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Permit 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*

Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
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GUIDE INFORMATION

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SUMMARY:	The Permit User Guide aids APHIS stakeholders (responsible persons, their agents and the general public) on the preparation of a permit application to introduce (import, move interstate, or release into the environment) organisms developed through genetic engineering (modified organisms). APHIS protects and enhances U.S. agricultural and natural resources using a science-based and risk-based regulatory framework to ensure the safe introduction of modified organisms. APHIS receives its regulatory authority from the Plant Protection Act of 2000 and oversees modified organisms in accordance with its regulations under 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). For more information: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology. Permits for the introduction of modified organisms under 7 CFR part 340 are electronically submitted to APHIS through APHIS eFile. This guidance functions as a resource for information requirements for all permit applications submitted 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.

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INTRODUCTION TO THE PERMIT PROCESS

APHIS regulations at 7 CFR part 340 govern the introduction (importation, interstate movement, and environmental release) of certain organisms developed using genetic engineering (modified organisms). You must have an active BRS permit to introduce a modified organism meeting the definition of a regulated article in 7 CFR part 340, unless the organism qualifies for a notification (an administratively-streamlined alternative to a permit applicable to plants that meet specified eligibility criteria) or is exempt from the requirement for a permit (see Appendix C). The purpose of this guide is to help you prepare a BRS permit application; the guide includes information requirements or permit applications.

The appendices include additional resources to help you navigate APHIS eFile, prepare Standard Operating Procedures (SOPs), and submit Confidential Business Information (CBI) (Appendix A); understand important regulatory definitions (Appendix B); learn about permitting exemptions (Appendix C); learn about additional information requirements for permit applications involving plant made pharmaceutical and industrial products (Appendix D); and samples of supplemental permit conditions (Appendix E);

Please note that other Federal and State plant quarantine laws may restrict or prohibit the interstate movement, importation, or release of the regulated article. Additional information for such restriction can be found from "Additional Federal and State Regulatory Requirements That May Apply to APHIS BRS Authorizations." For example, if you are conducting challenge-inoculation experiments in the field, use of an unmodified pathogen may still require additional permits. It is the applicant's responsibility to obtain any additional permits required by Federal and State law.

ORGANISMS SUBJECT TO 7 CFR PART 340

ORGANISMS SUBJECT TO 7 CFR PART 340

7 CFR part 340 regulates the introduction of organisms (including plants, insects, or microbes) and products developed using genetic engineering that meet the definition of "regulated article," which 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.

Regulated articles require an authorization from APHIS BRS for importation, interstate movement, or environmental release unless they are specifically exempt from the permitting requirements under §

340.2(b). If you are uncertain as to whether an organism or product is a plant pest or a regulated article, please contact: biotechquery@aphis.usda.gov.

ORGANISMS EXEMPT FROM 7 CFR PART 340 AUTHORIZATION REQUIREMENTS

Certain modified organisms may be exempt from the authorization requirements of 7 CFR part 340. See Appendix C for more information about these permitting exemptions.

CONTAINMENT FACILITIES

Although APHIS does not regulate the use of modified organisms in containment facilities (e.g., laboratory, contained greenhouse, or other contained structure), applicants are still responsible for preventing the unauthorized introduction of modified organisms from contained facilities. APHIS encourages applicants to ensure that destination facilities listed in permit applications follow containment guidelines established by USDA APHIS PPQ, the National Institutes of Health (NIH), or other similar guidelines.

SUBMITTING PERMIT APPLICATIONS FOR MODIFIED ORGANISMS

SET UP A LOGIN.GOV ACCOUNT AND REGISTER IN APHIS EFILE

Responsible persons (i.e., applicant) listed on an application must have their identity verified by Login.gov prior to registering in APHIS eFile.

APHIS EFILE APPLICATION OWNERSHIP (RESPONSIBLE PERSON)

The responsible person listed on an application must be a legal resident of the United States or designate an agent who is a resident of the United States. The responsible person:

- Is responsible for the information provided in the permit application and must sign the application,
- Will maintain control over the modified organism under permit during its introduction, and
- Ensures compliance with all conditions contained in any applicable permit and the requirements in 7 CFR part 340.

APHIS discourages the designation of temporary employees (e.g., post-doctorates or graduate students) as responsible parties.

For import and interstate movement permit applications, the responsible person may be the shipper or the recipient. In either case, the responsible person must make certain that all permit conditions are carried out.

APHIS eFile allows a designated person (application preparer) to prepare and submit an application on behalf of the responsible person. However, automated APHIS eFile communications about the application will only be sent to the responsible person.

CREATE AN APHIS EFILE PERMIT APPLICATION

You should submit your permit application to APHIS:

- At least 60 days prior to the proposed importation or interstate movement.
- At least 120 days in advance of the proposed release into the environment.

The APHIS eFile portal offers four methods to create applications:

1. **BRS Permitting Assistant (BRSPA).** Use this tool to start a new application instead of cloning an existing application or uploading an Extensible Markup Language (XML) file. You must enter information into the following fields when using the BRSPA:

    - **Organism (required).** Select the organism you want listed on your application. APHIS uses this information to determine if the modified organism is under our regulatory authority. If the organism is under our regulatory authority, APHIS uses this information to assign Supplemental Permit Conditions (SPCs) for preventing the unauthorized release, spread, dispersal and/or persistence of the modified organism in the environment during its importation, interstate movement, or environmental release.
    - **Intended Use (required).** Use this field to identify that your modified organism is intended for **"Traditional"**, **"Pharmaceutical"**, **"Industrial"**, or **"Phytoremediation"** purposes. If you are working with a plant modified to produce a pharmaceutical or industrial compound or intended for use in phytoremediation, select the appropriate category. For all other modified organisms, select **"Traditional."** APHIS uses this information to inform the addition of SPCs to the permit.
    - **What are you applying for (required).** Select "Permit." APHIS uses this information to select the appropriate outcome card in the BRSPA.
    - **Movement Type (required).** Select the type of introduction you will conduct with your modified organism. Please note that you CANNOT change the selected movement type of an application once you create a permit application. APHIS uses this information to determine the addition of SPCs to this permit. The selectable **Movement Type** are:
        - **"Import."** Authorizes the movement of modified organisms into the United States. Permits for importation cannot be combined with interstate movement or environmental release.
        - **"Interstate Movement."** Authorizes the movement of modified organisms between states.
        - **"Release."** Authorizes environmental releases and does not include transport of modified organisms between states.
        - **"Interstate Movement and Release."** Authorizes movement between states and environmental releases in a single permit application.

2. **Clone an existing application.** A streamlined option to create an application having some of the same data or attributes (CBI status, movement type) as a previous application.

3. **Upload an existing XML file.** Allows you to use an XML file to create an application.

4. **Amend an issued permit.** After receiving your permit, you can request an amendment to propose changes before the permit expires. Refer to the Changes to an Active Permit (after Issuance) section of this document for details on the types of changes you can make through the amendment process.

INFORMATION REQUIREMENTS FOR PERMIT APPLICATIONS

This section describes information requirements for a permit application and how APHIS uses that information during its review. Enter your specific permit data into the appropriate APHIS eFile data entry fields. Below, we state when a data field is required; in APHIS eFile you will see required data fields denoted by a red asterisk (*). Navigate within the sections of the permit application by selecting the different chevrons at the top of the screen.

APPLICATION DETAILS CHEVRON

Confidential Business Information (CBI) Section

Does this Application Contain CBI? (required) and **CBI Justification (required if the application contains CBI)**. These fields allow a responsible person to indicate and justify the inclusion of CBI in the application. Please note that if you are claiming CBI-protected data within an application, APHIS eFile will provide checkboxes to CBI-protect certain fields and you will need to place brackets [ ] around data in other fields (where checkboxes are not provided) to claim data as CBI-protected.

APHIS uses these fields to determine whether the marked information is CBI and, if so, to protect the information in APHIS eFile generated PDFs (No CBI, CBI-Included, CBI-Deleted PDFs). APHIS' receipt of, and any discussion with you involving, information marked as CBI does not indicate agreement with or acceptance of the CBI claims. APHIS will evaluate any CBI claims in accordance with 7 CFR § 1.8, if your submission is responsive to a Freedom of Information Act (FOIA) request, or prior to any publication of information in your application.

Related Activity Section

Enter information about your proposed regulated activities here:

Proposed Effective Date (required) and **Proposed Expiration Date (required).** Enter the date you propose to begin and end your regulated activities.

Authorized activities may occur only between the "Effective" date and the "Expires" date listed on the permit. The "Issued" date is the date that APHIS issues the permit.

APHIS uses your proposed dates to inform the final "Effective" and "Expires" dates of your permit as applicable. APHIS also uses your proposed duration to inform reporting requirements within the permit's SPCs.

APHIS generally[1] restricts the duration (time between effective and expiration dates) of permits as follows:

- Importation: one (1) year
- Interstate movement: one (1) year
- Environmental release for annual plants and non-plant organisms: one (1) year
- Environmental release for perennial plants: one (1) year to three (3) years

Hand Carry (required for "Import" permits only). Select **"Yes"** in this field if the modified organism will be imported in personal luggage or a personal vehicle. APHIS uses this information to determine the type of BRS import label to accompany the permit.

Number of Labels (**required for "Import" permits only).** Enter the number of BRS import labels you wish to receive. APHIS uses this information to determine the number of BRS import labels to accompany the permit. Note that BRS import labels may be reused; as a result, there is no benefit in requesting additional labels beyond the default value already listed.

Any Biological Material Accompanying the Organism During Movement (required for "Import" and "Interstate Movement" permits only). Indicate if any biological material (e.g., soil, host material, culture medium) will be moved with your modified organism. If you choose **"Yes"** for this field, you will need to describe the biological material accompanying the modified organism. APHIS uses this information to evaluate shipment containment.

Purpose of Permit (Intended Use, required). This field will prepopulate with your selection from the BRS Permitting Assistant or from a previous application. Otherwise, choose your purpose from the dropdown menu based on the intended use of your modified organism. If a modified organism is a regulated article as defined in 7 CFR part 340, it can generally be considered **"Traditional."** However, certain modified plants are considered **"Industrial," "Pharmaceutical,"** or **"Phytoremediation."** APHIS uses this information to inform the permit's SPCs to the permit.

