USDA Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

DOCUMENT ID:
BRS-GD-2025-0003

DATE:
February 19, 2025

Petition User Guide

with Reference To 7 CFR Part 340 – *Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests*

The information contained in this document is intended solely as guidance. Except where noted, persons may choose to follow APHIS guidance or follow different procedures, practices, or protocols that meet applicable statutes and regulations.

Language implying that guidance is mandatory (e.g., "shall," "must," "required," or "requirement") should not be construed as binding unless the terms are used to refer to a statutory or regulatory requirement.

Following the guidance contained in this document should not be construed as a guarantee of compliance with applicable statutes and regulations.

Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
United States Department of Agriculture

4700 River Road
Riverdale, MD 20737

GUIDE INFORMATION

ISSUING AGENCY/OFFICE:	Animal and Plant Health Inspection Service (APHIS) BiotechnologyRegulatory Services (BRS)
TITLE OF DOCUMENT:	Petition User Guide: with Reference to 7 CFR part 340 – Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe are Plant Pests
DOCUMENT ID:	BRS-GD-2025-0003
DATE OF ISSUANCE:	February 19, 2025
REPLACES:	1996 original version
SUMMARY:	This guide explains how to submit a petition seeking a determination of nonregulated status.[1] The guide outlines required information and other relevant details a person must present explaining the factual grounds describing why a modified plant should not be regulated under 7 CFR part 340.
DISCLAIMER:	The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Agency regulations.

[1] Per § 340.6, APHIS 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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INTRODUCTION

APHIS regulations at 7 CFR part 340 govern the introduction (importation, interstate movement, and environmental release) of certain organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests. Any person may submit to APHIS, a petition to seek a determination that an engineered plant (modified plant) that meets the definition of a "regulated article" is unlikely to pose a greater plant pest risk than the nonmodified plant from which it was derived, and therefore should not be regulated under this part.

A "regulated article" is:

> 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.

In other words, a regulated article is an organism or product that has been altered or produced using genetic engineering (1) that has one or more of its components derived from a plant pest or an unclassified or unknown organism; or (2) that APHIS "determines is a plant pest or has reason to believe is a plant pest." See also § 340.1 (defining relevant terms used in "regulated article" definition); and 52 Fed. Reg. 22,892 (June 16, 1987).

This guide explains how to submit a petition seeking a determination of nonregulated status.[2] The guide outlines required information and other relevant details a person must present explaining the factual grounds describing why a modified plant should not be regulated under 7 CFR part 340.

ASSESSMENT OF PLANT PEST RISK

APHIS evaluates petitions for determination of nonregulated status to assess whether modified plants are unlikely to pose a greater plant pest risk than the nonmodified plants from which they were derived (§ 340.6).

The regulations (§ 340.6(c)) require that petitions include information, scientific literature, copies of unpublished studies, and data from tests performed as available that provide:

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- A description of the biology of the nonmodified plant
- A detailed description of the differences in genotype between the modified and nonmodified plants
- A detailed description of the phenotype of the modified plant, and of any known and potential phenotypic differences from the unmodified plant
- Any relevant experimental data and publications
- Field test reports for all trials conducted under authorization pursuant to 7 CFR part 340

APHIS uses this information to assess whether the modified plant is unlikely to pose a greater plant pest risk than the unmodified plant from which it was derived. APHIS calls the assessment a Plant Pest Risk Assessment (PPRA). APHIS' PPRA will consider the following factors listed in § 340.6(c)(4):

- 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 weediness of any other 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
- Any other information which the Administrator believes to be relevant to a determination.

REQUIRED DATA AND INFORMATION

Petitions for determination of nonregulated status need to include information about how the genetic modification alters the plant's genotype and phenotype for APHIS to assess whether the modified plant is unlikely to pose a greater plant pest risk compared to the unmodified plant from which it was derived. APHIS' PPRA will compare the modified plant to a nonmodified "comparator plant" to assess whether the modified plant is unlikely to pose a greater plant pest risk. Multiple comparators may be used, and the choice of which comparator(s) to use depends on the scientific questions being addressed, the availability of suitable comparators, and specific regulatory requirements. Additionally, variations within cultivated varieties of the plant species are considered to provide context for any differences identified between the modified plant and the comparator and to determine if the modified plant is unlikely to pose a greater plant pest risk compared to a comparator.

