USDA-APHIS Biotechnology Regulatory Services

Permit User's Guide
With Special Guidance for ePermits

v. 3/7/2012

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

4700 River Road
Riverdale, MD 20737

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

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

Conversely, following the guidelines contained in this document should not be construed as a guarantee of compliance with applicable statutes and regulations.

Permit

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Quick Guide to Permits

The permit process allows for the introduction (importation, interstate movement, or environmental release) of certain genetically engineered organisms under conditions determined by the Administrator as described in 7 CFR part 340 (http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title07/7cfr340_main_02.tpl). The goal is to prevent the unintended release of the regulated article.

Introductions may not proceed without a permit or a notification from APHIS.

A permit application should be submitted to APHIS:

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

A review and evaluation is completed by APHIS; and the applicant will be notified if additional information is required or corrections need to be made to the permit application.

APHIS sends Confidential Business Information (CBI)-deleted copies of the permit application to State regulatory officials and tribes when appropriate for review in each State where the introduction has been proposed.

The person who is issued a permit must comply with permit conditions set forth in § 340.4 and supplemental conditions imposed by APHIS during its review.

Applicants must promptly notify APHIS of any unusual occurrences (§ 340.4(f)(10)(i-ii))that happen during the introduction.

All introductions are subject to inspection by Federal and/or State inspectors.

Planting/release reports must be submitted to APHIS as specified in the permit conditions.

A field test report must be submitted to APHIS within six months of the termination of an environmental release.

A courtesy permit may be issued for the introduction of genetically engineered organisms which are not subject to regulation to facilitate movement when the movement may be otherwise impeded.

Introduction

This Permit Guidance is provided to assist permit applicants and the general public understand the process for obtaining a USDA APHIS permit to import, move interstate, or release into the environment genetically engineered organisms that are regulated under 7 Code of Federal Regulations part 340. Most permits are submitted electronically through ePermits, therefore this document gives special emphasis to that system, and provides step-by-step guidance. Throughout the document the regulatory language from 7 CFR 340 and from the Federal Register is presented in grayed boxes, followed by an explanation of APHIS's current policies for permit administration.

The first section of the Permit Guidance explains what is regulated under 7 CFR part 340, offers resources to obtain additional information beyond that provided in the Permit Guidance, discusses containment facilities, gives timeframes for permit review and covers APHIS's implementation of the National Environmental Policy Act (NEPA).

The subsequent sections are organized to provide information needed to submit an ePermits permit application and to carry out regulated activities under 7 CFR part 340. Different types of permits require that different types of information be submitted and reviewed by APHIS. This section clarifies what type of permit to apply for, what information to include in an application and how to enter the information into ePermits. Reports, notices, inspections, special requirements for Pharmaceutical, Industrial and Phytoremediation Permits, and guidance for critical habitat analysis are explained in the document and in the appendices. Example permits that may be helpful to those new to the permit process can be found in the appendices.

> APHIS may issue guidelines regarding scientific procedures, practices, or protocols which it has found acceptable in making various determinations under the regulations. A person may follow an APHIS guideline or follow different procedures, practices, or protocols. When different procedures, practices, or protocols are followed a person may, but is not required to, discuss the matter in advance with APHIS to help ensure that the procedures, practices, or protocols to be followed will be acceptable to APHIS. Footnote 5 in § 340.3

The Permit Guidance reflects APHIS administrative processes to carry out the regulations and does not create or confer any rights for or on any person and does not operate to bind APHIS or the public. An applicant can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

Permits for the Introduction of Certain Regulated Articles

Regulated Articles 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 BELIEVE ARE PLANT PESTS.** 7 CFR part 340

> **Restrictions on the introduction of regulated articles.**
> (a) No person shall introduce any regulated article unless the Administrator is:

(1) Notified of the introduction in accordance with § 340.3, or such introduction is authorized by permit in accordance with § 340.4, or such introduction is conditionally exempt from permit requirements under § 340.2(b); and
(2) Such introduction is in conformity with all other applicable restrictions in this part.[1]
§ 340.0

Part 340 regulates, among other things, the introduction of organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests.
Footnote 1 in § 340.0

Donor organism. The organism from which genetic material is obtained for transfer to the recipient organism. § 340.1

Genetic engineering. The genetic modification of organisms by recombinant DNA techniques.
United States to release into the environment to move interstate or any attempt thereat. § 340.1

Introduce or Introduction. To move into or through the United States to release into the environment to move interstate or any attempt thereat. § 340.1

Genetic engineering. The genetic modification of organisms by recombinant DNA techniques.
Introduce or Introduction. To move into or through the United States to release into the environment to move interstate or any attempt thereat. § 340.1

Move (moving, movement). To ship, offer for shipment, offer for entry, import, receive for transportation, carry, or otherwise transport or move, or allow to be moved into, through, or within the United States. § 340.1

Plant pest. Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants. § 340.1

Recipient organism. The organism which receives genetic material from a donor organism. § 340.1

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. § 340.1

Vector or vector agent. Organisms or objects used to transfer genetic material from the donor organism to the recipient organism. § 340.1

Groups of organisms which are or contain plant pests and exemptions.
Groups of organisms which are or contain plant pests. The organisms that are or contain plant pests are included in the taxa or group of organisms contained in the following list. Within any taxonomic series included on the list, the lowest unit of classification actually listed is the taxon or group which may contain organisms which are regulated. Organisms belonging to all lower taxa contained within the group listed are included as organisms that may be or may contain plant pests, and are regulated *if they meet the definition of plant pest in § 340.1.*[4]

Note: Any genetically engineered organism composed of DNA or RNA sequences, organelles, plasmids, parts, copies, and/or analogs, of or from any of the groups of organisms listed below shall be deemed a regulated article if it also meets the definition of plant pest in § 340.1.
§ 340.2(a)

Any organism belonging to any taxa contained within any listed genera or taxa is only considered to be a plant pest if the organism "can directly or indirectly injure, or cause disease, or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants." Thus a particular unlisted species within a listed genus would be deemed a plant pest for purposes of § 340.2, if the scientific literature refers to the organism as a cause of direct or indirect injury, disease, or damage to any plants, plant parts or products of plants. (If there is any question concerning the plant pest status of an organism belonging to any listed genera or taxa, the person proposing to introduce the organism in question should consult with APHIS to determine if the organism is subject to regulation.) Footnote 4 in § 340.2(a)

Petition to amend the list of organisms.
General. Any person may submit to the Administrator a petition to amend the list of organisms in § 340.2 of this part by adding or deleting any genus, species, or subspecies. A petitioner may supplement, amend, or withdraw a petition in writing without prior approval of the Administrator and without prejudice to resubmission at any time until the Administrator rules on the petition. A petition to amend the list of organisms shall be submitted in accordance with the procedures and format specified by this section. § 340.5(a)

The regulations in Code of Federal Regulations (7 CFR part 340) (http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title07/7cfr340_main_02.tpl) under the Plant Protection Act (PPA) (7 U.S.C. 7701-7772) govern the introduction of regulated articles. Animal and Plant Health Inspection Service, Biotechnology Regulatory Services (APHIS BRS) regulates the introduction (importation, interstate movement, or environmental release) of certain genetically engineered (GE) organisms that may pose a risk to plant health (For more information on APHIS BRS see, http://www.aphis.usda.gov/biotechnology/brs_main.shtml). APHIS coordinates these responsibilities along with the other designated Federal agencies as part of the Federal Coordinated Framework for the Regulation of Biotechnology (http://www1.usgs.gov/usbiotechreg/).
The introduction of regulated articles under § 340.4 requires a permit with the exception of introductions that are either eligible for introduction under the notification procedure (For Notification Guidance, see http://www.aphis.usda.gov/biotechnology/notification.shtml) or are

conditionally exempt from 7 CFR part 340 requirements under § 340.2(b) (see **Exemptions under § 340.2(b)** below).

The list of organisms in § 340.2 may be amended according to the process described in § 340.5.

APHIS issues permits for the introduction of genetically engineered organisms, including plants, insects, or microbes that may pose a plant pest risk.

If you are uncertain as to whether the organism is a plant pest or a regulated article, please contact: Biotechquery@aphis.usda.gov.

Exemptions Under § 340.2(b)

Exemptions.
(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)

Certain genetically engineered organisms regulated under 7 CFR part 340 are exempt from regulation 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. A variance from the container requirements can be requested if the container requirements normally applicable to the movement of the regulated article under § 340.8 are inappropriate due to unique circumstances, see the section on **Variance** in this document.

Other Federal and State Regulations

Part 340 regulates, among other things, the introduction of organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests. The introduction into the United States of such articles also may be subject to other regulations promulgated under the Plant Protection Act (7 U.S.C. 7701–7772) and found in 7 CFR parts 319, 330, and 360. For example, under regulations promulgated in "Subpart-Nursery Stock, Plants, Roots, Bulbs, Seeds, and Other Plant Products" (7 CFR 319.37–3), a permit is required for the importation of certain classes of nursery stock whether such stock is genetically engineered or not. Accordingly, individuals should refer to those regulations before importing any nursery stock. Footnote 1 in § 340.0

Other Federal and State plant quarantine regulations may restrict or prohibit the interstate movement, importation, or release of the regulated article. It is the applicant's responsibility to obtain any additional permits required by Federal and State regulations.

- APHIS Plant Protection and Quarantine (PPQ) permits are required for the importation, transit, domestic movement and environmental release of plant pests and importation of biological control agents that are NOT genetically engineered and soil that may contain plant pests, see http://www.aphis.usda.gov/plant_health/permits/organism/index.shtml.