- **"Industrial Product."** The purpose of a permit for an industrial product is to introduce modified plants engineered to produce industrial compounds. Industrial products are modified plants that meet all the following criteria: (1) The plants are engineered to produce compounds that are new to the plant; (2) the new compound has not been commonly used in food or feed; and (3) the new compound is being expressed for non-food, non-feed industrial uses. Examples of industrial uses include detergent manufacturing, paper production, and mineral recovery.

- **"Pharmaceutical Product."** The purpose of a permit for a pharmaceutical product is to introduce plants that are modified to produce compounds intended for pharmaceutical use that require approval from at least one of the following agencies prior to commercialization:

[1] APHIS may approve a permit duration beyond three years based on research and development needs. APHIS will consider the biology of a plant as part of these requests. If longer permit durations are desired, submit an inquiry to biotechquery@usda.gov.

- FDA Center for Biologics Evaluation and Research (human biologics)
- FDA Center for Drug Evaluation and Research (human drugs)
- FDA Center for Veterinary Medicine (animal drugs)
- USDA Center for Veterinary Biologics (animal biologics)

- **"Phytoremediation."** The purpose of a phytoremediation permit is to introduce modified plants that are intended to degrade, extract, or accumulate contaminants. Plants that are modified for tolerance to atypical metal, pH, and salt concentrations, or other environmental stressors with no remediation intent are considered **"Traditional"** with stress tolerance phenotypes.

- **"Traditional."** Choose traditional for all other applications. Most permits fall under this category. The purpose of this category is to move organisms that have been modified to express a broad range of traits, such as:
  - Altered agronomic properties (plant development, morphology, flowering, yield, response to abiotic stressors such as drought, flood temperature, salinity, etc.)
  - Herbicide resistance
  - Altered resistance to biotic stressors (bacteria, fungi, insects, nematodes, viruses, etc.)
  - Altered product quality (increased nutrients, reduced antinutrients, flavor, color, etc.)
  - Marker genes (visual markers and those used to detect successful transformation)
  - Other traits as specified by the applicant

Means of Movement (required for importation and interstate movement permits only). Briefly describe how you will transport the modified organism. Common examples include mail, common carrier, or personal baggage. APHIS uses this information to evaluate containment of the shipment.

Applicant Reference Number (optional). You may provide a reference number for the application. This number is for your personal or organizational purposes only (e.g., for internal tracking).

Additional Information (optional). You may include additional information that supports the certification that you will introduce the modified organism in accordance with 7 CFR part 340. For example, you can enter the authorization number of a previously issued permit if your application intends to continue the environmental release authorized under that issued permit.

Please note this field is **required** for applications involving the release a modified organism, if the unmodified species is not already present in the United States. In these instances, you must include the country and locality where the donor organism, recipient organism, vector or vector agent, and regulated article were collected, developed, and produced.

ORGANISMS CHEVRON

Organisms Section

In this section, you can add or remove organisms from your application. In general, BRS permit applications are limited to a single species. However, you may combine multiple species in a single permit application under certain circumstances. APHIS outlines these circumstances in the instructional text in the *Organisms Section* of the permit application in APHIS eFile. A single permit application may include multiple constructs that each represent a different modification to the organism(s) listed in the

permit. If you remove your organism from the application, APHIS eFile will remove all new constructs and previously submitted constructs (PSCs) in your application that are associated with the organism.
Scientific Name (required) and Common Name (required). The scientific name and common name fields will prepopulate based on your organism selection from the BRS Permitting Assistant, the information listed in an existing application (if cloning was used), or the information listed in an XML file (if XML uploading was used). Additionally, you can manually search for and add the scientific name and common name in this section of the application. APHIS uses this information to inform the addition of SPCs to the permit.

Cultivar and/or breeding line and/or strain (optional). You may provide any relevant subspecies, cultivar, variety, breeding line, and/or strain information about the organism as necessary. Please note this information is **required** in the case of microbial species where pathogenicity is strain dependent.

SUPPLIER/DEVELOPER CHEVRON

Organism Supplier/Developer Details (required). You must provide information about the Supplier or Developer of your modified organism.

CONSTRUCT(S) CHEVRON

For APHIS, a construct is the DNA that is incorporated into the recipient genome of the organism(s) listed in the application, or the edits to the genome of the organism(s), resulting from a single transformation event. If a single organism or line will contain DNA sequences resulting from successive transformation events, then the DNA from these successive transformation events can be listed together as a single construct.

You must add at least one new construct or a previously submitted construct (PSC) to your application. In total, you may include up to 500 new constructs and PSCs in a single application. If you wish to submit more than 500 constructs, you must submit multiple applications and may link them to facilitate review. There is an option in eFile to clone constructs to save time.

New Constructs Section

Enter information related to the genetic modification(s) introduced into your organism in this section. Information for each construct is divided into three sub-sections within the Edit Construct pop-up:

- Construct Details
- Intended Trait(s)
- Genotypes

Additional information about these sections is detailed below.

Construct Details:

Construct Name (required). Provide a unique name to identify the transformed line or lines that all contain the same construct. This field allows applicants to consistently identify the transformed line(s) in all future documents submitted to APHIS (e.g., planting/release reports, permits, etc.). The designation can be a name, number, short phrase, or any other unique identifier provided by the applicant to assist

both the applicant and APHIS in tracking the transformed line. When necessary, APHIS uses this information to communicate with applicants about constructs.

Organism (required). Select the organism modified with your construct. If your construct was introduced into multiple organisms listed separately in your application, you must separately enter the construct for each organism[2]. APHIS eFile provides a construct cloning tool you can use to reduce data input. APHIS uses this information, in conjunction with other construct information, to evaluate the modified organism's potential to escape containment/confinement, and to inform the permit's SPCs.

Modification Method (required). Select the method used to insert your construct into the genome of your modified organism (e.g., biolistic, disarmed *Agrobacterium tumefaciens,* electroporation). Below are important considerations for entering information:

- For viruses, you may select **"Replicon"** or **"DNA synthesis"**.
- If the material inserted into the genome is itself expected to create further alterations, the modification method should refer only to the method of construct insertion into the genome (e.g., if disarmed *Agrobacterium tumefaciens* is used to insert genome editing mechanisms such as Cas9, the modification method selected should be **"Agrobacterium tumefaciens, disarmed"**).
- You should select **"Direct Injection"** when enzymes, templates, or plasmids are injected into a cell for the purpose of altering the genome (e.g., injection of Cas9).
- If you select **"Other"**, you should use the **Transformation Events/Construct Description** field to describe the modification method and provide references as necessary.

APHIS uses this information to evaluate the intended trait(s).

Transformation Events/Construct Desc. (optional). You may provide any construct-specific information that may be helpful to APHIS. If you selected "**Other"** as the **Modification Method**, include the modification method here.

Intended Trait(s):

In general, a construct can have one or more expression cassettes and each expression cassette can have an associated intended trait. An intended trait is composed of two characteristics, Trait and Phenotype:

Trait (required). Select your trait. The trait is a general category related to the phenotype of your modified organism. With a single exception, all traits conferred by the construct must be listed here. The exception occurs when the trait is used for selection and will not be employed during the regulated activities of an environmental release. For example, if your construct contains elements for the expression of antibiotic or herbicide resistance, listing the resistance trait is not required if resistance screening will not be included during your regulated activities.

[2] If you are submitting an interstate movement permit application for modified microbes moving from one contained facility to another contained facility, please follow the instructions for completing permit applications in our Guide for Submitting Permit Applications for Microorganisms Developed Using Genetic Engineering Under 7 CFR part 340.

Traits can be classified into 10 distinct categories:

1. AP – Agronomic Properties (e.g., increased yield, abiotic tolerances, early flowering, male sterility)
2. BR – Bacterial Resistance
3. FR – Fungal Resistance
4. HR – Herbicide Resistance
5. IR – Insect Resistance
6. MG – Marker Gene
7. NR – Nematode Resistance
8. OO – Other (anything that clearly does not fall into one of the other categories, e.g., empty vector control lines)
9. PQ – Product Quality (e.g., delayed fruit ripening, altered amino acid profile, enhanced floral characteristics, increased fruit solids)
10. VR – Virus Resistance

APHIS uses this information to inform the permit's SPCs. Additionally, in the case of toxins (e.g., a compound that confers pest resistance), APHIS uses this information during its release site analysis on threatened and endangered species.

Phenotype (required). Provide your phenotype. A phenotype is a set of observable characteristics of an organism resulting from the interaction of its genotype with the environment. The phenotype expands on the Trait category. For example, if your Trait is HT, then the phenotype is tolerance to a specified herbicide. It is important to note the directionality of your phenotype when entering your specific phenotype information (e.g., *increased* leaf blight resistance as opposed to leaf blight resistance or *early* flowering time as opposed to altered flowering time). APHIS uses this information to inform the permit's SPCs. Additionally, in the case of toxins (e.g., a compound that confers pest resistance), APHIS uses this information during its release site analysis on threatened and endangered species.

Genotypes:

A genotype is generally an expression cassette or a grouping of genetic elements containing a set of construct components leading to one or more intended trait(s). Note that the genotype of an organism comprises all genetic elements in a construct, including the genetic elements of selectable markers, even if those selectable markers will not be employed during the regulated activities of an environmental release and are not listed in the **"Intended Trait(s)"** section of a construct as a result.

How you enter this information into the genotypes section of the application depends on the insertion of the genetic material. These differences are described in additional detail below.

Genotype Category (required). Select from the following categories:

- "Empty Transformation Vector"
- "Gene Knock-Out"
- "Gene Silencer"
- "Gene(s) of Interest"
- "RNA Interference (RNAi)"
- "Screenable Marker"
- "Selectable Marker"
- "Virus Genome"
- "Wild Type"
- "Recombination Site"
- "Other"

You can select one or more of the listed genotype categories provided to enter construct component information into. If endogenous sequences are altered in your modified organism, select **"Gene Knock-Out**", **"Gene Silencer"**, or "**Gene(s) of Interest"** from the list of Genotype Categories, as appropriate. APHIS uses this information to broadly characterize each genotype category and help understand the relationship between it and the intended trait(s).

