's written notification of denial of a petition shall briefly set forth the reason for such denial. The written notification shall be sent by certified mail. Any person whose petition has been denied may appeal the determination in writing to the Administrator within 10 days from receipt of the written notification of denial.

(2) The appeal shall state all of the facts and reasons upon which the person relies, including any new information, to show that the petition was wrongfully denied. The Administrator shall grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. An informal hearing may be held by the Administrator if there is a dispute of a material fact. Rules of Practice concerning such a hearing will be adopted by the Administrator.

[58 FR 17057, Mar. 31, 1993, as amended at 59 FR 67611, Dec. 30, 1994; 62 FR 23957, May 2, 1997]

§ 340.7 Marking and identity.

(a) Any regulated article to be imported other than by mail, shall, at the time of importation into the United States, plainly and correctly bear on the outer container the following information:

(1) General nature and quantity of the contents;

(2) Country and locality where collected, developed, manufactured, reared, cultivated or cultured;

(3) Name and address of shipper, owner, or person shipping or forwarding the organism;

(4) Name, address, and telephone number of consignee;

(5) Identifying shipper's mark and number; and

(6) Number of written permit authorizing the importation.

(b) Any regulated article imported by mail, shall be plainly and correctly addressed and mailed to APHIS through any USDA plant inspection station listed in § 319.37–14 of this chapter and shall be accompanied by a separate sheet of paper within the package plainly and correctly bearing the name, address, and telephone number of the intended recipient, and shall plainly and correctly bear on the outer container the following information:

(1) General nature and quantity of the contents;

(2) Country and locality where collected, developed, manufactured, reared, cultivated, or cured;

(3) Name and address of shipper, owner, or person shipping or forwarding the regulated article; and

(4) Number of permit authorizing the importation;

(c) Any regulated article imported into the United States by mail or otherwise shall, at the time of importation or offer for importation into the United States, be accompanied by an invoice or packing list indicating the contents of the shipment.

[52 FR 22908, June 16, 1987. Redesignated at 58 FR 17056, Mar. 31, 1993, as amended at 58 FR 17059, Mar. 31, 1993; 62 FR 23958, May 2, 1997; 72 FR 43523, Aug. 6, 2007]

§ 340.8 Container requirements for the movement of regulated articles.

(a) *General requirements.* A regulated article shall not be moved unless it complies with the provisions of paragraph (b) of this section, unless a variance has been granted in accordance with the provisions of paragraph (c) of this section.[12]

(b) *Container requirements*—(1) *Plants and plant parts.* All plants or plant parts, except seeds, cells, and subcellular elements, shall be packed in a sealed plastic bag of at least 5 mil thickness, inside a sturdy, sealed, leakproof, outer shipping container constructed of corrugated fiberboard, corrogated cardboard, wood, or other material of equivalent strength.

(2) *Seeds.* All seeds shall be transported in a sealed plastic bag of at least 5 mil thickness, inside a sealed metal container, which shall be placed inside a second sealed metal container. Shock absorbing cushioning material shall be placed between the inner and outer metal containers. Each metal container shall be independently capable of protecting the seeds and preventing spillage or escape. Each set of metal containers shall then be enclosed in a sturdy outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(3) *Live microorganisms and/or etiologic agents, cells, or subcellular elements.* All regulated articles which are live (noninactivated) microorganisms, or etiologic agents, cells, or subcellular elements shall be packed as specified below:

(i) *Volume not exceeding 50 ml.* Regulated articles not exceeding 50 ml shall be placed in a securely closed, watertight container (primary container, test tube, vial, etc.) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(ii) *Volume greater than 50 ml.* Regulated articles which exceed a volume of 50 ml. shall comply with requirements specified in paragraph (b)(3)(i) of this section. In addition, a shock absorbing material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 1,000 ml. of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml. may be placed in a single, secondary container. The maximum amount of micro-organisms or etiologic agents, cells, or subcellular elements which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

(iii) *Dry ice.* If dry ice is used as a refrigerant, it shall be placed outside the secondary container(s). If dry ice is

[12] The requirements of this section are in addition to and not in lieu of any other packing requirements such as those for the transportation of etiologic agents prescribed by the Department of Transportation in Title 49 CFR or any other agency of the Federal government.

used between the secondary container and the outer shipping container, the shock absorbing material shall be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

(4) *Insects, mites, and related organisms.* Insects, mites, and other small arthropods shall be packed for shipment as specified in this paragraph or in paragraph (b)(3) of this section. Insects (any life stage) shall be placed in an escape-proof primary shipping container (insulated vacuum container, glass, metal, plastic, etc.) and sealed to prevent escape. Such primary container shall be placed securely within a secondary shipping container of crushproof styrofoam or other material of equivalent strength; one or more rigid ice packs may also be placed within the secondary shipping container; and sufficient packing material shall be added around the primary container to prevent movement of the primary shipping container. The secondary (styrofoam or other) container shall be placed securely within an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(5) *Other macroscopic organisms.* Other macroscopic organisms not covered in paragraphs (b) (1), (2), and (4) of this section which do not require continuous access to atmospheric oxygen shall be packaged as specified in paragraph (b)(3) or (b)(4) of this section. All macroscopic organisms which are not plants and which require continuous access to atmospheric oxygen shall be placed in primary shipping containers constructed of a sturdy, crush-proof frame of wood, metal, or equivalent strength material, surrounded by escape-proof mesh or netting of a strength and mesh size sufficient to prevent the escape of the smallest organism in the shipment, with edges and seams of the mesh or netting sealed to prevent escape of organisms. Each primary shipping container shall be securely placed within a larger secondary shipping container constructed of wood, metal, or equivalent strength material. The primary and secondary shipping containers shall then be placed securely within an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength, which outer container may have air holes or spaces in the sides and/or ends of the container, provided that the outer shipping container must retain sufficient strength to prevent crushing of the primary and secondary shipping containers.

(c) *Request for a variance from container requirements.* A responsible person who believes the container requirements normally applicable to the movement of the person's regulated article(s) are inappropriate due to unique circumstances (such as the nature, volume, or life stage of the regulated article) may submit in an application for a permit, a request for a variance from the container requirements. The request for a variance under this section shall consist of a short statement describing why the normally applicable container requirements are inappropriate for the regulated article which the person proposes to move and what container requirements the person would use in lieu of the normally prescribed container requirements. USDA shall advise the responsible person in writing at the time a permit is granted on the person's request for a variance.

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

§ 340.9 Cost and charges.

The services of the inspector during regularly assigned hours of duty and at the usual places of duty shall be furnished without cost.[13] 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.

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

[13] The Department's provisions relating to overtime charges for an inspector's services are set forth in 7 CFR part 354.