- APHIS PPQ permits are required for the importation into the U.S. and transit through the U.S. of regulated plants and plant products (genetically engineered or not genetically engineered) for consumption or propagation, see http://www.aphis.usda.gov/plant_health/permits/plantproducts.shtml.

- APHIS Veterinary Services regulates the import, export, and interstate movement of all animals and animal products (e.g., tissues, blood, and semen), including those that are genetically engineered, see http://www.aphis.usda.gov/animal_health/lab_info_services/about_nvsl.shtml.

- APHIS Animal Care regulates research facilities used for certain vertebrate animals, including vertebrate animals that are genetically engineered, see http://www.aphis.usda.gov/animal_welfare/.

- For more information on State regulations, the National Plant Board provides information about State-level quarantine laws, see http://nationalplantboard.org/laws/index.html.

Containment Facilities

APHIS does not regulate the use of GE organisms in containment facilities (e.g., laboratory, contained greenhouse, or other contained structure). However, unauthorized introduction of regulated GE organisms from such facilities are a violation of APHIS regulations. APHIS strongly encourages applicants to ensure that destination facilities follow containment guidelines established by the National Institutes of Health (NIH) or other similar guidelines.

For more information about containment facilities see,

- Guidelines for NIH Research Involving Recombinant DNA, see http://oba.od.nih.gov/rdna/nih_guidelines_oba.html
- Practical Guide to Containment— Greenhouse Research with Transgenic Plants and Microbes (Virginia Polytechnic Institute and State University, Information Systems in Biotechnology), see http://www.isb.vt.edu/Containment-guide.aspx

Time Frame for Review and Issuance of a Permit

Permit for release into the environment. An application for the release into the environment of a regulated article shall be submitted at least 120 days in advance of the proposed release into the environment. An initial review shall be completed by APHIS within 30 days of the receipt of the application. If the application is complete, the responsible individual shall be notified of the date of receipt of the application for purposes of advising the applicant when the 120 day review period commenced.[7] If the application is not complete, the responsible individual will be advised what additional information must be submitted. APHIS shall commence the 120 day review period upon receipt of the additional information, assuming the additional information submitted is adequate. § 340.4(b)

The 120 day review period would be extended if preparation of an environmental impact statement in addition to an environmental assessment was necessary.
Footnote 7 in § 340.4(b)

Limited permits for interstate movement or importation of a regulated article. An application for the interstate movement or importation of a regulated article shall be submitted at least 60 days in advance of the first proposed interstate movement and at least 60 days prior to each importation. An initial review shall be completed by APHIS within 15 days of the receipt of the application. If the application is complete, the responsible person shall be notified of the date of receipt of the application for purposes of advising the applicant when the 60 day review period commenced. If the application is not complete, the responsible person will be advised what additional information must be submitted. APHIS shall commence the 60 day review period upon receipt of the additional information, assuming the additional information submitted is adequate. § 340.4(c)

Renewals may receive shorter review. In the case of a renewal for a limited permit for importation that has been issued less than one year earlier, APHIS will notify the responsible person within 15 day either: (1) the renewal permit is approved or (2) that a 60 day review period is necessary because the conditions of the original permit have changed.
Footnote 9 in § 340.4(c)(2)

Administrative action on applications. After receipt and review by APHIS of the application and the data submitted pursuant to paragraph (a) of this section, including any additional information requested by APHIS, a permit shall be granted or denied. If a permit is denied, the applicant shall be promptly informed of the reasons why the permit was denied and given the opportunity to appeal the denial in accordance with the provisions of paragraph (g) of this section. If a permit is granted, the permit will specify the applicable conditions for

introduction of the regulated article under this part. § 340.4(e)

When a permit application is received by APHIS, a permit number will be assigned. Permit applications for interstate movement or importation shall be submitted at least 60 days before the planned movement date; permit applications for release shall be submitted at least 120 days before the planned release date. In some cases 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. Permit applications will be reviewed for completeness within 15 days for movement (interstate or importation) and within 30 days for release. If the application is not complete, the responsible person will be advised as to what additional information must be submitted in order to complete the review. When the application is deemed complete and APHIS has completed its review and NEPA analysis, APHIS will submit a copy of the confidential business information (CBI)-deleted permit application and proposed permit conditions to the State or tribal regulatory official as appropriate of destination or site of release to afford them an opportunity to review and comment on the proposed introduction. If a permit is issued, the applicant will be notified and the permit will specify the conditions of release or movement.

NEPA Document (EA or EIS)

According to APHIS's NEPA implementing procedures (7 CFR part 372, http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title07/7cfr372_main_02.tpl), releases may be categorically excluded from the requirement of conducting a NEPA document (typically an EA for field releases) because the means through which adverse environmental impacts may be avoided or minimized have been built into the confinement and containment actions themselves. However, an EA may be required when a release of genetically engineered organisms or products involves new species or organisms or novel modifications that raise new issues per § 372.5(d)(4).

If the agency determines that an environmental document must be prepared for an introduction, additional information may be requested from the applicant for this purpose. As field releases are conducted over several seasons, applicants should collect data that will assist the agency when it is deemed necessary to prepare future environmental documents. 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.

Because of the additional time required to complete a NEPA, publish it in the Federal Register for public comment and address any public comments, permit applications that will require a NEPA document , should be submitted at least one year prior to a requested release date. Contact APHIS as early as possible if you think an environmental document may be needed.

Applying for a Permit

Select the Type of Application and Submission Method

Electronic Permit Application

As part of the electronic Government (eGovernment) initiative APHIS makes available the internet based ePermits system. APHIS continues to offer both a paper process and the online ePermits system. Applicants are encouraged to take advantage of the ePermits option. This will help to expedite the entire permitting process. In addition to the ease of applying online, ePermits has other time-saving features, including tools to help generate new applications from previous submissions, the automated generation of Confidential Business Information (CBI)-deleted versions and the ability to submit subsequent notices and reports for issued permits.

Paper Submission

All applicants are strongly encouraged to submit electronically whenever possible. Submission of a paper copy permit may delay processing because APHIS staff must copy the application over to ePermits and then confirm the submitted data. To download a paper application (APHIS FORM 2000 Permit, http://www.aphis.usda.gov/brs/pdf/2000.pdf). If the application contains CBI information, submit two versions of the document: a complete version containing CBI and an edited version with the CBI redacted (http://www.aphis.usda.gov/brs/pdf/Doc_Prep_Guidance.pdf). Business submitters must claim and write a justification for information claimed as CBI. Each page claimed to contain CBI must be denoted "CBI-Copy" at the top of each page; then those claims are analyzed within APHIS.

Mail paper applications to:

APHIS BRS, Permit Staff
4700 River Road, 6th Floor, Unit 91
Riverdale, MD 20737

Set up an ePermits Account

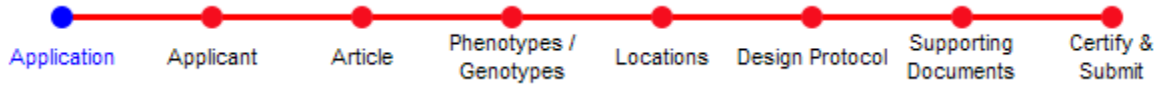
Users (permit applicants) are required to sign up for an eAuthentication account to access ePermits. An eAuthentication account consists of a User ID, a password, and your customer profile which contains information about you that will allow USDA to confirm that you have the correct permissions to view the website. Please note that USDA will only accept eAuthentication accounts from individuals. Currently USDA eAuthentication does not have the mechanism to issue accounts to businesses, corporations, or other entities.

Once you receive your User ID and password, it provides a centralized authentication service for all web-based services across the Federal government. Currently, USDA offers accounts with either Level 1 or Level 2 access. Level 1 is available immediately upon completing the on-line application. With Level 1 access applicants may complete the permit application online, but then must print their application and mail a signed and dated copy to APHIS. With Level 2 access, permitting activities related to the permit application and permit issuance occur over the internet. Level 2 access requires independent verification of identity. For further information on setting up an eAuthentication account:

- For general information about setting up an account: http://www.eauth.egov.usda.gov/eauthWhatIsAccount.html
- For further assistance in setting up an account: http://www.eauth.egov.usda.gov/USDA%20eA%20Registration%20Job%20Aid_v2.0.pdf
- To submit an online application: http://www.aphis.usda.gov/permits/learn_epermits.shtml

Helpful Tips for ePermits

- The first step in creating a permit is to select the type of application: (1) Permit or Notification; (2) CBI or no-CBI; (3) Release, Importation or Interstate movement; (4) Courtesy or Not Courtesy Permit. Because each type of application has different data entry fields, applicants must select the appropriate type of application before continuing to enter the permit information. Once a type of application is selected permit applicants cannot go back and change the type of application. Guidance for selecting the appropriate type of permit application is provided below. If you have questions about what type of permit is appropriate send an email to biotechquery@aphis.usda.gov.
- After the appropriate type of application is selected, navigate through the application by selecting the text under the dots in the navigation map (see figure below).



