

**USDA-APHIS Biotechnology Regulatory Services**

**Permit User's Guide**  
**With Special Guidance for ePermits**

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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](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.<sup>1</sup>
- § 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.*<sup>4</sup>

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](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](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](mailto: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](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](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](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/](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](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.<sup>7</sup> 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](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](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

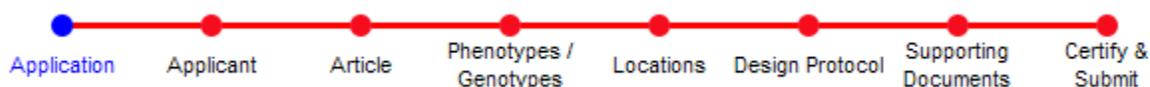
Users (permit applicants) are required to sign up for an eAuthentication account to access ePermits. An eAuthentication account consists of a User ID, a password, and your customer profile which contains information about you that will allow USDA to confirm that you have the correct permissions to view 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](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](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](mailto: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](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\\_Permits\\_DATA\\_TABLES\\_2\\_0.doc](https://epermits.aphis.usda.gov/ePermits/XML_SCHEMA/BRS_Permits_DATA_TABLES_2_0.doc)
- Contact ePermits Help desk if you are experiencing difficulties with [ePermitsHelp@aphis.usda.gov](mailto:ePermitsHelp@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](mailto: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](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 not 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<sup>1</sup>

### 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

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<sup>1</sup> 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](mailto: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](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](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](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.

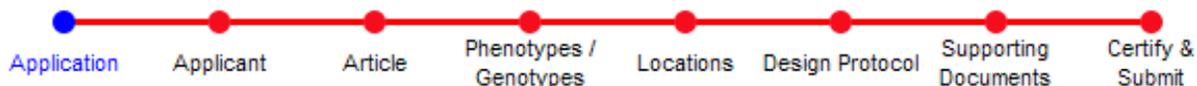
## Application Submission - Data Requirements

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](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](http://www.aphis.usda.gov/brs/fedregister/BRS_20030806a.pdf); 70 FR 23009-23011, [http://www.aphis.usda.gov/brs/fedregister/BRS\\_20050504a.pdf](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](mailto: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 Type**

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 Name**

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 Donor**

- 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/releases, 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<sup>2</sup>**

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?

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<sup>2</sup> 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.<sup>12</sup> § 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<sup>3</sup>**

#### **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**

<sup>3</sup> 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](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 material** 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](mailto: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](mailto: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 health 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](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](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)
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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

## Appendix - Guidance for Critical Habitat Analysis

### Required for Submitting Release Permits

Question: *Is the release site and/or the area requiring monitoring referred to as the action area (or the area within the boundaries of the possible release/monitoring area for sites where the release 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)?*

Guidance: The United States Fish and Wildlife Service (USFWS) is developing a database for public use that will provide current information on the status of critical habitat including spatial data. However, this tool is not yet fully functional and does not provide all data. For now, there is information available on the USFWS endangered species website (<http://www.fws.gov>) that can be used to locate critical habitat in relation to the field release site. However, the site has limitations. The critical habitat portal accessed through the site provides data to the county level, but it is incomplete. The critical habitat portal also has a mapping feature that can be used to provide more detail on the geographic location of the habitat; however, not all spatial information is available on the website and reliance on the mapping feature alone will not provide data that ensures compliance with the Act. It may be best to use the link to the webpage of the various USFWS Ecological Field Offices for more accurate information. Some local offices provide detailed critical habitat information on their websites that can be very useful. If in doubt, the office should be contacted. Below is a method that can be used to determine the presence of designated critical habitat and a couple options for determining the presence of proposed critical habitat. Their use will assure identification of critical habitat within the action area. Knowing the precise boundaries of the action area will make determinations easier. Applicants may use any method they chose provided it identifies all designated critical habitat and habitat proposed for designation within the action area.

#### To obtain information on species with designated critical habitat:

1. Go to the USFWS website (<http://www.fws.gov>) and navigate to the endangered species listing by State to view all listed species in the state.
2. Navigate to the list of all species with designated critical habitat to identify those species within the State that have critical habitat.
3. For those species that have critical habitat, use the species link to navigate to the Federal Register final rule designating the critical habitat for that species. This will provide specific information about the location of the critical habitat.

