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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 § 340.1⁴

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.)

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<p style="text-align: center;"><i>Kingdom Monera</i></p> <p style="text-align: center;">DIVISION BACTERIA</p> <p>Family Pseudomonadaceae</p> <p style="padding-left: 20px;">Genus Pseudomonas</p> <p style="padding-left: 20px;">Genus Xanthomonas</p> <p>Family Rhizobiaceae</p> <p style="padding-left: 20px;">Genus Rhizobium</p> <p style="padding-left: 20px;">Genus Bradyrhizobium</p> <p style="padding-left: 20px;">Genus Agrobacterium</p> <p style="padding-left: 20px;">Genus Phyllobacterium</p> <p>Family Enterobacteriaceae</p> <p style="padding-left: 20px;">Genus Erwinia</p> <p>Family Streptomycetaceae</p> <p style="padding-left: 20px;">Genus Streptomyces</p> <p>Family Actinomycetaceae</p> <p style="padding-left: 20px;">Genus Actinomyces</p> <p style="text-align: center;">Coryneform group</p> <p style="padding-left: 20px;">Genus Clavibacter</p> <p style="padding-left: 20px;">Genus Arthrobacter</p> <p style="padding-left: 20px;">Genus Curtobacterium</p> <p style="padding-left: 20px;">Genus Corynebacteria</p> <p>Gram-negative phloem-limited bacteria associated with plant diseases</p> <p>Gram-negative xylem-limited bacteria associated with plant diseases</p> <p>And all other bacteria associated with plant or insect diseases</p> <p>Rickettsiaceae</p> <p style="padding-left: 20px;">Rickettsial-like organisms associated with insect diseases</p> <p style="text-align: center;">Class Mollicutes</p> <p>Order Mycoplasmatales</p> <p>Family Spiroplasmataceae</p> <p style="padding-left: 20px;">Genus Spiroplasma</p> <p>Mycoplasma-like organisms associated with plant diseases</p> <p>Mycoplasma-like organisms associated with insect diseases</p> <p style="text-align: center;"><i>Superkingdom Eukaryotae</i></p> <p style="text-align: center;"><i>Kingdom Plantae</i></p> <p style="text-align: center;"><i>Subkingdom Thallobionta</i></p> <p style="text-align: center;">Division Chlorophyta</p> <p style="padding-left: 20px;">Genus Cephaleuros</p> <p style="padding-left: 20px;">Genus Rhodochytrium</p> <p style="padding-left: 20px;">Genus Phyllosiphon</p> <p style="text-align: center;">Division Myxomycota</p> <p>Class Plasmodiophoromycetes</p> <p style="text-align: center;">Division Eumycota</p> <p style="text-align: center;">Class Chytridiomycetes</p> <p>Order Chytridiales</p> <p style="text-align: center;">Class Oomycetes</p> <p>Order Lagenidiales</p> <p>Family Lagenidiaceae</p> <p>Family Olpidiopsidaceae</p> <p>Order Peronosporales</p>	<p>Family Albuginaceae</p> <p>Family Peronosporaceae</p> <p>Family Pythiaceae</p> <p>Order Saprolegniales</p> <p>Family Saprolegniaceae</p> <p>Family Leptolegniellaceae</p> <p style="text-align: center;">Class Zygomycetes</p> <p>Order Mucorales</p> <p>Family Choanephoraceae</p> <p>Family Mucoraceae</p> <p>Family Entomophthoraceae</p> <p style="text-align: center;">Class Hemiascomycetes</p> <p>Family Protomycetaceae</p> <p>Family Taphrinaceae</p> <p style="text-align: center;">Class Loculoascomycetes</p> <p>Order Myriangiales</p> <p>Family Elsinoeaceae</p> <p>Family Myriangiaceae</p> <p>Order Asterinales</p> <p>Order Dothideales</p> <p>Order Chaetothyriales</p> <p>Order Hysteriales</p> <p>Family Parmulariaceae</p> <p>Family Phillipsiellaceae</p> <p>Family Hysteriaceae</p> <p>Order Pleosporales</p> <p>Order Melanommatales</p> <p style="text-align: center;">Class Plectomycetes</p> <p>Order Eurotiales</p> <p>Family Ophiostomataceae</p> <p>Order Ascophariales</p> <p style="text-align: center;">Class Pyrenomycetes</p> <p>Order Erysiphales</p> <p>Order Meliolales</p> <p>Order Xylariales</p> <p>Order Diaporthales</p> <p>Order Hypocreales</p> <p>Order Clavicipitales</p> <p style="text-align: center;">Class Discomycetes</p> <p>Order Phacidiales</p> <p>Order Helotiales</p> <p>Family Ascocorticaceae</p> <p>Family Hemiphacidiaceae</p> <p>Family Dermataceae</p> <p>Family Sclerotiniaceae</p> <p>Order Cytarriales</p> <p>Order Medeolariales</p> <p>Order Pezziales</p> <p>Family Sarcosomataceae</p> <p>Family Sarcoscyphaceae</p> <p style="text-align: center;">Class Teliomycetes</p> <p style="text-align: center;">Class Phragmobasidiomycetes</p> <p>Family Auriculariaceae</p> <p>Family Ceratobasidiaceae</p> <p style="text-align: center;">Class Hymenomycetes</p> <p>Order Exobasidiales</p>
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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 Visaceae—parasitic species

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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 Nacobbiidae
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 Dermanysoidea
Order Acariformes
Suborder Prostigmata
Superfamily Eriophyoidea
Superfamily Tetranychidae
Superfamily Eupodoidea

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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 Meloidea
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

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(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.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

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

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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.

(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 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