- When entering data, some of the data entry boxes are required and these are denoted by an asterisk (*) in ePermits and in this guidance document. Other data may be used to assist APHIS in conducting its review and carrying out other functions associated with the permit, such as inspection and compliance.
- Use drop down menus when they are provided.
- Select **Continue** before leaving a data entry screen or the changes will be lost.
- If you cut and paste text from another document embedded electronic codes may be transferred along with the text, which may cause problems in application submission. To remove these codes paste text from a program like Notepad.
- Special characters (i.e., alpha, beta, gamma, infinity, etc.) may be used, see https://epermits.aphis.usda.gov/epermits/xml_schema/Special%20Characters%20for%20the%20Web.doc
- You must submit the movement permit application at least 60 days and the release permit application at least 120 days before the permitted activity will occur.
- Data entry boxes have maximum character limits. To check the character limits of all data entry boxes, see
  https://epermits.aphis.usda.gov/ePermits/XML_SCHEMA/BRS_Permit_DATA_TABLES_2_0.doc
- Contact ePermits Help desk if you are experiencing difficulties with ePermitsePermitshelp@aphis.usda.gov, (866) 794-2827.

Create a Permit Application

Log on to ePermits and select **Create an Application** and select **Biotechnology Regulatory Services.** If an application has been previously submitted, the permit can be copied and resubmitted (From the home screen, select **All saved applications**, select **Copy**).

For questions regarding APHIS notifications and permits send inquiries to biotechquery@aphis.usda.gov.

Permit or Notification

In the next screen for the purposes of this documentation it is assumed "BRS Permit for the Introduction of Genetically Engineered Organisms" will be selected.

The alternative is a BRS notification (§ 340.3), which is an administratively-streamlined alternative to a permit, applicable only to plants that meet specified eligibility criteria. The large majority of applications involving plant species are for notifications not permits. For further information on notifications, see User's Guide:
Notification, http://www.aphis.usda.gov/biotechnology/notifications.shtml.

Common reasons to submit a permit instead of a notification:

- The regulated organism is not a plant (e.g., virus, bacterium, fungus or insect)
- The function of the inserted genetic material is unknown
- The intended use is for the production of an industrial or pharmaceutical product
- The release will be conducted for more than one year (e.g., perennials that stay in the ground for more than one year)
- Introduced DNA is derived from an animal/human virus

Select Agent

The Agricultural Bioterrorism Protection Act of 2002 requires entities that possess, use, or transfer biological agents or toxins deemed a severe threat to animal or plant health or products to notify and register with APHIS. This law is designed to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies that could threaten public health and safety or American agriculture. A list of select agents and toxins is available at: http://www.selectagents.gov/. If the organism is a select agent, follow the instructions in ePermits for select agent permits.

Submission Method

Applicants can enter data directly into ePermits (**Web Form Entry**) or upload eXtensible Markup Language (**XML**) files. For more information on the rules governing the structure and content acceptable for XML permit applications and a sample XML permit, see https://epermits.aphis.usda.gov/ePermits/XML_SCHEMA/permit.html.

Application Ownership - Responsible Person or Preparer

The applicant is the person responsible for the information provided in the permit and who has control and will maintain control over the introduction of the regulated article to ensure compliance with Federal regulations and permit conditions. ePermits allows the option for a person to prepare the application and then forward the application to the responsible person for submission. Indicate if you are the preparer or the responsible person. At the end of the permit application process, the preparer will be prompted to send an email to the responsible person at the end of the application process. The responsible person then logs into ePermits to submit the application. All ePermits communications from APHIS regarding the permit will be made to the responsible person.

Select New Permit, Amendment, Renewal

Amendments

After a permit is issued, and prior to the expiration date, modifications may be made to the permit using the permit amendment process. When applying for a permit amendment the proposed changes should be clearly described. Because administrative and review steps are the same for an amendment as that for a permit, a permit amendment may take up to 60 days and a release amendment may take up to 120 days. At this time ePermits does not have the capability to amend permits via the XML process. They must be amended via the web forms method of entry.

Amendments may add certain items; the commonly requested amendments are to:

- Add genetic constructs
- Add release sites, in States already listed in the permit or new States
- Change disposal methods
- Change the date of plantings/releases, as long as they are after the effective date and before the expiration date
- Add or modify SOPs or Design Protocols
- Add containment facilities
- Increase the size of shipments
- Increase the acreage for release sites

Amendments may <u>not</u> be used to:

- Change the effective or 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[1]

Renewal

If you indicate that the permit is a renewal of a previously issued permit, information from the previous permit will be copied into the new ePermits application. The new permit application can

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

then be modified as needed. These modifications should be described as **Additional Information** in the **Application** section of the permit application. A renewal of an application is essentially treated similarly to a new application, with a comparison to the previous application aiding and perhaps expediting with the review process. If renewal is selected you will be asked to provide the permit number that is being renewed.

Courtesy Permit

Courtesy permit

(1) *Issuance.* The Administrator may issue a courtesy permit for the introduction of organisms modified through genetic engineering which are not subject to regulation under this part to facilitate movement when the movement might otherwise be impeded because of the similarity of the organism to other organisms regulated under this part.

(2) *Application.* A person seeking a courtesy permit shall submit on an application form obtained from APHIS data required by paragraphs (b) (1), (2), and (5) of this section and shall indicate such data is being submitted as a request for a courtesy permit. A person should also include a statement explaining why he or she believes the organism or product does not come within the definition of a regulated article. The application shall be submitted at least 60 days prior to the time the courtesy permit is sought.

(3) *Administrative action.* APHIS shall complete an initial review within 15 days of the date of receipt of the application. If the application is complete, the responsible individual shall be notified of the date of receipt of the application for purposes of advising the applicant when the 60 day review period commenced. If the application is not complete, the responsible individual will be advised what additional information must be submitted, and shall commence the 60 day review period upon receipt of the additional information, assuming the additional information submitted is adequate. Within 60 days from the date of receipt of a complete application, APHIS will either issue a courtesy permit or advise the responsible individual that a permit is required under paragraph (b) or (c) of this section. § 340.4(h)

Upon request, APHIS issues courtesy permits for nonregulated organisms upon request in order to facilitate their movement, which might otherwise be impeded because of the similarity of the organism to other regulated organisms. A genetically engineered organism is considered a regulated article if the donor organism, recipient organism, vector or vector agent used in engineering the organism belongs to one of the taxonomic groups listed in § 340.2 and is also a plant pest, or if there is a reason to believe it is a plant pest.

Since most transgenic *Drosophila* developed for research purposes do not contain genetic sequences from plant pests and are themselves not considered plant pests, most transgenic *Drosophila* do not require permits from APHIS for their movement. However, shipments manifested as "fruit flies" have recently raised agricultural and environmental concerns because this common name also refers to plant pests like the Mediterranean and oriental fruit flies.

In the past, APHIS has accepted courtesy permit applications for importations of nonregulated *Drosophila* that were based upon a template of a partially-completed APHIS Form 2000. Applications based upon this template are no longer being accepted to issue courtesy permits. APHIS requires applicants requesting a courtesy permit for *Drosophila* importations to apply

through ePermits with all required information, including details of the inserted construct. This information is necessary for APHIS to confirm that the transgenic *Drosophila* is not a regulated article before issuing a courtesy permit. For additional information, please contact biotechquery@aphis.usda.gov.

Similarly, the movement of products that have been purified from plants that are genetically engineered or produced using genetically engineered plant viruses do not require a permit under § 340. For example, if tobacco mosaic virus that is genetically engineered to produce a compound is inoculated onto nonregulated tobacco plants and the compound is purified from the inoculated tobacco plants using procedures that would eliminate the GE virus, a permit is not required for the movement of the purified compound. An applicant should supply data in the courtesy permit application validating the claim that the purified product does not contain genetically engineered tobacco mosaic virus. Following review of the data, APHIS may issue a courtesy permit to facilitate movement of the engineered product.

Select the Introduction Type

Number of Releases, Points of Origins, Destinations and Duration

A single permit application may request interstate movements that originate at multiple points of origin and goes to multiple destinations. For introductions into the environment, a single permit may request multiple plantings or releases (for microbes or insects) at multiple locations.

Importation permit applications must have only one point of origin and only one destination. Permit applications for importation cannot be combined with interstate movement or release.

Most release and movement permits are valid for only one year. The exception is for release permits for perennial plants or plants where the life cycle of the plant takes more than one year. Release permits for perennials can be valid for up to 3 years. However, for combined movement and release permits, even when the release portion of the permit extends beyond one year, the movement portion of the permit is valid for one year only. Applicants must reapply yearly for the movement portion of the release. *Drosophila* courtesy permits may extend up to 3 years.

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 activities associated with the introduction, excluding post-harvest volunteer monitoring, must be carried out after the effective date and before the expiration date listed on the permit. Applicants may submit applications and request that the "effective" date occur after the "date issued". The permit will be issued with only a single effective date using the earliest date entered in the permit application.

Select Confidential Business Information (CBI) or No CBI

Information determined to be CBI is protected from public disclosure. All documents submitted to APHIS are subject to the Freedom of Information Act (FOIA), which requires that records submitted to Federal agencies be made available to the public (http://www.aphis.usda.gov/brs/pdf/Doc_Prep_Guidance.pdf). APHIS provides the public with

documents it receives when formally requested through the APHIS FOIA office. Additionally, APHIS voluntarily makes many submitted documents freely available on its website (http://www.aphis.usda.gov/biotechnology/brs_main.shtml). FOIA exempts from disclosure certain types of information related to trade secrets and commercial or financial information, collectively referred to as CBI. Documents submitted to APHIS that contain CBI require special handling. Only the information deemed to be CBI will be withheld from public disclosure. This applies to information submitted by any method approved by APHIS.

