§ 340.0 Restrictions on the introduction of regulated articles.

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

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

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

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

\(^1\)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. 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).
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 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 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 derivved 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.
§ 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 may be 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.

GROUP VIROIDS
Superkingdom Prokaryotae
Kingdom Virus
All members of groups containing plant viruses, and all other plant and insect viruses

GROUP 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 Actinomycetacea
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

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.)