Construct Component (required). You must select one of the listed Construct Components provided or type in a Construct Component. If you wish to type in a Construct Component, select **"—None—"** from the drop-down menu and enter text into the **"*Construct Component if Not Listed"** field. If you are entering a new expression cassette as a genotype, enter the first component of the expression cassette (5'-to-3'). Later you will add additional components under the created genotype. If endogenous sequences are altered in your modified organism, select the appropriate Construct Component where the alteration occurred (e.g., if the alteration is an insertion into a gene, select *Gene*). The following component types are available in the drop-down:

- "3' UTR"
- "5' UTR"
- "Enhancer"
- "Epitope Tag"
- "Exon"
- "Flanking Element"
- "Gene"
- "Intron"
- "Leader Sequence"
- "Promoter"
- "Recognition Sequence"
- "Signal Sequence"
- "Spacer"
- "Targeting Sequence"
- "Terminator"
- "Transit Peptide"
- "Vector Sequence"

APHIS uses this information together with the construct component description to understand how a construct component contributes to the intended trait(s) and to inform the permit's SPCs.

Construct Component Name (required). Provide a one-to-three-word name based on the component (e.g., 35S promoter, catalase, extensin, PAT). If entering an acronym or unique name or code, consider including the full component name (i.e., full gene name) in the **Construct Component Description** field. APHIS uses this information to communicate with applicants about genetic elements when necessary.

Donor (required). Provide the scientific name (genus and species) of the organism from which the construct component was first described or obtained.

- For viruses, do not use abbreviations; spell out the name (e.g., *Cauliflower mosaic virus*, not *CaMV*).
- For a fusion or chimeric component (e.g., a hybrid gene formed from two or more genes), you should list all donor organisms corresponding to each fusion partner with a comma separating the individual donors.
- Whether cloned or synthesized, most construct components are derived from sequences originally found in a donor organism. If the original sequence has been altered, you should list the original donor organism then describe the nature of the modifications briefly in the **"Construct Component Description"** field.
- For synthetic sequences that could be considered truly artificial (e.g., linkers, spacers, and tags) and do not share significant sequence homology to an organismal source of sequences, list Synthetic as the donor.

APHIS uses this information to determine whether there may be additional regulatory obligations regarding the inserted sequence and contribute to the understanding of the function of a component. Please note that depending on the donor organism listed, a permit from another APHIS program (e.g., Division of Agricultural Select Agents and Toxins (DASAT) or Veterinary Services (VS)) may be needed.

In accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, you must indicate the donor name and indicate that the donor organism is a select agent if any of the donor organisms are on the select agent list or produce one of the toxins on the select agent and toxin list.

Construct Component Description (required). Provide a short statement (generally a phrase or sentence) describing the function of the construct component. For lesser-known components, you can optionally provide literature references to clarify the function of the component. Avoid the use of internal codes not referenced in publicly available sources in this field. APHIS uses this information to understand how a construct component contributes to the intended trait(s) and to inform the permit's SPCs.

Previously Submitted Constructs (PSCs) Section
A PSC may be added in addition to or in lieu of a new construct. A PSC is any construct listed on a previously submitted BRS application. There are several criteria that must be satisfied to add PSCs:

- The organism a PSC is associated with must be listed on the current application.
- The team sharing account of the PSC and current application must be the same.
- The CBI status of the PSC and the current application must be the same.

A PSC cannot be edited once added to an application. If a PSC requires revision, you must clone and save it (creating a new construct) using the identical name as the PSC. This will trigger PSC versioning, which effectively allows the most current version of a construct to be added as a PSC to future applications.

LOCATIONS CHEVRON

You may add four types of locations to a BRS application. These location types are detailed below:

- **"Origin"** location. This represents where regulated material is shipped from.
- **"Destination"** location. This represents where regulated material is received.
- **"Origin & Destination"** location. This represents a single location where regulated material is both shipped from and received.
- **"Release"** location. This represents a non-contained location where modified organisms are released into the environment.

You may submit up to 250 locations in an application. The number and type of locations required is dependent on the movement type listed on an application:

- Import applications must contain at least one **"Origin"** and one **"Destination"** location.

- Interstate Movement applications must contain at least one **"Origin"** location and one **"Destination"** location. An **"Origin & Destination"** location may substitute for either or both location requirements.
- Release applications must contain at least one **"Release"** location.
- Interstate Movement and Release applications must contain at least one **"Origin"**, one **"Destination"**, and one Release location type. An **"Origin & Destination"** location may substitute for either or both location requirements.

Location information fields are dependent on the location type . However, there are common information fields shared between location types. The text below provides more detail about these information fields and follows the structure used in APHIS eFile when you select the "Add Location" button. This will allow you to follow along as you work through the Location section.

Location Section (Origin, Destination, Origin & Destination, and Release Location Types)

These fields are common across all location types: **Location Name (required)**, **Street Address 1 (required)**, **Street Address 2 (optional)**, **Street Address 3 (optional)**, **Street Address 4 (optional)**, **City (required)**, **Country (required)**, **State/Province (required)**, **County (required)**, **Zip (required)**, and **Location Description (optional)**.

APHIS uses this information to identify locations and verify the address of a location if an inspection is required. APHIS also uses the County and State information to verify the provided GPS coordinates for each Release location and inform the permit's SPCs.

Previously Inspected by APHIS (required). This field is unique to **"Destination"** and **"Origin & Destination"** location types. Use this field to indicate a previous APHIS inspection of this location. If the response to this question is **"Yes"**, provide the APHIS facility number in the **Location Description (optional)** field to help APHIS verify the applicability of the inspection to the listed modified organism and activity detailed in the application.

APHIS uses this information to determine if the location is a contained facility, inform the permit's SPCs, and determine if a site inspection is necessary prior to issuing a permit.

Location Unique ID (required). This field is unique to the **"Release"** location type. Use only alphanumeric characters in this field. A location unique ID must be unique within each application. APHIS uses this information to assist in identifying release locations in both the application and any required self-report identified in the SPCs.

Materials Section (Destination and Origin & Destination location types)

Quantity (required), **Material Type (required)**, and **Unit of Measure (required)**. These fields are unique to **"Destination"** and **"Origin & Destination"** location types. The quantity entered in this field should represent the total (cumulative) amount of material you plan to ship over the lifetime of the permit for each location. For example, if you list 50 pounds of seed in this field, you could ship 10 pounds of seed 5 times, or 50 pounds of seed 1 time. If your plans change and you need to move a larger quantity of

material, you must submit a permit amendment and receive authorization for the larger quantity before moving it. APHIS uses the information provided to inform the permit's SPCs.

Release Details Section (Release location type)

The following fields are unique to **"Release"** location types:

Number of Proposed Releases (required). The Number of Proposed Releases indicates how many times you anticipate releasing your modified organism into the environment within the permit's duration.

- For multiple plantings, enter the number of plantings that will occur at a location. This is the number of times the listed **Number of Acres** (or the actual acreage, if your planted acreage is less than the value listed in that field) is planted while the permit is valid. For example, if the **Number of Acres** is one acre and the full acre is harvested and subsequently replanted with a regulated article(s) in the permit, the number of proposed plantings is two. If the one acre is planted over several weeks and a total of one acre is harvested with no subsequent replanting, the number of proposed plantings is one.
- One release may span several days. However, if there is a gap of more than 30 days when no releases take place, the next release date will constitute the beginning of a new release. In this scenario, the number of proposed releases is greater than 1.
- You may propose a greater number of plantings/releases than will be released to cover unexpected release needs. Please note that certain reporting requirements apply to authorized releases that are not released.

APHIS uses the provided information to inform the permit's SPCs related to confining the modified organism during its release into the environment. Additionally, APHIS uses this information in its National Environmental Policy Act (NEPA) analysis to determine if there is any significant impact on the human environment from the release of the modified organism.

Number of Acres (required). This field represents the maximum proposed quantity in acres for a single release at this Location.

- For a single planting/release, enter the maximum proposed quantity in acres that will be in the ground at any given time. For multiple plantings/releases, enter the acreage for the largest planting/release at the location (not the sum of acreage for all plantings/releases at the location).
- For non-plant organisms (e.g., microbes and arthropods), indicate the largest area of release.
- If the release is something other than plantings in the ground (e.g., plants in pots), you should indicate the number of the plants in the **"Location Description"** field and provide the number of acres the pots will occupy in this field.

APHIS uses the provided information to inform the permit's SPCs related to confining the modified organism during its release into the environment. Additionally, APHIS uses this information in its NEPA analysis to determine if there is any significant impact on the human environment resulting from the release of the modified organism.

Is Location within Critical Habitat (required). Use this field to indicate if the proposed release location is within Critical Habitat for Threatened and Endangered Species.

APHIS uses the information provided to inform the permit's SPCs related to confining the modified organism during its release into environment. APHIS also uses this information in its Threatened and Endangered Species analysis to determine if there is any significant impact on the human environment resulting from the release of the modified organism and associated activities.

Site Specific Information Section (Release location type)

Release Site History (required). This field is only present on **"Release"** location types. Use this field to describe the land use history of the release location and its adjacent areas. Indicate if the land has been in agricultural production. Specify the type of agricultural activity (e.g., cropping, pasture, orchard, managed forest). Describe the areas around the location. For example, is this an agricultural research farm surrounded by other agricultural research or production; are there sexually compatible species in the surrounding area; is this area used for breeding studies of the same species that is in the application?

APHIS uses the information provided to inform the permit's SPCs related to confining the modified organism during its release into the environment. APHIS also uses this information in its NEPA analysis of the activity detailed in the application to determine if there is any potential for significant impact on the human environment (e.g., from converting forested land to cultivated land) resulting from the release of the modified organism.

GPS Coordinates Detail Section (Release location type)

This section is unique to **"Release"** location types. Click the "Add GPS Coordinates" button to open the Add GPS Coordinates popup window, then enter your GPS coordinates.

Latitude (required) and **Longitude (required)**. Enter GPS coordinate pairs here. When mapped in geolocation software, this information identifies the Release location and the area to be monitored (includes the area monitored for isolation distance) (see Figures 1 and 2). You must enter GPS coordinates in decimal degrees and provide at least four and no more than six coordinate pairs. Ensure at least one coordinate pair represents the NW corner of the field. If you are uncertain about the specific location where the release will occur, ensure that the area identified by the provided GPS coordinates contains the likely release site.

APHIS uses this information to help verify other information provided about the Release location, including **State/Province (required)**, **County (required)**, **Location Description (optional), and Release Site History (required)**. APHIS also uses this information to inform SPCs and in its Threatened and Endangered Species and NEPA analysis determine if there is any significant impact on the human environment resulting from the release of the modified organism.

Figure 1. Use GPS coordinates to identify the Release location. You can submit coordinate pairs for a larger area than the Number of Acres you propose to plant to encompass the isolation distance to be monitored.