For more information about the type of information that can be claimed as CBI see, http://www.aphis.usda.gov/brs/pdf/Doc_Prep_Guidance.pdf.

Or contact:

Document Control Officer
USDA APHIS BRS
4700 River Road, Unit 91
Riverdale, Maryland 20737
(301) 851-3892 or (301) 851-3877

When entering information into ePermits that is to be protected as CBI, surround it with square brackets ([ ]). If you try to use another separator, your CBI will not be protected. Before submission, take a look at a pdf CBI-deleted version of the permit application to check for any CBI information.

Application Submission – Data Requirements

The application shall include the following information:

(1) Name, title, address, telephone number, signature of the responsible person and type of permit requested (for importation, interstate movement, or release into the environment);

(2) All scientific, common, and trade names, and all designations necessary to identify the: Donor organism(s); recipient organism(s); vector or vector agent(s); constituent of each regulated article which is a product; and, regulated article;

(3) Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article;

(4) A description of the means of movement (e.g., mail, common carrier, baggage, or hand carried (and by whom));

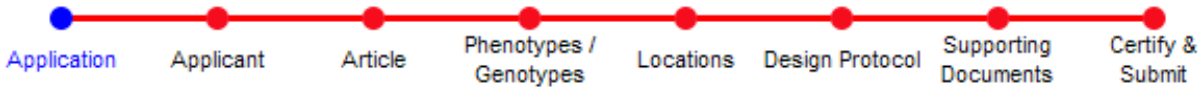
(5) A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics);

(6) A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article;

(7) Country and locality where the donor organism, recipient organism, vector or vector agent, and regulated article were collected, developed, and produced;

(8) A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design;
(9) The quantity of the regulated article to be introduced and proposed schedule and number of introductions;
(10) A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: Donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and regulated article;
(11) A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location; pilot project location; production, propagation, and manufacture location; proposed sale and distribution location);
(12) A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations;
(13) A detailed description of any biological material (e.g., culture medium, or host material) accompanying the regulated article during movement;
(14) A detailed description of the proposed method of final disposition of the regulated article.
§ 340.4(b)

Enter your specific permit data into the appropriate ePermits data entry boxes. Navigate within the sections in the permit by selecting the different dots, or the text below it, on the red line (=Metro Map).



Provide a CBI Justification Statement

If the application contains ***Confidential Business Information** (CBI), it must be justified in terms related to competitive harm due to its release. Information is not protected from disclosure simply because the applicant does not want the information to be made public. The applicant must include a statement justifying all claims of CBI. The statement must be detailed enough to demonstrate that each piece of information claimed as CBI meets the definitions of trade secret or commercial or financial information. Each piece of information that is claimed as CBI must be justified in the statement. For examples of the type of information that can be claimed as CBI and the definitions of commercial or financial harm, see http://www.aphis.usda.gov/brs/pdf/Doc_Prep_Guidance.pdf.

Purpose of Permit

*Choose the **Purpose of the Permit** from the drop down menu.

Industrial Product

Select **Industrial** if the engineered plant meets all three of the following criteria (68 FR 46434-46436, http://www.aphis.usda.gov/brs/fedregister/BRS_20030806a.pdf; 70 FR 23009-23011, http://www.aphis.usda.gov/brs/fedregister/BRS_20050504a.pdf):

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.
3. The new compound is being expressed for non-food, non-feed industrial uses.

Industrial uses include, but are not limited to, detergent manufacturing, paper production, biofuels and mineral recovery. Designation of industrial applies only to plants. Microbes that are engineered to produce industrial compounds should be entered as "traditional".

Pharmaceutical Product

Select **Pharmaceutical** if the compounds produced are intended for pharmaceutical use and would need to be approved from at least one of the following agencies prior to commercialization:

- 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

Select **Phytoremediation** if the compounds produced are intended for phytoremediation or mineral recovery. Applicants are encouraged to consult with APHIS for traits involving phytoremediation or mineral recovery to determine if these require a permit or are eligible for notification. For instance, plants would require a permit when engineered for phytoremediation or mineral recovery even if the plants are not intended for final use in food or feed. Alternatively, plants engineered for tolerance to heavy metals and which do not accumulate heavy metals and/or toxins and plants engineered for metabolic pathway research may qualify for notification.

Traditional

Select **Traditional** for all other permits. The majority of permits fall under this category.

Means of Movement

***Means of Movement** - Indicate if by mail, common carrier, baggage or hand carried.

Additional Information

Use this section to include any additional information that may support the applicant's certification that the regulated article will be introduced in accordance with § 340.4. The information provided here will appear at the end of the final permit application.

Variance

General requirements. A regulated article shall not be moved unless it complies with the provisions of paragraph (b) of this section, unless a variance has been granted in accordance with the provisions of paragraph (c) of this section. § 340.8(a)

Request for a variance from container requirements. A responsible person who believes the container requirements normally applicable to the movement of the person's regulated article(s) are inappropriate due to unique circumstances (such as the nature volume or life stage of the regulated article) may submit in an application for a permit a request for a variance from the container requirements. The request for a variance under this section shall consist of a short statement describing why the normally applicable container requirements are inappropriate for the regulated article which the person proposes to move and what container requirements the person would use in lieu of the normally prescribed container requirements. USDA shall advise the responsible person in writing at the time a permit is granted on the person's request for a variance. § 340.8(c)

***A variance** from the container requirements can be requested if the container requirements normally applicable to the movement of the regulated article under § 340.8 are unsuitable due to unique circumstances (see under the section **Confinement Protocols for Movement** for the regulations at § 340.8). Acceptable variances generally require a minimum of two levels of containment where each level can independently contain the regulated article in the event of a breach of one level of containment. Applicants should consider the following in deciding on the alternate packaging: the amount of the material being moved, the distance, the method of movement, the construction and capacity of containers and their suitability for the regulated article being shipped, and how the container will be sealed.

Container variance requests may be submitted with the permit application or requested before the application is submitted. APHIS will review the variance request for adequacy in containment, and notify the applicant if the variance was approved or denied. A container variance is assigned a variance number and may be applicable to the permit application and future permits. If a previously approved variance is being applied to the permit application, briefly summarize why the variance is applicable.

Applicant

Person. Any individual, partnership, corporation, company, society, association, or other organized group. § 340.1

Responsible person. The person who has control and will maintain control over the introduction of the regulated article and assure that all conditions contained in the permit and requirements in this part are complied with. A responsible person shall be a resident of the United States or designate an agent who is a resident of the United States. § 340.1

The responsible person (= applicant) will maintain control over the introduction of the regulated article and assure compliance with the permit conditions and regulatory requirements. The

responsible person must have an ePermits account and be a resident of the United States, or must designate an agent who is a resident of the United States. APHIS discourages the designation of temporary employees (e.g., post-doctorates or graduate students) as responsible parties.

For 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.

Provide the **Title, *First Name, *Last Name,** applicant **Position, *Organization Name**

Organization Code - If you enter an existing Organization Code, when you submit the permit an email will be sent to the organization's administrator. If you do not have an Organization Code and would like one assigned please contact: Cynthia.A.Eck@aphis.usda.gov.

Provide the ***Address, *City, *State, County/Province, Township/Island, *State, *ZIP Code, *Day Telephone, FAX, Alternate Telephone, *Email 1, Email 2** (ePermits correspondence will only be sent to the email address listed as Email 1. The second email address may be used for communications outside of ePermits.

Article

The responsible person may apply for a single limited permit for the interstate movement of multiple regulated articles in lieu of submitting an application for each individual interstate movement. § 340.4(c)(1)

A single permit application may include multiple lines derived from more than one transformation event and/or multiple constructs. In general all lines described in a single permit are from the same species.

If you wish to apply for a movement permit for more than one species, separate the regulated articles by a comma. In some rare cases release permits for more than one species that are biologically similar may be combined in a single permit (e.g., *Nicotiana* spp, *Citrus* spp.). In all cases, list out the names of all the species contained in the permit.

***Scientific Name**
Provide the scientific name for the recipient organism. Please use the drop down menu.

Common Name, Cultivar and/or Breeding Line may be provided.

***Biological Material Accompanying the Regulated Article**
Any biological material (e.g., culture medium or host material) accompanying the regulated article during movement should be described.

***Provide the country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed, and produced.**

- If the recipient organism is a plant or animal pest provide the strain, isolate, race, pathovar, etc. Indicate if the strain, isolate, race or pathovar of the pathogen is known to be present at the destination.
- If the origin is outside of the U.S. indicate if the virulence (host range and disease severity) is similar to strains known to occur in the U.S.

Article Supplier/Developer and a Summary Processes, Procedures, and Safeguards Description for Releases

A detailed description of the processes procedures and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination release and dissemination in the production of the: Donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and the regulated article. § 340.4(b)(10)

Article Supplier/Developer United States Verification
Provide the name of the person who developed and/or supplied the regulated article for this permit application and indicate if they reside in the United States.

Article Supplier/Developer Summary
Provide the name, address and phone number of the article supplier or developer: ***First Name, *Last Name, *Address, *Zip Code** and ***Telephone number.** Provide the **Country** if the supplier or develop resides outside the United States.

For releases (not required for movement permits) describe the ***Processes, Procedures, and Safeguards** that were used or will be taken in the production of the regulated article to prevent contamination, release or dissemination of the donor, recipient or vector/vector agent; constituent of each regulated article which is a product; and the regulated article.