The analysis in a petition can rely on many types of data and information, including observational information, experimental results, references to scientific literature and published reports, and logical reasoning based on established scientific understanding. Synthesis of information from cited references may be sufficient for many components of a petition, depending on the topic and availability of existing scientific evidence. In some cases, new experimental results may be necessary to understand how a genetic modification may pose potential plant pest risks.

APHIS requires the following information:

BIOLOGY OF THE NONMODIFIED PLANT

Include the taxonomy and a description of the biology of the nonmodified recipient plant, including habitats where the plant is found inside and outside of cultivation, reproductive biology and ecology, evidence of reported weediness, discussion of sexual compatibility with cultivated, wild, and weedy free-living relatives, and the extent of weediness of its sexually compatible relatives. When APHIS has previously evaluated a plant taxon, applicants may include a summary description of the nonmodified plant.

RELEVANT EXPERIMENTAL DATA AND PUBLICATIONS

TRANSFORMATION METHODS AND GENOTYPE DIFFERENCES

Transformation method
Specify what transformation method was used to create the genetic modification. For Agrobacterium-based transformation protocol (or similar methods), the applicant must indicate how the Ti plasmid-based vector was disarmed (i.e., all tumorigenic DNA was removed). For other methods of transformation, the applicant must describe the sources of the components of the plasmid (or other DNA including possible carrier DNA). Applicants can provide citations that describe the transformation procedure. Applicants must also describe any significant modifications of transformation, strain designation, tissue regeneration, etc.

Description of inserted DNA
Provide the names and functions of the gene(s), promoters, terminators, leader sequences, enhancers, introns, and any other sequences that are inserted or used for gene expression or modification in the plant. Applicants must indicate the nucleotide position of each component within the inserted DNA, the source of each inserted DNA component, and when available, include a reference for the source.

Applicants must provide the sequence of all inserted DNA in a format that can be read by sequence analysis tools or word processing software. If there have been any changes to the source sequences, the applicant must highlight the changes and provide the translated amino acid sequence of any protein coding sequences.

Applicants must describe other intended changes made to the modified plant's DNA (e.g., genome edits) when plant pest DNA sequence remains. In these scenarios, the applicants must describe those genetic modifications and submit a sequence of the modified region with an alignment to the sequence in the nonmodified plant (in addition to providing the inserted sequence containing plant pest DNA).

Genome integration assessment
Provide a description, with supporting evidence, of the number and composition of full and partial insertion events and confirmation of stable integration into the plant's genome. Applicants may use any methodology of their choosing for this purpose provided that it clearly supports the conclusions. If the modified plant contains unintended genetic sequences, such as backbone sequences, as a result of the transformation, describe whether they could plausibly generate any additional phenotypes.

PHENOTYPE DESCRIPTION OF THE MODIFIED PLANT

Describe changes to the plant's phenotype that are known or plausibly expected to occur based on the mechanism of action of the genetic modification. This will include how the genetic modification leads to the intended phenotype changes, and the extent to which the genetic modification may or may not also affect other aspects of the plant's biology that demonstrably or plausibly lead to other phenotypes. For example, if the genetic modification is intended to change an aspect of plant physiology, the petition will describe the mechanisms by which the genetic modification affects plant physiology to adequately understand all the observed and plausible differences in the physiology of the modified plant compared to the nonmodified comparator. This description may include evidence or arguments about the extent of the differences to the comparator.

The amount and type of information presented may vary depending on the genetic modification and the plant, and the evidence already available for each. For cases when the effects of the genetic modification on an aspect of the plant's phenotype are already well-documented, a synthesis of existing information with references may be sufficient to describe the expected effects. However, if there is little information available in the literature about the genetic modification or its effect on the plant, direct experimental results regarding the phenotype and relevant safety information of the plant will be needed.