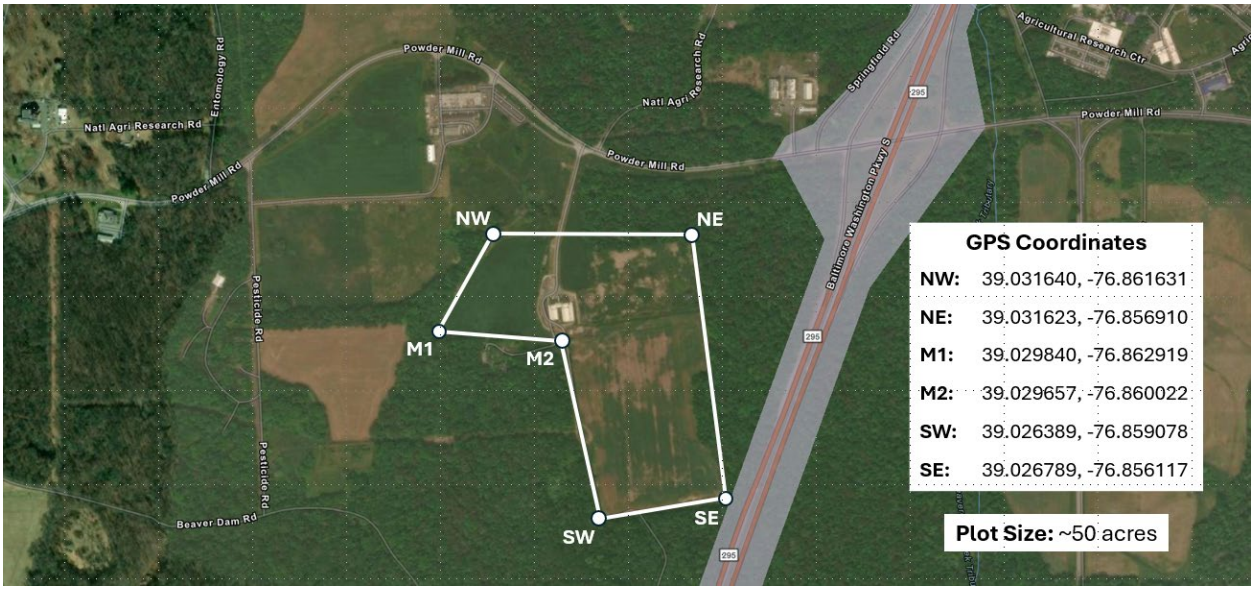

Figure 2. Use GPS coordinates to identify the boundaries of a Release location. You can enter up to six coordinates pairs to delineate boundaries and limit the release location to agricultural land. NW: northwest. NE: northeast. SW: southwest. SE: southeast. M1, M2: middle 1, middle 2.

Agents Section (Origin, Destination, Origin & Destination, and Release location types)

These fields are common across all location types:

- Primary Contact (optional)
- First Name (required), Last Name (required)
- Title (required)
- Organization (optional)
- Address (optional), City (optional), Zip (optional)
- Day Phone (required), Alternate Phone (optional), Fax (optional)
- Email (required), and Alternate Email (optional)

APHIS uses this information to identify individuals responsible for carrying out permit conditions to prevent the unauthorized release, spread, dispersal and/or persistence in the environment during the importation, interstate movement, or environmental release of the modified organism. APHIS may also use the information to identify a location-specific contact in the event of an inspection.

SOPS & ATTACHMENTS

Standard Operating Procedures (SOP)

APHIS eFile will not accept an application unless at least one document with the attachment type **"SOP"** is uploaded to the SOPs & Attachments section. In your SOP, describe how you and/or your agents will contain the modified organism during movement and at the points of origin and destination, including intermediate destinations, and confine it during an environmental release to prevent the unauthorized release, spread, dispersal and/or persistence in the environment. For import and interstate movement permits, you should provide information that is sufficient for APHIS to determine that the shipment procedure aligns with the requirements in 7 CFR part 340, or an approved variance (see Appendix E), and that any laboratory and greenhouse research will occur in containment facilities that can prevent any accidental escape of the modified organism. For release applications, you should provide information that is sufficient for APHIS to determine that the protocols are adequate for confinement based on the biology of the modified organism, its proximity to sexually compatible species, and the genotype and phenotype resulting from the modification (the intended trait).

Attachments

You may attach other documents to assist in reviewing your application. These are known as the attachment type **"Attachment"**. For example:

- Files concisely listing all intermediate locations and their addresses **(required if there are intermediate locations)**. Intermediate locations are contained facilities where regulated material may be found that are not otherwise listed in the locations section of a permit. Examples include: containment laboratories in close proximity to a destination location where the material is grown or tested after receiving at the destination or buildings where harvested material is stored after a confined release.
- Files expanding on the containment and/or confinement procedures detailed within the SOP, such as photographs of facilities and containers.
- Construct supporting files, such as vector maps, peer-reviewed literature, etc.

REVIEW & SUBMIT CHEVRON

In the Review & Submit chevron, make a final review before submitting your application. Any absent information for required fields will be noted toward the top of the page; review your application details and correct/add details based upon the instructions provided. Once you have reviewed all details, certify that the information is complete and accurate to the best of your knowledge in the Confirm Information & Submit section at the bottom of the page and then use the Continue button to proceed to the Application Detail page.

CERTIFY AND SUBMIT AN APPLICATION

You must certify and submit your permit application on the Application Detail page for APHIS to begin its review. Once you have successfully submitted your application, you will be able to see the application PDF under the Notes and Attachments section of the Application Details page (This may take several minutes to an hour to generate, depending on the size of your application.)

SUBMISSION OF "LINKED" PERMIT APPLICATIONS

APHIS considers applications submitted at the same time and containing the same constructs and/or locations for a given modified organism and activities to be linked permits. To facilitate communication between multiple biological scientists reviewing linked permits and the responsible person, APHIS requests that the responsible persons submitting linked permits send an email to BRSPermits@usda.gov to advise APHIS of the submission of linked applications. In this email, please include the authorization or application number of the linked applications and include a list of information that is identical within the linked applications (e.g., all location information is identical in these linked permits).

APHIS ACTIONS UPON RECEIPT OF A PERMIT APPLICATION

If an application includes all required information noted above, APHIS will generally issue or deny a permit for importation or interstate movement within 60 days, and a permit for environmental release only or interstate movement and environmental release within 120 days.

If APHIS finds that an application is missing required information, APHIS will advise the responsible person of the missing required information within 30 days for environmental release permits or 15 days for importation or interstate movement permits.

In some cases, the preparation of National Environmental Policy Act (NEPA) documents (e.g., Environmental Assessment (EA) or Environmental Impact Statement (EIS)) will extend the review and processing period.

Once APHIS completes its technical review, appropriate environmental analysis, and assigns permit conditions, APHIS submits a CBI-deleted draft permit along with permit conditions to State or

Tribal regulatory officials, as appropriate, to afford them an opportunity to review and comment on the proposed activities that you specified in the draft permit.

APHIS NEPA DETERMINATION (EA OR EIS)

APHIS' National Environmental Policy Act (NEPA) implementing procedures (7 CFR part 372) establish categorical exclusions for certain types of activities. A NEPA Categorical Exclusion applies to a class of actions that APHIS has determined do not individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an Environmental Assessment (EA) nor an Environmental Impact Statement (EIS) is normally required. APHIS has established a categorical exclusion for permitting for confined field releases of organisms or products developed using genetic engineering, unless an exception applies. An exception may apply, and an EA or EIS may be required, when a confined field release of modified organisms or products involves new species or organism or novel genetic modifications that raise new issues. 7 CFR § 372.5(d)(3).

If APHIS prepares an EA or an EIS prior to issuing a permit, APHIS may request additional information from the responsible person. The information would typically consist of data relating to potential effects on non-target organisms, humans, wildlife, and the environment from exposure resulting from the introduction. If you are working with a new species or organism or a novel modification that may raise new issues, please consult with us as soon as possible so we can discuss the timeline for preparing relevant environmental documents.

SELECT AGENTS

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188; June 12, 2002) requires that the United States improve its ability to prevent, prepare for, and respond to acts of bioterrorism and other public health emergencies that could threaten either public health and safety or American Agriculture. Individuals possessing, using, or transferring agents or toxins deemed a severe threat to public, animal or plant health, or to animal or plant products must notify either the Secretary of the Department of Health and Human Services (42 CFR part 73) or the Secretary of the Department of Agriculture (9 CFR part 121).

A current list of select agents and toxins which the HHS and USDA consider select agents can be viewed at https://www.selectagents.gov/sat/list.htm.

Additional information regarding the Federal Select Agent Program can be found in Executive Order 13546 and at CFR websites mentioned above.

PERMIT CONDITIONS AND PERMIT ISSUANCE

APHIS will assign standard conditions according to the regulations and SPCs that are tailored to the permit. APHIS will send you draft permit conditions in APHIS eFile for your review and response. You may agree or disagree with the text of each permit condition.

If a permit is issued, you will be notified by email. The permit's duration will be listed on the permit itself. A permit is valid from the "Effective" date through the "Expires" date listed on the permit. The

"Issued" date is the date that APHIS issues the permit. All authorized activities associated with the introduction, excluding post-harvest volunteer monitoring, must be carried out after the "Effective" and before the "Expiration" dates listed on the permit.

DELETE OR WITHDRAW AN APPLICATION

You can only delete applications that have not been submitted. When you delete an application, all the data from the application will be deleted.

You can only withdraw submitted applications. That is, you can withdraw permit applications any time after submitting but before a permit is issued.

ADMINISTRATOR WITHDRAWAL OR DENIAL OF A PERMIT

A permit which has been issued may be withdrawn by an inspector or the Administrator if he/she determines that the holder thereof has not complied with one or more of the conditions listed on the permit. Failure to allow the inspection of the premises shall be grounds for the denial of the future permit applications.

If the permit application is denied, APHIS will inform the applicant the reasons for the denial and give the applicant the opportunity to appeal the denial. Any person whose permit has been withdrawn or any person who has been denied a permit may appeal the decision in writing to the Administrator within ten (10) days after receiving the written permit of the withdrawal or denial. The appeal shall state all the facts and reasons upon which the person relies to show that the permit was wrongfully withdrawn or denied. The Administrator shall grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow.