Phenotypes/Genotypes Summary

Phenotypic Designations

Provide a phenotypic and genotypic description and origin of all transgenic DNA. Refer to the attached permits for examples of correctly formatted entries. Select **Add.**

Phenotypic Designation Name is a unique designation given to a transformed line or lines that all contain the same construct. This field allows applicants to consistently identify the transformed line in all future documents submitted to APHIS (e.g., planting/release reports, permits, or petitions to grant nonregulated status, 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. Events with multiple constructs (stacks) would be considered a single phenotype designation.

Each unique phenotype designation is separately added to the application. If phenotype designations are similar, there is an option in ePermits to copy and edit the entered construct information to save time.

Event/Line(s)
List line(s) to be introduced which carry a given construct. Use Commas to separate multiple lines/events.

***Construct(s)**
Provide the name of the construct that was inserted to generate the identifying line(s).

***Mode of transformation**
Provide the method used to insert the construct into the plant genome (e.g., biolistic transformation, disarmed *Agrobacterium*-mediated transformation, etc.) selecting from the drop down menu (preferred method) or type in your own.

Phenotype Description

A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics). § 340.4(b)(5)

For release permit applications (not required for movement applications, but may be provided), provide a short summary of the phenotype.

Phenotypes
***Phenotype Category**

Select one or more of the appropriate two-letter codes from the drop down menu. If the construct confers more than one phenotype, select all of the codes that apply.

VR = Virus Resistant
HT = Herbicide Tolerant
IR = Insect Resistant
FR = Fungus Resistant
BR = Bacterium Resistant
NR = Nematode Resistant
PQ = Product Quality
AP = Agronomic Properties
MG = Marker Genes
OO = Other

Product quality - delayed ripening of fruit, altered amino acid or oil profile, modified seed storage proteins, enhanced floral characteristics for ornamentals, increased solids in fruit, etc.
Agronomic properties - increased yield, drought tolerance, cold tolerance, tolerance to environmental stresses, enhanced nitrogen use, male sterility, etc.
Other - Anything that does not clearly fall into one of the other categories. For example, control lines transformed with empty vectors.

***Phenotype**
Enter or use the drop down menu for the specific phenotype/trait created by the genetic modification. For example, if the category is HT, then the phenotype is tolerance to a specific herbicide.

If the recombinant line contains more than one phenotypic category, select **Add Phenotype**; if not, select **Continue.**

Genotype

A detailed description of the molecular biology of the system (e.g., donor recipient vector) which is or will be used to produce the regulated article. § 340.4(b)(6)

*****Provide all inserted genetic material: See examples in the **Appendix - Sample Permit Applications**.

Select the **genotype** from the drop down menu (Gene Silencer, Gene of Interest, Screenable Marker or Selectable Marker), or type in a value.

Construct Components

Enter each construct component, one at a time. until each component (promoter, gene, etc.) is added. Keep selecting **Add to Construct Components** until all components are added individually.

***Construct Component <u>Type</u>**
Select the construct component type from the drop-down menu (e.g., 3'UTR, 5'UTR, enhancer, promoter, gene or terminator) or enter in your own. The construct component types are entered one at a time and should be selected in the 5' to 3' order (e.g., promoter, gene, terminator).

***Construct Component <u>Name</u>**
Enter a one to three word summary based on the gene or phenotype (e.g., catalase, extensin, peroxidase, Cry1Ab, etc.). Only common components should be abbreviated (e.g., 35S, GUS, GFP, NPTII, BAR, NOS, etc.).

***Construct Component <u>Donor</u>**

- Provide the scientific name (genus and species) of the organism from which the genetic material was obtained.
- Manually enter the scientific name only if it cannot be found in the drop-down menu.
- For viruses do not use abbreviations; spell out the name (enter Cauliflower Mosaic Caulimovirus, not CMV).

- If there are two or more donor organisms, separate their names with a comma (e.g., Genus species1, Genus species2).
- If the sequence was synthesized *in vitro* based on the sequence from an organism, enter the organism from which the sequence originated. Indicate that the donor is "synthetic" or "artificial sequence" only when the origin is truly synthetic (e.g., histidine tag).

***Construct Component Detailed Description of Function**
Provide a detailed description of the construct component function. Spell out abbreviated genes (e.g., beta- glucuronidase, green fluorescent protein, etc.). Indicate if the genetic element is truncated or modified. For lesser known components you may provide references to assist APHIS in conducting the review.

If applicable, indicate the donor name and indicate that the donor organism is a select agent, when any of the donor organisms are on the select agent list or is an organism that produces one of the toxins on the select agent and toxin list, in accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. A list of select agents and toxins is available at http://www.selectagents.gov/.

Add All Construct Components
Select **Add to Construct Components** or select **Continue**. (You must add more than one construct component before proceeding.) Construct component types can be sorted to order 5' to 3' if they were not originally entered in this order, by using the up and down arrows.

In ePermits, genotype refers to a single gene. If the construct contains 2 genes, then the applicant must complete the construct components section twice, once for each of the 2 genes.

Phenotypes/Genotypes Summary

Select "**I want to enter a new genotype for this designation**" to add another **genotype** if it has the same phenotype as the construct just entered.

Select "**I want to view ALL phenotypic designations or add a new description**" if you want to add another phenotypic designation (e.g., a new line). This will take you back to the primary "Phenotypic Designations" page where you can review what you have entered, and add, edit, copy, or delete as needed. Continue this process until all constructs that will be covered by the permit are included.

Select **"I am done entering all the phenotypic designations(s) for this permit application"** when finished adding all genetic data.

Interstate Movement & Release Locations Summary

Add points of origins and destinations for a movement permit; add release sites for release permits.

Location – Movement Permits

If a permit is sought for multiple interstate movements between contained facilities the responsible individual shall specify in the permit application all the regulated articles to be moved interstate; the origins and destinations of all proposed shipments; a detailed description of all the contained facilities where regulated articles will be utilized at destination; and a description of the containers that will be used to transport the regulated articles. A limited permit for interstate movement of a regulated article shall only be valid for the movement of those regulated articles moving between those locations specified in the application. If a person seeks to move regulated articles other than those specified in the application, or to a location other than those listed in the application, a supplemental application shall be submitted to APHIS. § 340.4(c)(1)

The responsible person seeking a permit for the importation of a regulated article shall submit an application for a permit prior to the importation of each shipment of regulated articles. § 340.4(c)(2)

Point of Origin

For movement permit applications provide the *** Location name, *County/Province, *State.**

For importation permit applications provide the ***Country of Origin.**
Select **Enter New Contact**, and then enter ***First Name, *Last Name,*Telephone.**

Destination

For movement permit applications provide the *** Location name, *County/Province, *State.**

Start and End Dates

Provide the***Proposed Start Date** and ***Proposed End Date.** See the section above entitled "**Number of Releases, Points of Origins, Destinations and Duration**" for guidance of the maximum duration of movement permits.

Quantity

*Quantity – Provide an estimate of the maximum quantity or regulated article(s) representing the total quantity of all movements for the duration of the permit. This quantity can only be increased with a permit amendment.

***Unit of Measure –** Use the drop down menu to select kilograms, pounds, individuals, milliliters, etc.

***Material Types –** Use the drop down menu to select: adults, eggs, eppendorf tubes, flowers, fruit, larvae, leaves, petri dishes, plantlets in vitro, pupae, roots, seeds, stems, whole plants, or enter a material type. Multiple types can be indicated.

***Destination inspection** – Provide information on any previous facility inspection by APHIS and the associated permit number.

Select **Enter New Contact,** and then enter ***First Name**, ***Last Name**,***Telephone**

Location – Release Permits

Location Unique ID

The ***Location** Unique ID allows the identification of each site in the application and subsequent reports. Each Unique ID can only be used once within the application and must be different for each location. It should consist only of letters, numbers and dashes (no special characters other than dashes are allowed). The same Unique ID may be used for the same location on different permits (or notifications), but must be unique within each permit.

GPS Coordinates Location Name

***Location Name** is that used to designate the location, such as "Green's Farm."
***County/Province,*State**. The county name provided must be that of the release site, not the grower or contact person associated with the site.

***Provide GPS Coordinates** for the proposed release site in decimal degrees format. Round coordinates to six decimal places. For most all U.S. locations the latitude values are positive (17.0 to 50.0) and the longitude values are negative (-68.0 to -160).

If only one coordinate pair is entered it should be located close to the northwest corner of the proposed release location. If the exact location of the release site is yet to be determined, provide GPS coordinates for the boundaries that encompass the possible area that will contain the release and the area to be monitored (includes the area monitored for separation distance).

If the GPS Coordinates are CBI
If you indicated that the application contains CBI, you may check the CBI box if the coordinates are CBI. Unlike other CBI information contained in the permit application, do not enclose the GPS coordinates in brackets**.**

***Release Site History**
Provide the land use history prior to this application. If the land has been in agricultural production, indicate for approximately how many years has the release site and the area to be monitored been used as such. Specify the type of agricultural activity (e.g., cropping, pasture, orchard, managed forest). If the permit application is a renewal, be sure to update the land use history to include recent field release activity.

Describe the areas around the research site. 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?

If you are changing the type of land use by establishing this release, please explain the nature of the change. For example, are you converting pasture land to an agricultural cropping system; are you converting a noncommercial forest into a research or commercial operation; are you converting pasture or grasslands into a biofuel research area? APHIS requires information on changes in land use history and sexually compatible species in the area because they could impact isolation conditions or threatened or endangered species (TES), including critical habitat.

