§ 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 The petitioner shall include copies of scientific literature, copies of unpublished studies, when available, and data from tests performed upon which to base a determination.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 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

[11] See footnote 5 in § 340.3.

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 (non-

[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.