CHANGES TO AN ACTIVE PERMIT (AFTER ISSUANCE)

CHANGE THE RESPONSIBLE PERSON FOR A PERMIT

In the event the responsible person has changed, submit the revised information to APHIS in writing by email at BRSpermits@usda.gov. Please ensure the individual assuming the role of the responsible person has registered in APHIS eFile before sending your request. APHIS BRS may reach out to original and new responsible persons to confirm account setup and visibility of records.

To change the responsible person, please submit a request on an organization letterhead. Your request should include the following information:

- Authorization number(s)
- Current Responsible Person Name

- Current Responsible Person Username (login.gov User ID) – if available, for verification purposes
  Requested New Responsible Person Username (login.gov User ID)
- Requested New Responsible Person Name: First, Middle (if any), Last
- Requested New Responsible Person Email
- Requested New Responsible Person Phone Number(s)
- Organization Name

AMENDMENTS

If, after permit issuance, you need to make a change, you can submit a permit amendment. Commonly requested amendments include:

- Adding constructs or lines/strains/events
- Adding environmental release sites
- Changing disposal methods
- Adding or modifying SOPs
- Adding containment facilities
- Increasing the size of shipments
- Increasing the acreage for release sites

Amendments may not be used to:

- Change the responsible person (or transfer ownership)
- Change the expiration dates of the permit
- Add new recipient species
- Add new plantings/releases that extend the permit beyond the expiration date
- Remove a release location or construct[3]

When applying for an amendment, clearly describe the proposed changes in the **Amendment Description** field of the application. This field only appears in amendment applications within the Related Activity section of the Activity Detail chevron. Although processing a request to amend a permit is generally faster than processing a new application, processing times may vary based on the complexity of the change and volume of pending applications. You may only submit an amended permit request using APHIS eFile web interface. We do not accept amended permit applications via XML upload.

[3] There is no need to remove this information from an approved permit. If a location or construct will not be used, that information will be reflected in the planting reports.

VERSION HISTORY

February 12, 2025	Updated to align with the original biotechnology regulations (CFR part 340) in place prior to May 2020, due to court vacatur of the modernized regulations on December 2, 2024
September 10, 2024	Full updates to align with USDA's Modernized Biotechnology Regulations (7 CFR part 340—Movement of Organisms Modified or Produced Through Genetic Engineering) and the APHIS eFile portal for submitting permit applications
February 7, 2020	Made initial changes to reflect implementation of USDA's Modernized Biotechnology Regulations (7 CFR part 340—Movement of Organisms Modified or Produced Through Genetic Engineering); version unpublished
March 8, 2017	Fix broken hyperlinks
May 30, 2012	Permits Guidance, Appendices and Sample Permits were combined into a single document
March 7, 2012	Combines and updates previous guidance documents
December 7, 2011	"USDA-APHIS BRS User's Guide Permit, Appendix - Pharmaceutical, Industrial and Phytoremediation Permits" supersedes "Guidance for APHIS Permits for Field Testing or Movement of Organisms Intended for Pharmaceutical or Industrial Use" Version July 9, 2008
July 9, 2008	Guidance for APHIS Permits for Field Testing or Movement of Organisms Intended for Pharmaceutical or Industrial Use
1992	Section III. Sample Application for Release into the Environment

APPENDIX A - ADDITIONAL RESOURCES RELATED TO THE PERMITTING PROCESS

Visit this FAQ page to learn more about Login.gov and see our APHIS eFile First Time User Guide for assistance with registering in APHIS eFile.

APHIS offers several other resources related to the Permitting process; links to individual resources are provide below. Links to these resources can also be found at our webpages for Biotechnology Permits or APHIS eFile Permitting Resources and Training.

See the following resources for more information on using the BRS Permitting Assistant:
- BRS Permitting Assistant User Guide
- Quick Reference for Using the BRSPA

For resources that focus on the technical aspects of APHIS eFile navigation and use, please refer to the following documents:
- APHIS 2000 Permit Application and Compliance Reporting Job Aid
- BRS Applicant Training Slides and Videos
- Guide to Submitting Data for Reports and Notices in APHIS eFile

For resources that expand on the data requirements in BRS permit applications, notices, and reports, please refer to the following documents:
- APHIS Recommendations for Best Management Practices for Authorized Field Trials of Regulated Herbicide-Resistant Crops
- BRS User's Guide: General Document Preparation Guidelines for Submission to BRS
- Guidance for Submitting Confidential Business Information (CBI) in Submission to APHIS BRS
- Guide to Submitting Data for Reports and Notices in APHIS eFile
- Guide for Submitting Permit Applications for Microorganisms Developed using Genetic Engineering Under 7 CFR part 340
- SOP Template for Traditional APHIS BRS Permits
- SOP Template for APHIS BRS Modified Microbe Movement Permits
- Suggestions for SOP Submissions for Traditional APHIS BRS Permits
- Q&As on Working with Modified Microorganisms

The following resources can be utilized to access help with various aspects of the permitting process:
The APHIS eFile help wizard is a self-service application where users can find answers to common questions and create a ticket for additional assistance. The APHIS eFile help wizard is accessed using the "Get Help" tab on the APHIS eFile portal landing page or directly through the following link: APHIS eFile help Wizard.

Utilize the following email inboxes to get assistance on various aspects of BRS and its permitting process:
- biotechquery@usda.gov for general questions about BRS.
- brspermits@usda.gov for general questions about BRS permitting.
- brscompliance@usda.gov for general questions about permit compliance, including reporting and incidents.
- BRS.eFile@usda.gov for help with APHIS eFile and XML uploading to create BRS applications.

APPENDIX B - DEFINITIONS

Terms used in the singular form in this part shall be construed as the plural, and vice versa, as the case may demand. The following terms, when used in this part, shall be construed, respectively, to mean:

- ***Administrator*.** The Administrator of the Animal and Plant Health Inspection Service (APHIS) or any other employee of APHIS to whom authority has been or may be delegated, to act in the Administrator's stead.
- ***Agent*.** A person who is designated by the responsible person to act in whole or in part on behalf of the permittee to maintain control over an organism under permit during its movement and ensure compliance with all applicable permit conditions and the requirements in 7 CFR part 340. Multiple agents may be associated with a single responsible person or permit. Agents may be, but are not limited to, brokers, farmers, researchers, or site cooperators.
- ***Animal and Plant Health Inspection Service (APHIS).*** An agency of the United States Department of Agriculture (USDA).
- ***Courtesy permit*.** A written permit issued by the Administrator, in accordance with § 340.4(h).
- ***Donor organism*.** The organism from which genetic material is obtained for transfer to the recipient organism.
- ***Environment*.** All land, air, and water; and all living organisms in association with land, air, and water.
- ***Expression vector***. A cloning vector designed so that a coding sequence inserted at a particular site will be transcribed and translated into protein.
- ***Genetic engineering*.** The genetic modification of the organisms by the recombinant DNA techniques.
- ***Inspector*.** Any employee of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or other person, authorized by the Administrator, in accordance with law to enforce the provisions of this part.
- ***Interstate*.** Trade, traffic, or other commerce (A) between a place in a State and a point in another State, or between points within the same State but through any place outside that State; or (B) within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.[4] From any State in to 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)*.** (A)To carry, enter, import, mail, ship, or transport; (B) to aid, abet, cause, or induce the carrying, entering, importing mailing shipping, or transporting; (C) to offer to carry, enter, import, mail, ship, or transport; (E) to release into carry, enter, import, mail, ship, or transport; (E) to release into the environment; or (F) to allow any of the activities described in a preceding subparagraph.[5]
- ***Organism*.** Any active, infective, or dormant stage of life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-

[4] This definition is from the Plant Protection Act; the definition 7 CFR part 340, which predates enactment of and is superseded by the PPA definition, is "from any State in to or through any other State."
[5] This definition is from the Plant Protection Act; the definition 7 CFR part 340, which predates enactment of and is superseded by the PPA definition, is "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."

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, association, joint venture or other legal entity.[6]
- ***Plant.*** *Any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture*, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a root, and a seed.[7]
- ***Plant pest*.** Any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: (A) A protozoan. (B) A nonhuman animal. (C) A parasitic plant. (D) A bacterium. (E) A fungus. (F) A virus or viroid. (G) An infectious agent or other pathogen. (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.[8]
- ***Product*.** Anything made by or from, or derived 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

[6] This definition is from the Plant Protection Act; the definition 7 CFR part 340, which predates enactment of and is superseded by the PPA definition, is "any individual, partnership, corporation, company, society, association, or other organized group." 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."

[7] This definition is from the Plant Protection Act; the definition 7 CFR part 340, which predates enactment of and is superseded by the PPA definition, is "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."

[8] This definition is from the Plant Protection Act; the definition 7 CFR part 340, which predates enactment of and is superseded by the PPA definition, is "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."

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.

- ***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 of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territories or possessions 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.

APPENDIX C - PERMITTING EXEMPTIONS

Certain regulated articles are exempt from the requirement for authorization for **interstate movement only** (not applicable to importations or release) provided they qualify by meeting **all** of the criteria provided by § 340.2(b) and are shipped according to § 340.8. The criteria of § 340.2(b) is detailed below:

(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
      (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. § 340.2(b).

APPENDIX D - PHARMACEUTICAL, INDUSTRIAL, AND PHYTOREMEDIATION PERMITS

In 2003 (68 FR 11337-11340), APHIS modified its permit confinement measures and procedures to verify compliance and to enhance the transparency of permits intended for pharmaceutical and industrial (PMPI) use to include:

- a larger perimeter fallow zone (50 ft);
- cleaning of field equipment and storage facilities using APHIS-approved procedures;
- dedicated planting and harvesting equipment and storage facilities;
- planting restrictions in the subsequent growing season;
- APHIS approved training; and
- additional compliance and inspection oversight by APHIS.

This appendix provides guidance on the additional information requirements for PMPI permits including guidance for preparing PMPI SOPs. This appendix also provides information on the additional supplemental permit conditions, inspections and reporting requirements for PMPI permits.