Critical Habitat Analysis for Threatened and Endangered Species

APHIS analyzes the potential for effects of the permit on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act (ESA). To facilitate this analysis, permit applicants should provide their preliminary Critical Habitat analysis which is reviewed by APHIS and used in our final analysis.

*Is the proposed release site and/or the area requiring monitoring (or the area within the boundaries of the possible release/monitoring area for sites where the release site has yet to be determined) within designated critical habitat for a listed threatened or endangered species or within habitat proposed for designation under the Endangered Species Act (16 U.S.C., Section 1531, Endangered Species Act (ESA) of 1973, as amended)? For guidance on conducting critical habitat analysis, see, **Appendix - Guidance for Critical Habitat Analysis**.

Start and End Dates

Provide the ***Proposed Release Start Date** and***Proposed Release End Date.** This timeframe represents the time the regulated article is released. The duration of the permit, may extend for a longer timeframe (See the section above entitled "Number of Releases, Points of Origins, Destinations and Duration" for the maximum duration of release permits.)

Number of Proposed Plantings or Releases

Enter the number of ***plantings** (for plants) **or releases** (for microbes or insects) that are proposed at this location for the duration of the permit. 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. Provide a number, do not state "multiple," "many," etc.

You may propose a greater number of releases or plantings/releases than is actually planted or released to cover unexpected planting/release needs. Additional plantings/releases beyond those indicated in the permit are only authorized under a permit amendment so long as they do not extend the expiration date of the original permit.

For multiple plantings
Enter the number of plantings that will occur at this location. This is the number of times the total proposed quantity is planted in a year. For example, if the total proposed quantity is one

acre and the full acre is harvested and replanted, the number of proposed plantings is two. If the one acre is planted over several weeks and a total of one acre is harvested, the number of proposed plantings is one.

For multiple releases
Enter the number of releases that will occur at this location.

Total Proposed Quantity

Enter the maximum proposed quantity in acres that will be in the ground at any given time. For permits where the release site size is CBI, if possible, provide APHIS with a non-CBI total acreage for the entire permit (in the Comments field) to include in the State letter. For microbes and insects indicate the largest area of release. For multiple plantings/release**s**, this value should represent the area of the largest planting /release, not the sum of all the plantings/releases. The area should exclude any sexually compatible border rows of non-GE crops, if planted. 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 **Comments** field. Additional acreage is only authorized under a permit amendment.

For each location, enter a New **Contact**.

Design Protocols - Proposed Experimental Description and Production Design for Movement[2]

In the Design Protocols section describe procedures used to prevent unauthorized release into the environment and dissemination of the regulated article. Factors to consider are as follows:

Destination or Release Description for Movement

***Provide the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location; pilot project location; production, propagation, and manufacture location; proposed sale and distribution location).**

For plants
- What is the intended use?
- What are the final and intermediate destinations?

For microbes
- What is the intended use (e.g., virulence testing, DNA extraction for genetic analysis, etc.)?
- Where will it be used (e.g., laboratory, growth chamber, greenhouse)?
- Will plants be inoculated? If so, how will plants be inoculated and what plants will be inoculated?

[2] Design Protocols will be reviewed by APHIS to ensure compliance with the regulations.

- How is the pathogen dispersed?
  - If the pathogen be vectored by insects, what measures will be in place for insect control?
  - If the pathogen is splash dispersed, what actions will be taken to ensure that it is not splash dispersed?
  - If the pathogen is water dispersed, what measures will be taken to treat the water?

Confinement Protocols for Movement

General requirements. A regulated article shall not be moved unless it complies with the provisions of paragraph (b) of this section, unless a variance has been granted in accordance with the provisions of paragraph (c) of this section.[12] § 340.8(a)

Container requirements

(1) *Plants and plant parts.* All plants or plant parts, except seeds, cells, and subcellular elements, shall be packed in a sealed plastic bag of at least 5 mil thickness, inside a sturdy, sealed, leak-proof, outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(2) *Seeds.* All seeds shall be transported in a sealed plastic bag of at least 5 mil thickness, inside a sealed metal container, which shall be placed inside a second sealed metal container. Shock absorbing cushioning material shall be placed between the inner and outer metal containers. Each metal container shall be independently capable of protecting the seeds and preventing spillage or escape. Each set of metal containers shall then be enclosed in a sturdy outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(3) *Live microorganisms and/or etiologic agents, cells, or subcellular elements.* All regulated articles which are live (non-inactivated) microorganisms, or etiologic agents, cells, or subcellular elements shall be packed as specified below:

(i) *Volume not exceeding 50 ml.* Regulated articles not exceeding 50 ml. shall be placed in a securely closed, watertight container (primary container, test tube, vial, etc.) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(ii) *Volume greater than 50 ml.* Regulated articles which exceed a volume of 50 ml. shall comply with requirements specified in paragraph (b)(3)(i) of this section. In addition, a shock absorbing material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 1,000 ml. of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml. may

be placed in a single, secondary container. The maximum amount of micro-organisms or etiologic agents, cells, or subcellular elements which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

(iii) *Dry ice***.** If dry ice is used as a refrigerant, it shall be placed outside the secondary container(s). If dry ice is used between the secondary container and the outer shipping container, the shock absorbing material shall be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

(4**)** *Insects, mites, and related organisms***.** Insects, mites, and other small arthropods shall be packed for shipment as specified in this paragraph or in paragraph (b)(3) of this section. Insects (any life stage) shall be placed in an escape-proof primary shipping container (insulated vacuum container, glass, metal, plastic, etc.) and sealed to prevent escape. Such primary container shall be placed securely within a secondary shipping container of crushproof styrofoam or other material of equivalent strength; one or more rigid ice packs may also be placed within the secondary shipping container; and sufficient packing material shall be added around the primary container to prevent movement of the primary shipping container. The secondary (styrofoam or other) container shall be placed securely within an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(5) *Other macroscopic organisms.* Other macroscopic organisms not covered in paragraphs (b)(1), (2), and (4) of this section which do not require continuous access to atmospheric oxygen shall be packaged as specified in paragraph (b)(3) or (b)(4) of this section. All macroscopic organisms which are not plants and which require continuous access to atmospheric oxygen shall be placed in primary shipping containers constructed of a sturdy, crush-proof frame of wood, metal, or equivalent strength material, surrounded by escape-proof mesh or netting of a strength and mesh size sufficient to prevent the escape of the smallest organism in the shipment, with edges and seams of the mesh or netting sealed to prevent escape of organisms. Each primary shipping container shall be securely placed within a larger secondary shipping container constructed of wood, metal, or equivalent strength material. The primary and secondary shipping containers shall then be placed securely within an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength, which outer container may have air holes or spaces in the sides and/or ends of the container, provided that the outer shipping container must retain sufficient strength to prevent crushing of the primary and secondary shipping containers. § 340.8(b)

The requirements of this section are in addition to and not in lieu of any other packing requirements such as those for the transportation of etiologic agents prescribed by the Department of Transportation in Title 49 CFR or any other agency of the Federal government. Footnote 12 in § 340.8(a)

***Provide a description of the containers that will be used to transport the regulated article.**

Describe how contained movements of the regulated material will be conducted to prevent dissemination during transit, and how the regulated material will be stored at the destination facility to prevent unintended release.

- How will the regulated material be packaged?
- How will the materials be identified, labeled and segregated in transit and during storage?
- How will the regulated article be kept separate from other organisms?
- How will the regulated article be maintained in a manner so as to prevent the dissemination and establishment of plant pests?
- How will the regulated article be maintained only in areas and premises specified in the permit?
- How will the regulated article be identified with a label showing the name of the regulated article, and the date of importation?
- How will the material be identified so that persons handling the regulated articles will know that subsequent introductions (interstate movement or release not covered under the existing permit) require APHIS authorization?

The shipping container requirements described in § 340.8 must be followed. If any variation from these methods will be used, a variance must be requested and approved (see **Variance** above).

Marking and Identity

Marking and identity.
(a) Any regulated article to be imported other than by mail, shall, at the time of importation into the United States, plainly and correctly bear on the outer container the following information:
(1) General nature and quantity of the contents;
(2) Country and locality where collected, developed, manufactured, reared, cultivated or cultured;
(3) Name and address of shipper, owner, or person shipping or forwarding the organism;
(4) Name, address, and telephone number of consignee;
(5) Identifying shipper's mark and number; and
(6) Number of written permit authorizing the importation.
(b) Any regulated article imported by mail, shall be plainly and correctly addressed and mailed to APHIS through any USDA plant inspection station listed in §319.37–14 of this chapter and shall be accompanied by a separate sheet of paper within the package plainly and correctly bearing the name, address, and telephone number of the intended recipient, and shall plainly and correctly bear on the outer container the following information:
(1) General nature and quantity of the contents;
(2) Country and locality where collected, developed, manufactured, reared, cultivated, or cured;
(3) Name and address of shipper, owner, or person shipping or forwarding the regulated article; and
(4) Number of permit authorizing the importation;
(c) Any regulated article imported into the United States by mail or otherwise shall, at the time of importation or offer for importation into the United States, be accompanied by an invoice or packing list indicating the contents of the shipment. § 340.7

For import permits, refer to section § 340.7 (above) for package marking and identity during shipment.

Once the permit is issued, importation labels will be mailed directly to the applicant through the mail, generally 2-3 days after issuance.

No person shall move a regulated article interstate unless the number of the limited permit appears on the outside of the shipping container. § 340.4(c)(1)

For interstate movement permits, the permit number should be located on the outside of the package during movement under permit.