As part of the phenotype description, applicants must indicate which inserted sequences are expressed in the plant. For any expressed DNA, provide a general description of the expression product and its expression profile, i.e., whether the expression is constitutive or inducible (if so, what inducing factors) and whether expression is expected to be ubiquitous throughout the plant or tissue-specific (if so, what tissues). Quantitative expression levels are expected to only be necessary if they are critical to understanding the potential risk of the modified plant.

If applicants provide experimental results, they must be analyzed using the appropriate statistical analysis. When unpublished information or an opinion has been supplied by a scientific expert, a letter communicating the information must be included in the petition. If the unpublished information provided is data resulting from scientific research, then these data can be provided as a personal communication either in a letter from the researcher or in the text of the petition. In either case the materials and methods, data analysis, and discussion of the results must be provided in detail. Unsupported assertions about the results of the experiment are not acceptable.

Data from field tests in foreign countries are acceptable. If data were obtained in a foreign country, the applicant must submit information about the environments in which the data were obtained and a justification of how this information informs conclusions about plant pest risk in the United States.

INFORMATION FOR CITED REFERENCES

Petitions need to include complete citation information for all cited references and pdf copies of all the cited references.

FIELD TEST REPORTS

If any field tests were conducted on the regulated modified plant under BRS permit or notification procedures, the petition must include a table of authorization numbers for all authorized permits and notifications submitted prior to submission of a petition for determination of nonregulated status.

OPTIONAL DATA AND INFORMATION

Applicants may provide information relevant to the National Environmental Policy Act (NEPA). Especially helpful, would be information relevant to agronomic practices that affect the environment and socioeconomic analysis for any crops never subjected to an EA. Especially for small acreage crops, there may not be much public information on how and where the crop is produced, the parts of the value chain associated with the crop, and economic information related to the crop.

SUBMISSION TIPS

PRESUBMISSION CONSULTATION

APHIS is available for consultation with stakeholders who have questions about the petition process. APHIS strongly encourages early, pre-submission consultation for all potential applicants regarding data and information that may be necessary for APHIS to determine that a modified plant is unlikely to pose a greater plant pest risk than the nonmodified plant. Contact BRS.Petitions@usda.gov to request a consultation.

PETITION SUBMISSION PROCEDURES AND CONFIDENTIAL BUSINESS INFORMATION

SUBMISSION PROCEDURES

Applicants shall submit petitions electronically to BRS.Petitions@usda.gov. If the petition file(s) may be too large for email transmittal, applicants should contact BRS.Petitions@usda.gov to request an alternative electronic submission method.

If the applicant requires a paper submission, please submit to Biotechnology Regulatory Services, Animal and Plant Health Inspection Service, 4700 River Road, Riverdale, Maryland 20737–1237.

Petitions shall include a dated cover letter and be 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. 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) _____
(Email Address) _____
(Mailing Address) _____
(Telephone Number) _____

CONFIDENTIAL BUSINESS INFORMATION

If the petition, as well as any additional supporting information provided, does not contain Confidential Business Information (CBI), applicants must mark it “Does Not Contain CBI” or “No CBI.”

If the petition, as well as any additional supporting information provided, does contain CBI, applicants must submit two copies of the petition, a CBI copy and a CBI-deleted copy. Each page of the CBI copy must be marked “CBI Copy.” In addition, those portions of the petition which are deemed CBI shall be so designated. The CBI-deleted copy shall be marked “CBI-Deleted Copy,” have all such CBI deleted, and have marked on each page where the CBI was deleted: ''CBI Deleted.''

APHIS will evaluate any CBI claims in accordance with applicable laws and procedures before releasing information in a petition submission to the public. APHIS’ goal is to undertake this review as close in time as possible to any public release of information. The review will include communication with the applicant about claims of CBI, if any. In APHIS’ experience, minimizing CBI claims in published materials fosters public acceptance of plant products of biotechnology and is important to enable informed public comment on plant pest risk assessments. CBI designations expire 10 years after the date of the submission unless the submitter requests and provides justification for a longer designation period. 7 CFR 1.8(c).

For further information on submitting petitions with or without CBI, see the Guide for Submitting CBI.

VERSION HISTORY

February 19, 2025	Completely revised version
1996	Original document