ADDITIONAL INFORMATION REQUIREMENTS

Permit applications for pharmaceutical or industrial products include additional information requirements:

- Provide a one to two-page description of the gene product and its current or potential use.
- If the gene leads to a product intended for an industrial or other non-food/feed use, indicate if it is the gene product or a down-stream product.
- If the gene product is for therapeutic use (e.g., an antibody or vaccine), provide the type of antibody (IgG, IgM, etc.), the epitope or antigen, and the disease and target component of the immune system.
- Indicate if the gene product is new to the plant or is commonly found in plants used for food or feed.
- Provide an assessment of gene sequence homology to known toxicants or proteins known to or likely to harm non-target organisms.
- Indicate if the cloning procedure has altered the amino acid sequence of the protein and indicate if this change is expected to change the biological properties of the protein.
- Compare the properties of the engineered protein/enzyme with the native molecule.
- Compare levels produced in the modified plant with those of known, naturally occurring toxic compounds and address possible non-target exposure routes (groundwater, foraging animals, pollen dispersal, etc.).
- Address whether the engineered protein is expected to affect worker safety or to have effects (dermal, inhalation, toxicity, etc.) on non-target invertebrates (earthworms, bees, etc.) and vertebrates (birds, rabbits, rodents, etc.).
- Indicate whether engineering has or is likely to affect biological properties related to confinement measures (e.g., dormancy, pollen viability, etc.).
- Indicate where the product is in the regulatory review process with other agencies.

Permit applications for phytoremediation products include additional information requirements:

- Data or references to show whether the engineering has altered, or would be expected to alter, the levels of any naturally occurring toxicant in the plant or the accumulation or the release of toxic compounds recovered during phytoremediation.
- Would any compounds that accumulate or result from breakdown be expected to affect worker safety or to have toxic effects on non-target organisms: invertebrates (earthworms, bees, etc.) and vertebrates (birds, rabbits, rodents, etc.).
- Indicate whether engineering has or is likely to affect biological properties related to confinement measures like seed dormancy, pollen viability, etc.
- Indicate where the product is in the regulatory review process with other agencies.

CONFINEMENT MEASURES

APHIS requires greater confinement measures for pharmaceutical and industrial corn.

PERIMETER FALLOW ZONE

To prevent regulated plants from inadvertently commingling with plants to be used for food or feed, you must maintain a perimeter fallow zone of at least 50 feet around the release site in which no crops are grown to be harvested or used for food or feed. You may grow plants in the 50-foot fallow zone if they are not used for food or feed.

SOPS AND CLEANING OF FIELD EQUIPMENT AND SEED CLEANING AND DRYING EQUIPMENT

Submit Standard Operating Procedures (SOPs) that describe how a particular task or operation will be carried out. Processes described in the SOPs should be followed for the duration of the permit and post-harvest monitoring period. SOPs must be dated or have a version number. APHIS must review and approve SOPs for equipment cleaning prior to use.

Provide the following information in the SOPs for Cleaning of Field Equipment and Seed Cleaning and Drying Equipment:

- Methods for cleaning equipment used for planting/inoculation and harvesting, as well as other field equipment (e.g., tractors and tillage attachments, such as disks, plows, harrows, subsoilers) used from the time of planting/inoculation through the post-harvest monitoring period.
- Indicate where cleaning will take place. Field equipment cleaning should be carried out in the release site, fallow zone, building or other regulated area designated in the permit or SOPs.
- Describe how you will clean equipment used to transport seeds or harvested material after transportation.

SOPS AND RESTRICTIONS FOR DEDICATED PLANTING AND HARVESTING EQUIPMENT

To prevent the modified organism from being inadvertently removed from the site, planting and harvesting equipment must be dedicated for use in the permitted environmental release site(s) from the time of planting through the end of harvesting. After use in the pharmaceutical or industrial release(s) is

complete, dedicated planters and harvesters must be thoroughly cleaned and inspected by APHIS before being returned to general use.

After harvest, the permittee will not be required to obtain APHIS authorization to use this equipment on APHIS permitted sites (same sites or different sites) planted with the same regulated crop, with the target protein(s) authorized under this permit, in subsequent growing seasons. A harvester does not have to be dedicated for the season as long as the pharma releases are harvested last, and the harvester is then inspected by APHIS before being returned to general use.

APHIS must provide permission before planting and harvesting equipment can be used on any sites planted to crops not included in your permit. The permittee must submit a notice to APHIS at least 21 calendar days in advance of cleaning this equipment so that APHIS can complete an inspection to ensure that the equipment has been cleaned appropriately. This is done by submitting a Cleaning Notice (Return to General Use Notice) through APHIS eFile, email (BRScompliance@usda.gov), or mail.
In addition to the information required for Cleaning of Field Equipment and Seed Cleaning and Drying Equipment SOPs, provide the following information in the SOPs for dedicated equipment (i.e., planters and harvesters):

- If the equipment is moved between release sites, provide the method(s) used to prevent the release of the modified organism (e.g., seed) between release sites.
- Provide the make, model and Vehicle Identification Number (VIN), serial number or any other way to uniquely identify the dedicated field equipment. SOPs should be applicable to the specific make and model of the equipment.
- Indicate the final disposition of material recovered during cleaning operations. Viable plant material should be destroyed or handled appropriately to maintain containment. Non-viable material may be disposed of through appropriate waste disposal methods, depending on the constructs and where in the plant the protein is expressed.
- This equipment must be posted as restricted to authorized personnel only. When not in use, it needs to be locked or secured to prevent use by unauthorized personnel or all dedicated equipment must be labeled indicating for NON-FOOD/ NON-FEED USE ONLY.

DEDICATED STORAGE FACILITIES FOR EQUIPMENT AND MODIFIED ORGANISMS

Dedicated facilities for the storage of equipment and modified organisms (locked or secured buildings, bins, or areas) must be posted as restricted to authorized personnel only and used for storage of dedicated equipment and modified organisms. All dedicated storage facilities must be labeled indicating for NON-FOOD/ NON-FEED USE ONLY.

Before returning these facilities to general use, they must be cleaned in accordance with procedures that APHIS reviews and approves. The permittee must submit a notice to APHIS at least 21 calendar days in advance to allow for APHIS to complete an inspection to ensure that the facilities have been cleaned appropriately. APHIS must grant permission before facilities are returned to general use. This is done by submitting a Cleaning Notice (Return to General Use Notice) through APHIS eFile, email, Fax or mail.

POST HARVEST LAND USE RESTRICTIONS

Production of food and feed crops at the release site and the perimeter fallow zone is restricted during one or more growing seasons following harvest or termination of the release to ensure volunteer plants are adequately monitored for and controlled to prevent mixing with other commodities and persistence in the environment. The same release site may be used in subsequent years for pharmaceutical or for industrial use under permit. You must obtain approval from APHIS prior to planting any food or feed crop at the release site and perimeter fallow zone during the post-harvest monitoring period. Please note APHIS will not grant permission where there is a reasonable potential for the modified organism to become mixed with the proposed food or feed crop during harvesting.

PERSONNEL TRAINING PROGRAM

Permittees are required to carry out an APHIS approved training program to ensure personnel follow the confinement procedures put forth in the permit and SOPs and comply with all Permit Conditions. All personnel should be trained or work directly under the supervision of someone who has been trained. The training should include instruction pertaining to the duties for which they are responsible. Records of who was trained, for what activity, and when they were trained must be maintained and be made available upon request at the time of inspection.

If a training program has been approved with a previous permit, you must resubmit the training materials that will be used for each permit. If any changes have been made to previously approved training materials, please note this in the new application.

The training program must be submitted with the permit application and should cover all aspects related to the permitted activities and conditions at all the intermediate and final destinations listed in the permit application. For example, these may include, but not be limited to the following:

- The regulations at 7 CFR part 340 for release, interstate movement, and importation as applicable to the permittee's activities:
  - Plant Protection Act, which addresses the consequences of noncompliance (7 U.S.C. 7734 (Sec. 424))
  - FR Notice (68 FR 11337-11340) on Field Testing of plants Engineered to Produce Pharmaceutical and Industrial Compounds
- The training should include all aspects related to permit activities, including those described in the permit, the standard permit conditions, the supplemental permit conditions and the SOPs.
- The training should include methods for inspecting, monitoring, and recording activities that are undertaken to meet the conditions of the permit. For example, this could include monitoring or reporting forms, seed inventory and transport forms, or witness verification that critical procedures were performed according to SOPs and/or permit conditions.
- The training program should be applicable to all personnel who handle, store, perform field activities with, or transport modified organisms, or who are responsible for regulatory affairs, or those who manage these activities.
- Personnel should know who has authorized access to the release site and other restricted areas. Persons having access should receive training that addresses site security and how to prevent unauthorized access to modified organisms.

- Personnel should be made aware of reporting requirements for accidental or unauthorized releases and appropriate remedial measures to address spills or loss of containment of modified organisms.

COMPLIANCE AND INSPECTIONS

To ensure compliance with regulations and permit conditions, APHIS' policy for pharmaceutical and industrial releases is to conduct inspections at critical control points in the production cycle of the regulated article.

- BRS will inspect each release site.
- For new applicants or organizations with no history of performing field trials with these types of traits, or organizations with compliance issues identified in the past two years, BRS will conduct at least four in-person inspections (after planting, during flowering, at harvest, post-harvest and/or VM inspection).
- For applicants or organizations with a proven track record (2+ years) of successfully performing field trials involving these types of traits with no noncompliance cited in the past two years, BRS will conduct three inspections (after planting or during flowering, during or shortly after harvest, and one VM inspection).
- BRS will conduct Return to General Use (RTGU) inspections for equipment and facilities, as needed.

REPORTS AND NOTICES

Additional Reports and Notices are required for permits designed for pharmaceutical and industrial intent. A report is the submission of required information; a notice is the alert of some action to occur in the near future. For information on what reports must be submitted, when, where, and how to submit the reports, refer to the permit conditions. For information on what to include in these reports and notices and how and when to submit the reports and notices through APHIS eFile, consult the Guide to Submitting Data for Reports and Notices in APHIS eFile located on the Biotechnology Guidance and Resources Page.

APPENDIX E – SAMPLE SUPPLEMENTAL PERMIT CONDITIONS

Supplemental Permit Conditions for Interstate Movement of Plants

1. **Authorized Activities**. You are authorized for **interstate movement** as described in this permit. This permit requires compliance with permit conditions found in 7 CFR part 340 and supplemental permit conditions described below (collectively, "permit conditions").

   This permit is NOT valid for any importation or environmental release.

2. **The Conditions in This Permit Are Controlling**. You must comply with the conditions described in this permit. You should ensure any Standard Operating Procedures (SOP) meets the conditions described in this permit. If an SOP conflicts with or does not address permit conditions, you must follow these permit conditions.

3. **Duration.** This permit is valid for a period of **one (1) year** as identified by the effective and expiration dates of this permit.