Final Disposition

***The proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations;**

- How will the regulated material be securely stored in a containment facility or devitalized in a way that will prevent persistence in the environment?
- How will the packing material, shipping containers, and any other material accompanying the regulated article be treated to prevent the dissemination and establishment of plant pests?

Design Protocols - Proposed Experimental Description and Production Design for Release[3]

Production Design

***Provide the purpose for the introduction of the regulated article including a detailed description of the proposed experimental** (e.g., observation of agronomic characteristics, laboratory research, type (if any) of commercial product, phytoremediation, mapping virulence pathways, biological control, biomass production, etc.) **and/or production design**. If the introduction is part of a product development project, provide a non-confidential statement in layman's language about the intended use of the product.

Destination or Release Description for Release

***Provide the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location; pilot project location; production, propagation, and manufacture location; proposed sale and distribution location).**

Describe where the regulated articles will be stored or grown. What will be the intended use?

Confinement Protocols for Release

[3] Design Protocols will be reviewed by APHIS to ensure compliance with the regulations.

Describe in detail the actions that will be taken throughout the duration of the permit and during the monitoring timeframe to maintain the regulated material at the release site and keep it separated from nonregulated material. Actions taken may consider the following:

Site Selection

- Can the isolation distance be maintained for the duration of the release?
- What is the proximity to sexually compatible wild or weedy relatives?
- Is the location prone to flooding, high winds, animal incursion, or public access? If such circumstances should occur, provide measures that will be taken to avoid such situations.
- Can equipment be moved between the storage facility and release sites so as to minimize the loss of containment (e.g., to reduce the distance and avoid entering other fields)?
- Can markers be placed at the release site that are readily visible and not easily dislodged so that vehicles do not knock over the markers?
- How will access to the site be restricted to avoid unauthorized access (e.g., fencing etc.).
- Can the release site be accessed during the volunteer monitoring period?

Activities During the Release

- How will the release site be identified by flags, stakes and markers; and kept separated from other planting/release sites?
- Will there be alleys between the release site and neighboring release sites sufficient to allow movement of planting/release and harvesting equipment and other farm implements in such a way that seed or vegetative propagules do not become deposited outside of the release site and mixed with other materials?
- Will there be a fallow zone immediately surrounding the release site to prevent inadvertent mixing with other nonregulated materials?
- What type of isolation methods will be employed?
- What equipment will be used (e.g. planting, inoculation, harvesting, etc.) and will it be cleaned at the release site?
- Will persons granted access to the release site be cognizant of actions that must be taken to confine the regulated article to the release site?
- If bagging or netting is used or plants are not allowed to flower, how often and during what timeframe will the plants be checked for intact bags or presence of flowers?
- How and how often will the site be monitored for deleterious effects on plants, nontarget organisms, or the environment?
- After harvest, how will the regulated material be labeled and kept separate from nonregulated material?

Plants

- Will the surrounding land be maintained free of reproductively compatible plants? The Association of Seed Certifying Agencies (AOSCA) publishes methods for maintaining seed-stock purity. These methods include temporal and spatial isolation requirements, land use history, volunteer monitoring, etc. Isolation distance standards are published in

AOSCA's "Yellow Book," which is only available online to members. However, seed isolation distances based upon AOSCA standards for most common crops are published in the Federal Seed Act Regulations (§ 201.76, see, http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title07/7cfr201_main_02.tpl). APHIS considers these requirements as a reasonable starting point for designing confinement measures. It may be prudent to allow extra distance as a safety measure. All proposed isolation distance for release sites are evaluated on a case-by-case basis.

- What methods will be used to confine the pollen to the release site? What is the frequency and duration of monitoring to ensure confinement? Such as:
  - isolation distance to sexually compatible wild or cultivated species
  - pollen or pollination-proof caging, fine mesh screen
  - bagging prior to flowering
  - border rows to dilute and/or trap transgenic pollen
  - flower removal prior to pollination
  - plant growth regulators to block reproductive development
  - temporal isolation
  - netting to prevent pollination by insects
  - use of a species, cultivar or engineered line that is sterile
- Are the seeds easily disseminated by wind, water or animals? If so what measure will be taken to confine the regulated material to the release site? Such as:
  - use of screens or levees
  - isolation from crops of the same type
  - netting or bagging to prevent access by birds or insects

Microbes – Viruses, Bacteria & Fungi

- Can transgenes be transferred out of the engineered organism to other organisms? If so, explain the mechanism and include data, if available, on the frequency and species of organisms that could be potential recipients.
- Is the pest able to move and establish itself on other species in the surrounding environment?
- Does the pest reproduce and survive on other plant species at the release site and surrounding environment?
- What strain, isolate or pathovar is being used? Will plants be inoculated?
- For greenhouse work: What are containment measures for transport of microbe between lab and greenhouse?
- How is inoculation conducted at the release site?
- How is the microbe transmitted; and what control measures are required to conduct a release?
- Will weed host plants be removed? If so, what is duration and frequency of removal?
- Secondary spread of organism:
  - Is secondary spread possible? If so, how is secondary spread controlled?
  - Can the microbe be vectored by an insect? If so, what control measures are in place to prevent insect contamination?

  - Can the organism be transmitted via seed? If so, how are seeds maintained and disposed of?
- Is disposition appropriate given the organism's life cycle?
- Will plants be inoculated?
- Will plants be transformed?
- Generally, only pathogens that are widely prevalent in the release site area are allowed to be released.
- What are containment measures for transport of microbes between lab or greenhouse and the release site?
- Only pathogens that are the same or less virulent than the wild-type are allowed to be released. A virulence test in the laboratory or greenhouse is required prior to environmental release.
- What is the host range of the organism?

Final Disposition for Release

***Describe methods to be used to destroy or devitalize the regulated materia**l after use (e.g., autoclaving, composting, chemical treatment), or how the regulated material will be returned to and maintained in a containment facility. Termination of the release into the environment must occur on or before the expiration date of the permit unless the permit has been renewed, except for multiyear permits for perennial that are renewed before the permit expires.

- After harvest, how will the regulated material be labeled and kept separate from nonregulated material?
- How will the remaining material at the release site after harvest be devitalized (e.g., turned into the ground, treated with an herbicide, etc.)?
- How long after harvest will the remaining material be devitalized?
- If there is reproductive material (viable material that could remain viable in the absence of human intervention (e.g., seeds, vegetative propagules, insects, inoculated plant material) remaining on the soil surface, what measures will be taken to ensure that they are not dispersed by wind or animal?
- In the case of woody perennial species, trees, and vines, how will the plants be devitalized (e.g., cutting and mulching, chipping, autoclaving, oven baking, or incineration, in accordance with local regulations, etc.)? How will you ensure that any underground plant parts capable of reproduction are removed and likewise devitalized?
- How will viable material be removed from the release site and moved to a containment facility?

Volunteer Monitoring

- What methods will be used to minimize the likelihood of volunteers in subsequent seasons (e.g., disking, chemical treatment etc.)?
- What will be the duration (when will it start and stop) and frequency of monitoring and removal of volunteer plants to ensure that the regulated material or their offspring will not persist in the environment?

- How will the release site and border area be marked to identify the area for volunteer monitoring?
- How will seed dormancy affect the period of time needed to monitor for volunteers?
- How will the release site and border area be used in the following growing season (e.g., growing morphologically distinct plants, fallow, growing regulated plants, etc.)?

***Supporting Documents**
If you would like to attach supporting documents to your application select **Attach Document**, including CBI and CBI-deleted versions if appropriate. All attachments should be dated and indicate a version number if appropriate.

The following types of file extensions are accepted by ePermits: txt, html, htm, doc, wp, wpd, xls, pdf, gif, jpeg, jpg, bmp, and vsd.

Permits Intended for Pharmaceutical or Industrial Use
APHIS requires additional SOPs and personnel training for plants that are engineered to produce compounds intended for pharmaceutical or industrial use (68 FR 11337-11340). See **Appendix – Pharmaceutical, Industrial and Phytoremediation Permits.**

***Application Validation**
Any required data entry boxes that are missing data will be displayed.

Certify and Submit

Before the permit application is submitted to APHIS, click the **Printable Version** tab to view your permit as a pdf to ensure that the submitted information is correct, especially with regard to the submission of CBI. If the applicant is being prepared by someone who is not the applicant, this is the stage in the permitting process where the permit application can be transferred to the applicant for signature.

Select *Certify and Submit to submit the permit application to APHIS.
Shortly after APHIS receives a permit application, APHIS assigns a permit application number to the submission. This number will be shown after the application is submitted and will be the reference number used by APHIS to refer to your application. Please note the number.

How to Find Out if APHIS Received the Permit Application?

To determine if APHIS has received the permit application, refer to the APHIS-BRS website that is updated after every business day (see, http://www.aphis.usda.gov/biotechnology/status.shtml).

How do Applicants Communicate with APHIS?

To communicate with APHIS regarding the permit, send an email to: Biotechquery@aphis.usda.gov.

After APHIS has received an application, APHIS may request more information or the applicant may wish to submit additional information to the permit application.

If the application was submitted via ePermits, and APHIS requests more information, the applicant will receive an email notice indicating to login to ePermits. If the applicant wishes to add additional information or attach new documents, the applicant can request APHIS to send the application back to the applicant via ePermits.

If the applicant sends the application outside of ePermits, and APHIS requests more information, the applicant will be asked to provide the information via email or phone. If the applicant wishes to add additional information, contact APHIS by phone or email.

