§ 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 re-submission 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 The petitioner shall include copies of scientific literature, copies of unpublished studies, when available, and data from tests performed upon which to base a determination.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, agricul-
tural or cultivation practices, effects of the regulated article on non-
target organisms, indirect plant pest effects on other agricultural products, 
transfer of genetic information to organ-
isms 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 un-
modified recipient organism shall also 
be included.

(5) Field test reports for all trials 
conducted under permit or notification 
procedures, involving the regulated ar-
ticle, that were submitted prior to sub-
mission of a petition for determination of 
nonregulated status or prior to sub-
mission 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 observa-
tion, resulting data, and analysis re-
garding all deleterious effects on 
plants, nontarget organisms, or the en-
vironment.

(d) Administrative action on a petition.
(1) A petition for determination of non-
regulated 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 peti-
tion number. The petition number 
shall identify the file established for 
all submissions relating to the peti-
tion. APHIS will promptly notify the 
petitioner in writing of the filing and 
the assigned petition number. If a peti-
tion 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 pe-
tition, APHIS shall publish a notice in 
the FEDERAL REGISTER. This notice 
shall specify that comments will be ac-
cepted from the public on the filed pe-
tition during a 60 day period com-
mencing with the date of the notice. 
During the comment period, any inter-
ested person may submit to the Admin-
istrator, 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 deci-
sion. The decision shall be placed in 
the public petition file in the offices of 
APHIS and notice of availability pub-
lished in the FEDERAL REGISTER.

(e) Extensions to determinations of non-
regulated status. (1) The Administrator 
may determine that a regulated article 
does not pose a potential for plant pest 
risk, and should therefore not be regu-
lated under this part, based on the simi-
larity of that organism to an ante-
cedent organism.

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

(3) APHIS will announce in the Fed-
eral Register all preliminary deci-
sions to extend determinations of non-
regulated status 30 days before the de-
cisions become final and effective. If 
additional information becomes avail-
able that APHIS believes justifies 
changing its decision, it will issue a re-
vised 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 peti-
tion has been denied may appeal the 
determination in writing to the Admin-
istrator within 10 days from receipt of 
the written notification of denial.
§ 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, leak-proof, outer shipping container constructed of corrugated fiberboard, corrugated 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 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-