4. **Scope of Authorization.** Your permit lists the plant(s) and locations(s) authorized. You are also authorized for contained use of the plant(s) at any intermediate locations described in this permit or associated SOP(s). For ease of reading, the conditions below use the word "plant" to refer to the plant(s) listed in your permit.

5. **The Responsible Person and Designated Agents.** If you designate an agent to act in whole or in part on your behalf, they must maintain control over the regulated material described in this permit during its movement and ensure compliance with all applicable permit conditions and the requirements in 7 CFR part 340. The act, omission, or failure of any agent may also be deemed your act, omission, or failure.

6. **Responsibilities After Permit Expiration.** After the expiration date on this permit, the plant remains regulated and you must continue to prevent unauthorized release, spread, dispersal, and/or persistence in the environment until the plant is devitalized, or APHIS has determined the plant is not a regulated article.

7. **Proposed Changes to an Issued Valid Permit.** To make changes to an issued permit, you must submit a permit amendment. You must contact APHIS Permitting staff via phone (301-851-3886) or email (BRSPermits@usda.gov) and obtain an amended permit before deviating from the issued permit. Changes may include: additional constructs (including any other identifying information, e.g., lines/events) or new locations.

8. **Record Maintenance**. You must maintain records related to the introduction of the regulated article that demonstrate compliance with all permit conditions and that include information related to:

   A. the addresses and any other information necessary to identify all intermediate and final destinations where the regulated material was maintained or used, including the approximate amount and type of regulated material and cultivar or line identification, for each location; and
   B. location and method of final disposition.

9. **Containment in Transit**. You must ensure containment of the regulated material in accordance with the container requirements found in 7 CFR part 340. APHIS also grants a variance to these container requirements provided you ensure your packaging includes redundant layers to prevent loss of regulated material, and, at a minimum, such packaging must include redundant layers to prevent loss of regulated material, and, at a minimum, must include a layer comprised of a solid container (cardboard box, hard plastic tote, etc.) and a layer comprised of secure material (super sac, paper, plastic, or fiber bag, etc.). Both layers must be adequately sealed.

10. **Containment and Storage at Destinations.** The regulated article must only be used at destination locations following containment protocols and in a structure that provides physical confinement constraints that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure, designed to prevent dissemination and establishment of the organism. You must ensure the regulated material is in a locked container or room or in a building or room with access restricted to authorized personnel only.

11. **Devitalization and Disposition.** Upon expiration of the permit, you must render viable regulated material (except any retained for future use) non-viable prior to disposal. You must ensure that waste materials, containers, implements, and equipment that have come in contact with the regulated material are free of the viable regulated material before disposal or use with nonregulated material. Appropriate means of devitalization include, but are not limited to, heat or steam treatment, incineration, or grinding.

12. **Reporting a Possible or Actual Unauthorized Release or Unusual Occurrence.** In the event of a possible or actual Unauthorized Release, you must report the discovery to APHIS Compliance staff via phone (301-851-3935) immediately and via email (BRSCompliance@usda.gov) within 24 hours of discovery. If your call advances to voicemail, you must leave a message describing the discovery. In the event of an unusual occurrence (excessive mortality or unanticipated effects on non-target organisms) or substantially different characteristics of the plant from those listed in this permit, you must report the discovery to APHIS Compliance staff via email (BRSCompliance@usda.gov) within 5 working days of discovery.

    Examples of Unauthorized Releases include but are not limited to: loss of package during interstate movement/importation, dispersal of regulated material due to damaged packaging materials, any damage incurred to the facility where the regulated material is located (e.g., flooding, fire, earthquake damage), and movement of regulated material with an unauthorized construct.

Supplemental Permit Conditions for the Environmental Release of Corn or Soybean:

1. **Authorized Activities**. You are authorized for environmental release as described in this permit. You must comply with permit conditions found in 7 CFR 340 and the supplemental permit conditions described below (collectively, "permit conditions").

   This permit is NOT valid for any importation or interstate movement.

2. **The Conditions in This Permit Are Controlling**. You must comply with the conditions described in this permit. You should ensure any Standard Operating Procedures (SOP) meets the conditions described in this permit. If an SOP conflicts with or does not address permit conditions, you must follow these permit conditions.

3. **Duration**. Your environmental release is authorized for a period of **1 year**, beginning on the effective date and ending on the expiration date indicated on this permit.

4. **Scope of Authorization.** Your permit lists the plant(s) and Release Site(s) authorized for environmental release. You are also authorized for contained use of the plant(s) at any intermediate locations described in this permit or associated SOP(s). For ease of reading, the conditions below use the word "plant" to refer to the plant(s) listed in your permit.

5. **The Responsible Person and Designated Agents**. If you designate an agent to act in whole or in part on your behalf, they must maintain control over the regulated material described in this permit and ensure compliance with all applicable permit conditions and the requirements in 7 CFR part 340. The act, omission, or failure of any agent may also be deemed your act, omission, or failure.

6. **Responsibilities After Permit Expiration**. After the expiration date on this permit, the plant remains regulated and you must continue to prevent unauthorized release, spread, dispersal, and/or persistence in the environment until the plant is devitalized, or APHIS has determined the plant is not a regulated article. Except for plant material you retain for future use, you must render all viable regulated plant material non-viable by appropriate means (such as incineration, steam treatment, grinding) prior to disposal.

7. **Release Confinement**.

   A. **Border Rows**. If planted, border rows must:
      i. fall within the boundary of the GPS coordinates authorized for the Release Site; and
      ii. be treated as regulated since they are part of the environmental release.

   B. **Perimeter Zone**. You must maintain a perimeter zone no less than **10 feet** wide or that is wide enough for equipment clearance, whichever is greater, around each Release Site planted under this permit. You may include your perimeter zone as part of the reproductive isolation zone for a Release Site (as noted below). Perimeter zones must:
      i. be in place from the time of planting through the end of the post-termination volunteer monitoring period;
      ii. fall within the boundary of the GPS coordinates authorized for the Release Site;
      iii. lie outside the boundary of any maintained border rows;
      iv. be treated as regulated since they are part of the environmental release;

v. be fallow or planted with a crop that is sexually incompatible with and morphologically distinct from the regulated plant; and
vi. be managed to:
    a. prevent comingling with nonregulated plants, and
    b. allow the detection and removal of any plants that are sexually compatible with the plant.

C. Reproductive Confinement. You must maintain the regulated plant in a manner that prevents gene flow to nonregulated sexually compatible plants using one or more of the isolation options listed below.

Isolation Options for Corn Releases

Spatial Isolation
Prior to planting, you must establish a 660-foot isolation zone around each Release Site that is free from nonregulated sexually compatible corn. You may include the perimeter zone around the Release Site when establishing your 660-foot isolation zone. To ensure you maintain this 660-foot isolation zone throughout the release period, you must establish and implement a monitoring schedule that is biologically appropriate for your regulated corn to detect and remove any nonregulated sexually compatible plants (including previous season volunteers) from the isolation zone before they reach anthesis/flower.

Physical Isolation
Prior to pollen shed, you must terminate the release or remove or bag all tassels on regulated corn. To ensure you maintain physical isolation, you must establish and implement a monitoring schedule that ensures your method prevents pollen flow for the duration of pollen production.

Temporal Isolation
If you use temporal isolation, you must time the planting to ensure the regulated corn's flowering period does not occur during the flowering period for any nonregulated sexually compatible corn within the 660-foot spatial isolation zone. To ensure you maintain temporal isolation throughout the release, you must establish and implement a monitoring schedule to ensure the regulated corn's pollen shed does not occur during silking of nonregulated sexually compatible corn within 660 feet of the release.

Spatial Isolation for Soybean Releases

Prior to planting, you must establish a 10-foot isolation zone around each Release Site that is free from sexually compatible soybean. The minimum 10-foot perimeter zone (noted above) may serve as the isolation zone around the Release Site. To ensure you maintain this 10-foot isolation zone throughout the release, you must establish and implement a biologically appropriate monitoring schedule to detect and remove any sexually compatible soybean from the isolation zone before they reach anthesis/flower.

8. Equipment Cleaning. You must clean any equipment and tools that come into contact with the plant. Equipment includes transport (e.g., trucks, trailers), field equipment (e.g., chemical

applicators, tractors and attachments such as disks, plows, harrows, subsoilers, planters and combines), and processing equipment.

A. You must clean equipment in a manner that ensures it is free of all viable regulated material prior to use with any nonregulated material;
B. You must clean equipment within an authorized Release Site or clean the equipment in a manner that ensures it is free of any viable material that could dislodge before moving it to another location for additional cleaning;
C. You must dispose of viable regulated material recovered during cleaning in a manner that prevents unauthorized release, spread, dispersal, and/or persistence in the environment (e.g., contained retention at an authorized location or destruction);
D. You must monitor any permeable or outdoor cleaning surfaces and areas for volunteers as described in supplemental permit condition "Post Termination Volunteer Monitoring Requirements."

9. **Record Maintenance.** You must maintain records related to the introduction of the regulated article that demonstrate compliance with all permit conditions and that include information related to:

A. Environmental Release: Your records must indicate the locations of each release (e.g., GPS coordinates, map), dates of activities (including planting and termination), location, and final disposition of all regulated material.
B. Reproductive Confinement*:* Your records must include (1) the confinement method and monitoring frequency used to ensure confinement for each release; (2) if using spatial isolation, the dates you monitored the isolation zone; (3) the estimated number of sexually compatible plants you removed (if any) each time you monitored the isolation zone, and (4) the method you used to devitalize sexually compatible plants found in the isolation zone.

Corn
If you used physical isolation, your records must include the dates you bagged or removed tassels or placed and replaced tassel bags for corn planted at each Release Site.

If you used temporal isolation, your records must document how you monitored the growth stage for the corn and any sexually compatible plants within 660 feet of the release to demonstrate the corn's pollen shed did not occur during silking of any sexually compatible plants within 660 feet.

C. Equipment Cleaning: Your records must demonstrate how you cleaned all equipment used in the release, including cleaning location, cleaning date, whether you recovered any viable material, and disposition of any recovered viable material.
D. Locations: Your records must include the addresses and any other information necessary to identify all intermediate and final destinations where you used or stored regulated material.

10. **Terminating the Environmental Release.** On or before the permit expiration date, at any planted Release Site, you must render the regulated plant nonviable (i.e., not able to germinate, grow, or survive) by appropriate means (e.g., combining, mowing, incineration, steam treatment, grinding) or store it in a contained facility in a location authorized under this permit or a movement permit for

the same plant to prevent their unauthorized release, spread, dispersal, and/or persistence in the environment.