How does ePermits Communicate with ePermit Applicants?

Permit applicants (not the permit preparer, if there is a permit preparer) will receive an email from ePermits to log into ePermits. The sender will be BRS_NoReply@aphis.usda.gov and the subject will be **ePermits - BRS Permit for Permit # permit number**. If there are two email addresses provided in the permit application, ePermits will only send messages to the addressed listed as email 1. The second email address may be used for communications outside of ePermits.

APHIS Actions Upon Receipt of a Permit Application

When a Permit is submitted through ePermits, an APHIS Regulatory Permit Specialist will review for administrative completeness; and then it is assigned to a Biotechnologist.

The Biotechnologist will carry out the review and evaluation which will include the following:

- Examine the inserted genetic material, the regulated article and the intended use to determine if the proper type of application has been submitted.
- Check to see if all the inserted genetic material is provided appropriately.
- Evaluate the design protocols for adequacy of confinement to the release site and of containment during movement.
- Determine if the introduction would present a risk of plant pest introduction.
- Conduct a Threatened and Endangered Species and NEPA analysis.
- When the genetic material is from a select agent, confer with the APHIS Select Agent Program.
- If the permit is for a release into the environment of a microbe engineered to control pests, confer with EPA.
- If the permit is for the movement or release of a pest, confer with APHIS PPQ.
- Determine and apply appropriate Permit Conditions and supplemental conditions.
- Prepare a state and tribe when appropriate letter for release permits that summarizes the review.

Permit Conditions

Permit conditions. A person who is issued a permit and his/her employees or agents shall comply

with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Administrator to be necessary to prevent the dissemination and establishment of plant pests:

(1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests.

(2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of plant pests.

(3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit;

(4) The regulated article shall be maintained only in areas and premises specified in the permit;

(5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article;

(6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation;

(7) The regulated article shall be subject to the application of measures determined by the Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article;

(8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the Administrator to be necessary to prevent the spread of plant pests;

(9) A person who has been issued a permit shall submit to APHIS a field test report within 6 months after the termination of the field test. A field test report shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

(10) APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences:

(i) Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article;

(ii) In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms);

(11) A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:

(i) Import or offer the regulated article for entry only through any USDA plant inspection station listed in §319.37–14 of this chapter;

(ii) Notify APHIS promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

(iii) Mark and identify the regulated article in accordance with § 340.7 of this part.

§ 340.4(f)

APHIS will apply permit conditions according to § 340.4 (f) and supplemental permit conditions that are tailored to the permitted action, the regulated article and its phenotypic expression.

After review of the permit application by the Biotechnologist and by APHIS management, the draft permit conditions will be sent electronically to the permit applicant. The responsible person must sign off on each permit condition and resubmit the permit application.

When it is determined that an application is complete, APHIS shall submit to the State department of agriculture of the State where the release is planned, a copy of the initial review and a copy of the application marked, "CBI Deleted", or "No CBI" for State notification and review. § 340.4(b)

The CBI-deleted permit application and draft permit conditions will then be sent to the State and tribe when appropriate for review and comment. When the permit application is returned from the State and further reviewed by APHIS, the permit may then be issued. When the permit is issued, applicants are notified by email.

Withdrawal or Denial of a Permit

Failure to allow the inspection of a premise prior to the issuance of a permit or limited permit shall be grounds for the denial of the permit. § 340.4(d)

Any 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. APHIS will confirm the reasons for the withdrawal of the permit in writing within ten (10) days. 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 of 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. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator. § 340.4(g)

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.

A permit application may be withdrawn by the applicant anytime after submission and prior to issuance. The request to have a permit withdrawn must be done in writing either by email or mail:

Email:
Steven.M.Bennett@aphis.usda.gov

Mail:
Animal and Plant Health Inspection Service (APHIS)

Biotechnology Regulatory Services (BRS)
Regulatory Operations Program
4700 River Rd. Unit 91
Riverdale, MD 20737

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.

Changes to a Permit after Issuance of a Permit

Change the Responsible Person for a Permit

In the event that the responsible person has changed, promptly submit the revised information to APHIS in writing either by email or mail:

Email:
BRSPermits@aphis.usda.gov

Mail:
USDA APHIS BRS ROP Permits
4700 River Road, Unit 91
Riverdale, MD 20737

If major changes to the application need to be made prior to the introduction but after the issuance of a permit, such as additional constructs or lines, additional destinations for introduction of the regulated article or new release sites, applicant could submit an amendment to an already issued permit, or submit a new permit. See **Amendments** above.

Decision Not to Carry Out the Release

Following issuance of the permit, if the applicant decides not to carry out a release into the environment, the responsible party shall notify APHIS in the planting/release report of any sites that will not be planted. Responsible parties are encouraged to report to APHIS decisions not to release in a timely manner to avoid APHIS inspections of releases that did not take place.

Notification of Unusual Occurrences or Unauthorized or Accidental Release

APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences:

i. Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article;
ii. In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms). § 340.4(f)(10)(i-ii)

The applicant is required to notify APHIS of any unusual occurrences associated with the introduction of regulated articles under permit. In the event of any accidental or unauthorized release of the regulated article, the applicant must orally notify APHIS immediately, and in writing within 24 hours. Events that may require immediate action include, but are not limited to: potential dispersal of regulated material outside the approved area of introduction by high winds or flooding, accidental release of the regulated article in the wrong location, planting/release of a variety with an unauthorized construct, damaged packaging materials, or materials lost in shipping.

If the regulated organisms are observed to have any characteristics that are different from those described in the permit application—particularly those characteristics related to plant pest risk—the applicant must notify APHIS in writing within five working days. Any unexpected changes in the plant's phenotype should be reported. Additionally, any unexplained effects on plant heath such as crop failure or significant plant death, or unexpected impacts on non-target organisms, should be reported.

If a release site is damaged or destroyed to the extent that the release is prematurely terminated, a written report of the unusual occurrence must be submitted to APHIS. Further, APHIS recommends that the damage or destruction be included with the required field test report (see **Reports and Notices** below). Indicate clearly that the report is both a report of an unusual occurrence and the final field test report.

In the event of any of these unusual occurrences, contact APHIS as described in the permit conditions. Failure to notify APHIS of unusual occurrences in the required time frames can result in legal action, civil penalties, or criminal charges.

Compliance and Inspection

Any regulated article introduced not in compliance with the requirements of this part shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary to prevent the introduction of such plant pests. § 340.0(b)

An inspector may hold, seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of plants, plant pests, or other articles in accordance with sections 411, 412, 421, and 434 of the Plant Protection Act (7 U.S.C. 7711, 7712, 7731, and 7754).
Footnote 2 in § 340.0(b)

An inspector may inspect the site or facility where regulated articles are proposed, pursuant to a permit, to be released into the environment or contained after their interstate movement or importation. Failure to allow the inspection of a premise prior to the issuance of a permit or limited permit shall be grounds for the denial of the permit. § 340.4(d)

An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article; § 340.4(f)(5)

All introductions under permit are subject to inspection. Access to records, release sites and related facilities (e.g., buildings for equipment, seed storage, processing, disposal, etc.) must be provided when requested by authorized personnel. Authorized inspectors may include persons from APHIS and/or State regulatory officials. An inspector may hold, size, quarantine, treat, and apply other remedial measures necessary to prevent the spread of plant pests.

All permits receive at least one inspection within each State where a release occurs. Plants engineered to produce pharmaceutical or industrial proteins are inspected seven times (before, during, and after the release). These inspections are performed at critical times during release, including: prior to release, during planting/release, during flowering, during harvest/termination, and post-harvest. APHIS maintains a comprehensive database that captures and tracks inspection-related information to assure that all required inspections are accomplished for each permit.

For more information on inspections,
see, http://www.aphis.usda.gov/biotechnology/compinsp_process.shtml.

Reports and Notices

A report is the submission of required information; a notice is the alert of some action to occur in the near future. For what reports (e.g., unintended effects, planting or environmental release, field test, volunteer monitoring, etc.) and notices refer to:

- For information on what, when, and how to submit the reports and notices, refer to the permit conditions.
- For additional information on submitting planting/environmental release reports refer to **Appendix - Planting and Environmental Release Reports** and **Appendix - Consolidated Monthly Planting and Reports**
- For information on what to include in these reports and notices and how and when to submit the reports and notices through ePermits, consult the permit conditions and the guidance provided in the "ePermits BRS Reports and Notices User Guide" (see https://epermits.aphis.usda.gov/epermits/xml_schema/BRS_Reports_and_Notices_User_Guide.pdf)
- Termination is typically defined by harvesting or destroying the regulated article(s). Because APHIS does not always know the actual termination date in advance, APHIS considers the field test report to be due no later than six months after the expiration of the permit.
- For multiyear permits, the field test data report is due even if the permit has been renewed.

Records

The responsible person shipping a regulated article interstate shall keep records for one year demonstrating that the regulated article arrived at its intended destination. § 340.4(c)(1)

The responsible person importing a regulated article shall keep records for one year demonstrating that the regulated article arrived at its intended destination. § 340.4(c)(2)

Applicants who have received permits for importation and interstate movement must keep records for one year demonstrating that the regulated article arrived at its intended destination.

Version History

1992	Section III. Sample Application for Release Into the Environment.
7/9/2008	Guidance for APHIS Permits for Field Testing or Movement of Organisms Intended for Pharmaceutical or Industrial Use
3/7/2012	Combines and updates previous guidance documents