#### To obtain information on species with proposed critical habitat:

The USFWS website does not provide a listing of proposed critical habitat, making this task more difficult. Below are possible methods:

##### Method A.

1. Go to the USFWS website (<http://www.fws.gov>) and navigate to the link for species proposed for listing.

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2. Follow the link for individual species to the Federal Register notices for these species. Look for one proposing designated critical habitat and look to see if the release site and/or monitoring area are geographically included in the proposed designation. This will identify proposed critical habitat for species proposed for listing.
3. USFWS sometimes proposes designated critical habitat for species that have already been listed, and sometimes the rule for listing the species may be final while the decision on critical habitat is still pending. To look for these, go to the USFWS webpage that provides a State by State list of all listed species within a given state.
4. For each species, use the species link to search for a Federal Register notice proposing critical habitat and review the document to see if the release site or monitoring area are geographically included in the proposal.

Method B. Another and perhaps easier way to determine if the release site and/or area requiring monitoring is in proposed designated habitat is to look at the USFWS centralized library for Federal Register Documents. This method will likely be easier for states with many listed species.

1. Go to the USFWS website (<http://www.fws.gov>) and navigate to the endangered species listing by State to view all listed species in the state.
2. Navigate to the endangered species program page and to the link for "Laws and Policies." Follow the link to the USFWS centralized library for Federal Register Documents and look under proposed rules for the species identified in step 1.
3. For each species, search for a Federal Register notice proposing critical habitat and review the document to see if the release site or monitoring area are geographically included in the proposed designation. Caution: The USFWS guidelines are to reach a determination on designating the habitat as critical within one year of the proposal. However, this target is frequently not met and some may be pending for years. To assure compliance, it will be necessary to look back several years.

Perhaps the best method that can be used to obtain information on designated critical habitat and proposed critical habitat for a given area is to directly contact the USFWS. Links to the various USFWS regional and field offices can be found at <http://www.fws.gov>.

It is important to note that critical habitat is not limited to the geographical area occupied by the species at the time of listing, but may include other areas if determined to be essential for the conservation of the species. Critical habitat may be unoccupied for a number of reasons including the extirpation of the species from this portion of the range. Critical habitat may be in areas unsuitable for the species, but may be restored to suitability with proper management. Some critical habitat may never be occupied by the species, but was designated or proposed because it is essential for conserving the species by maintaining factors constituting the species' habitat. An example would be designating the headwaters of a stream as critical habitat in order to provide sufficient water quality for a species living downstream.

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*Question: If "Yes" to the above question, provide the genus/species name and common name for all species that have designated critical habitat or habitat proposed for designation within the release site and monitoring area.*

Guidance: Self explanatory.

*Question: If "Yes" to above question, provide an analysis of the effects of the proposed release on designated critical habitat and habitat proposed for designation. Indicate if the proposed release will have "no effect" or "may affect" the designated critical habitat and/or habitat proposed for designation.*

Guidance: Generally, if a release site is actually in or very near critical habitat, it may be best to use an alternate site. If this is not practical, the release site could still possibly be used if an effects analysis determines that the release will have "no effect" on the critical habitat.

The focus of the effects analysis should be on the habitat's constituent elements, not on the presence of the species. The Federal Register notice that designates particular critical habitat provides useful information on the constituent elements (biological and physical attributes that are essential to the species' conservation, such as: space; food, water and nutrition; cover or shelter; reproduction; and special habitats) that were the reason for the decision to designate or propose the habitat as critical. However, some critical habitat designations predate the requirement for identification of constituent elements or habitat qualities necessary to allow a species to survive and recover from the threat of extinction. In such cases, the analyst should use the best available scientific and commercial data to determine and document those characteristics of the designated or proposed critical habitat that support the species' survival and recovery.

If the constituent elements are not found in the release site and area being monitored, it is possible that the release would have "no effect." If the release site and area being monitored does contain constituent elements of the habitat, a "may affect" determination may be appropriate. The nature of the regulated article, related activities within the action area (staging, processing etc.), past and current land use activities, and the constituent elements of the designated habitat should be considered. Generally, it would be expected that if a release site is currently in agricultural production, there would be no effect on the habitat because there would be no change in the use. However, this needs to be carefully reviewed, as each situation is different. The nature and activities of the field trial in comparison to prior agricultural use should be considered and discussed, especially if they are a key factor supporting the final determination.

Keep in mind that the "action" includes all aspects of the release and field trial including interdependent actions (having no independent utility apart from the proposed action) and interrelated actions (part of a larger action and depend on the larger action for justification). The analysis must consider both the direct (immediate) and indirect (later in time, but reasonably certain to occur) effects.