11. **Post-Termination Volunteer Monitoring.** After you terminate the environmental release at each planted Release Site, you must monitor for, remove, and destroy any volunteer plants to prevent the plant from spreading, dispersing, and/or persisting in the environment without authorization.

    A. Volunteer Monitoring Areas. You must monitor for volunteer plants in:
    i. any planted Release Site (including the perimeter zone and any border row areas)
    ii. any areas where you disposed of the plant and any associated viable material (other than authorized landfills);
    iii. any areas where you cleaned equipment and/or loaded equipment onto transport vehicles (including areas within and outside a Release Site).
    iv. During the volunteer monitoring period, only erosion control plantings or cover crops that are morphologically distinct and sexually incompatible with the regulated plant may be grown within the release site and volunteer monitoring areas.

    B. Volunteer Monitoring Period and Intervals:
    i. **For all Planted Release Sites**: You must monitor for volunteer plants when conditions are favorable for the plant's germination and/or growth. If you experience an unusual event (e.g., heavy rain, high winds, flood), you may extend the intervals described below by 2 calendar days.

    If you observe volunteer plants during either of the last 2 consecutive monitoring intervals, you must continue monitoring for volunteer plants until you find zero volunteer plants for 2 consecutive monitoring intervals. Whether within the original monitoring period or the additional monitoring period, the last 2 consecutive monitoring intervals must collectively cover 30 days for releases that **do not** result in the setting of seed or 60 days for releases that **do** result in the setting of seed.
    ii. **For Planted Release Sites in the Continental United States that set seed:** You must monitor for volunteer plants in intervals that do not exceed 30 days, for a period of not less than 1 year, beginning on the day you terminated the environmental release.
    iii. **For Planted Release Sites in Hawaii and United States Territories that set seed:** You must monitor for volunteer plants in intervals that do not exceed 30 days, for a period of no less than 6 months, beginning on the day you terminated the environmental release.
    iv. **For any Planted Release Site terminated prior to seed set:** You must monitor for volunteer plants in intervals that do not exceed 30 days, for a period of no less than 1 month, beginning on the day you terminated the environmental release. At least two monitoring intervals must occur (see B.i. above).

    C. Volunteer Removal. You must destroy all volunteers before anthesis/flowering.

    D. Reporting Post-Termination Volunteer Monitoring. You must report post-termination volunteer monitoring activities as described below in "Post-Termination Volunteer Monitoring Reports, Annual (Interim) and Final."

    E. Volunteer Monitoring when Planting Back to Same Species, Regulated. If APHIS authorizes all or part of a Release Site to be planted to the same species for the next growing season:
    i. You must comply with the post-termination volunteer monitoring requirements of this permit until a new regulated planting occurs.

ii. Once the new planting occurs, you must follow the monitoring requirements for the planted area as described in the new permit.
iii. You must continue to monitor any unplanted areas according to the monitoring requirements of this permit.

12. **Use of Regulated Material as Food or Animal Feed.** This permit does not authorize food/feed use of the regulated material. If you use viable regulated material for food or feed for experimental purpose under a separate approval, you must destroy any animal waste that contains viable regulated material in a manner that maintains its confinement.

13. **Reporting Requirements.** You must submit reports to APHIS that are described in the reporting requirements below.

    APHIS prefers report submission using APHIS eFile reporting modules. Step-by-step instructions for submission through APHIS eFile are located in Guide to Reports and Notices and the *APHIS 2000 Permit Application and Compliance Reporting Job Aid* on the APHIS eFile Training webpage (https://www.aphis.usda.gov/aphis/banner/help/efile/efile-training). For further assistance with APHIS eFile submission, please contact APHIS eFile communications (eFile.Communications@usda.gov).

    Alternatively, you may submit reports by email or postal mail. If you are claiming Confidential Business Information (CBI) within reports, you must submit both CBI and non-CBI copies following the regulations of 7 CFR 340.7.

    Email reports to:
    BRSCompliance@usda.gov

    Postal mail reports to:
    Animal and Plant Health Inspection Services
    Biotechnology Regulatory Services
    Document Control Officer
    4700 River Rd. Unit 146
    Riverdale, MD 20737

For the Reports listed in sections 14-16, the following data elements auto-populate in APHIS eFile once you select the site(s) you are entering data for: Authorization number; regulated plant (species); Release Site name, address (or GPS coordinates), county, and state; Location Unique ID; Release Site Agent, name and contact information (telephone number and email address).

14. **Planting (Environmental Release) Reports**. Following an environmental release (e.g., planting or placement in an uncontained greenhouse or shade house), you must submit a planting/environmental release report within 30 days from the date of planting. Your report must include the Environmental Release Unique ID (this differs from Location Unique ID) and, if you replanted a Release Site, you must provide Environmental Release Unique IDs for the original and subsequent release. Reports must also include:

    A. Release start date

B. Anticipated termination date
C. Total acreage of release (do not include acreage of border rows or perimeter zones)
D. A list of all constructs released
E. GPS coordinates (in decimal degrees) with accuracy to a minimum of five decimal places to identify the planting
F. Any comments you choose to provide

NOTE: If you do not make a release at Release Site listed in your permit, ***you must still submit a planting/release report of "no planting/release"*** no later than 30 calendar days after the permit expiration date.

15. Field Test Report, Final. You must submit a final Field Test Report no later than 180 calendar days after the permit expiration date for each planted Release Site. You must submit this report even if APHIS issues a new permit for release at the Release Site. Reports must:

A. Indicate if you rendered the plants nonviable (i.e., not able to develop, grow, or survive) prior to harvest and, if so, include:
  i. The date you rendered the plants nonviable;
  ii. Destruction methods (e.g., mowing, burning, soil cultivation, herbicide application, disposal at authorized landfill);
  iii. Actual stage of plant development when rendered nonviable (e.g., vegetative or reproductive); and
  iv. Destruction location.
B. Indicate if you harvested the plant and any viable material. If yes, include:
  i. Harvest completion date;
  ii. If you retained material, indicate the location (including address) of contained facility where you are storing viable material and a description of what you stored at that location (including quantity); and
  iii. If destroyed, describe the method of destruction or disposal (e.g., burned, ground, authorized landfill) and date.
C. If you rendered the plant or associated viable material nonviable at the Release Site, include:
  i. The date you rendered the plant and associated material nonviable in the field; and
  ii. Describe how you rendered it nonviable in the field, including the method of destruction (e.g., burned, hammer-milled) and/or disposition (tilled, buried) method(s).
D. Describe any deleterious effects on plants, non-target organisms, or the environment. Include any relevant methods of observations, observations on other crops, and resulting data and analyses.
E. Indicate if you have submitted any of the following:
  i. A report on the accidental or unauthorized release of the regulated article;
  ii. A report that characteristics of the permitted species are substantially different from those listed in the application; or
  iii. A report of any unusual occurrence.

16. **Post-termination Volunteer Monitoring Reports, Interim and Final.** You must submit a post-termination volunteer monitoring report (VMR) for each release at a Release Site, as follows:

    A. A final VMR is due no later than three months following the end of the VMR period as described in "Post-Termination Volunteer Monitoring."
    B. For volunteer monitoring periods longer than 1 year, Interim VMRs are due annually as follows:
        i. The first interim VMR is due no later than 13 months after you terminated the environmental release;
        ii. Subsequent Interim VMRs are due 1 year after the date you submitted the previous interim VMR; and
        iii. The final year of volunteer monitoring is reported as a final VMR (see (A) for due date requirements).
    C. Please note: Even if you obtain a new permit for the Release Site, you must submit VMRs regardless of obtaining a new release permit for the Release Site(s).
    D. VMRs must include:
        i. Environmental Release Unique ID(s)
        ii. Start date of monitoring period for each Volunteer Monitoring area
        iii. End date of the monitoring period for each Volunteer Monitoring area (only required for Final VMR)
        iv. Volunteer monitoring dates for each Volunteer Monitoring area
        v. Volunteer monitoring locations (you must report observations for all areas, including each Release Site, as described in section (A) of condition "Post-Termination Volunteer Monitoring")
        vi. Observations for each volunteer monitoring date and Release Site including:
            a. If no volunteers were observed, specify "no volunteer observed"
            b. If volunteers were observed, include:
                1. Number of volunteers observed (if more than 100 in number, follow an estimation strategy and include an estimate number);
                2. Actions taken to destroy volunteers
        vii. If the interval requirements noted in "Post-Termination Volunteer Monitoring" were not met, include an explanation of why you deviated from the monitoring interval
        viii. Indicate if the report is interim or final
    E. You must submit a VMR regardless of whether monitoring occurred. A "no monitoring" report must include:
        i. Environmental Release Unique ID(s)
        ii. The notation "no monitoring"
        iii. Reason for no monitoring
        iv. Indication of whether the report is interim or final

17. **Proposed Changes to an Issued Valid Permit.** To make changes to an issued permit, you must submit a permit amendment. You must contact APHIS Permitting staff via phone (301-851-3886) or email (BRSPermits@usda.gov) and obtain an amended permit before deviating from the issued permit. Changes may include SOP revisions, modification of the constructs (such as identifying information related to the lines/events); new destinations (including any changes to intermediate or final location(s)/destination(s) (including intra- and interstate locations)); or adjustments to Release Sites or acreage.

18. **Reporting a Possible or Actual Unauthorized Release or Unusual Occurrence.** In the event of a possible or actual Unauthorized Release, you must report the discovery to BRS Compliance staff via phone (301-851-3935) immediately and via email (BRSCompliance@usda.gov) within 24 hours of discovery. If your call advances to voicemail, you must leave a message describing the discovery. In the event of an unusual occurrence (excessive mortality or unanticipated effects on non-target organisms) or substantially different characteristics of the plant from those listed in this permit, you must report the discovery to APHIS Compliance staff via email (BRSCompliance@usda.gov) within 5 business days of the discovery.

    Examples of Unauthorized Releases include dispersal of regulated material via weather events such as flooding or high winds; loss of confinement at an authorized location; planting at a location not authorized in this permit; release of an unauthorized construct; loss of containment during shipping; incursion by livestock during an environmental release; and intentional or accidental movement of viable regulated material away from authorized locations.

    For additional information on notifying APHIS, contact: BRSCompliance@usda.gov.