

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]

§ 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

⁴Any 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.)

§ 340.2

7 CFR Ch. III (1–1–97 Edition)

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
 Rickettsial-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 Leptolegnielleaceae

Class Zygomycetes

Order Mucorales
 Family Choanephoraceae
 Family Mucoraceae
 Family Entomophthoraceae

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 Ascophariales

Class Pyrenomycetes

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

Class Discomycetes

Order Phacidiales
 Order Helotiales
 Family Ascocorticaceae
 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

Animal and Plant Health Inspection Service, USDA

§ 340.2

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 Nematoda

Class Secernentea

Order Tylenchida

Family Anguinidae
 Family Belonolaimidae
 Family Caloosiidae
 Family Criconeematidae
 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 Tetranychoidae

 Superfamily Eupodoidea

 Superfamily Tydeoidea

 Superfamily Erythraenoidea

 Superfamily Trombidioidea

 Superfamily Hydryphantoidea

 Superfamily Tarsonemoidea

§ 340.2

7 CFR Ch. III (1–1–97 Edition)

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 Ephydriidae
 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 *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