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The effects analysis will result in either a “no effect” or “may affect” determination for the effect of the action on designated critical habitat. In supporting the determination, focus on the effects on the constituent elements of the habitat, not on the effect on the species. A “no effect” determination is made when the proposed action will not affect the designated critical habitat. “May affect” is an appropriate determination when a proposed action may have any effect on the designated critical habitat, even if they are entirely beneficial. If a “may affect” determination is reached, it must be determined if the action is likely or not likely to adversely affect the designated critical habitat. A “may affect, not likely to adversely affect” determination is appropriate when effects on designated critical habitat are expected to be discountable, insignificant, or completely beneficial. Discountable effects are those that are extremely unlikely to occur. Insignificant effects relate to the size of the impact. An example of this would be a situation where runoff from an agricultural field would have an effect on a constituent element of the habitat, but the field release is so minor compared to other agricultural activities in the vicinity that the added effect of the field release would be immeasurable. Beneficial effects are positive effects without any adverse effects (there can be no “balancing” wherein the benefits of the action would be expected to outweigh the adverse effects). APHIS reviews the analysis that is provided.

APHIS will be required to consult with USFWS for any “may affect” determination on designated critical habitat. If the determination is “may affect, not likely to adversely affect,” an informal consultation with USFWS is required. Failure to obtain USFWS concurrence with this determination requires initiation of formal section 7 consultation as does reaching a “may affect, likely to adversely affect” determination. This determination is appropriate when the effect of the action is not discountable, insignificant, or beneficial or the overall effect is beneficial, but is also likely to cause some adverse effects. The formal consultation process will end with a decision by the USFWS (usually written in a Biological Opinion) on whether the action will result in adverse modification/no adverse modification of designated critical habitat.

For habitat proposed for designation, a conference with USFWS is required if the action is likely to “adversely modify” the proposed critical habitat, as opposed to the lesser threshold of “may affect” when dealing with habitat currently designated as critical habitat. The term “adverse modification” is defined by USFWS as the direct or indirect alteration that appreciably diminishes the value of critical habitat for the conservation of the species. The modification to the habitat must have the effect of jeopardizing the existence or recovery of a species. Generally, it must affect all proposed designated critical habitat or a part that is vital for survival of the species.

### **The final analysis report should include the following:**

- a. A list of species in the release area and monitoring area that have designated critical habitat.
- b. A list of species in the release area and monitoring area that have critical habitat proposed for designation.

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c. For each species, an effects analysis of the action on the critical habitat. Provide a brief description of the critical habitat including its constituent elements. Focus on the effect of the action on the “constituent elements” that are essential to the species. Include all activities that will be part of the action including mobilization, harvesting, processing, and demobilization.

d. Explain any proposed measures to reduce or avoid impacts.

e. Conclusions for each species, a determination of “no effect” or “may affect” designated critical habitat. If a “may affect” determination is reached, it must be determined if the action is likely or not likely to adversely affect the designated critical habitat. For proposed designated critical habitat, determine if there is “adverse modification” to the habitat or “no adverse modification.”

f. Literature cited.

g. List of preparers with contact information.

h. Maps, diagrams, photos if appropriate.

### Version

12/14/2011

Updates hyperlinks of Guidance Related to Critical Habitat Analysis available at <http://www.aphis.usda.gov/biotechnology/permits.shtml>.

## Appendix - Pharmaceutical, Industrial and Phytoremediation Permits

In 2003, APHIS modified its permit confinement measures and procedures to verify compliance and to enhance the transparency for permits intended for pharmaceutical and industrial use to include: a larger perimeter fallow zone (50 ft); cleaning of field equipment and storage facilities using APHIS-approved procedures; dedicated planting and harvesting equipment and storage facilities; planting restrictions in the subsequent growing season; APHIS approved training; and additional compliance and inspection oversight by APHIS (68 FR 11337-11340).

As part of a government-wide effort to increase transparency, APHIS posts to its website a NEPA document (including EA and EIS) and the Supplemental Permit Conditions for Pharmaceutical, Industrial, and Phytoremediation permits, see [http://www.aphis.usda.gov/brs/ph\\_permits.html](http://www.aphis.usda.gov/brs/ph_permits.html).

### Additional Data Requirements

Additional information is required for the submission of permits intended for pharmaceutical and industrial use as follows:

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

Additional information is required for the submission of permits intended for phytoremediation use as follows:

## Appendix - Pharmaceutical, Industrial and Phytoremediation Permits

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

### Confinement Measures

*APHIS will institute the following changes in field test permit conditions for pharmaceutical corn.*

A. APHIS will require that there will be no corn grown within 1 mile (5,280 feet) of the field test site throughout the duration of any field test which involves open-pollinated corn. This establishes a physical isolation distance that is eightfold greater than the isolation distance required for the production of foundation seed (660 feet). When pollen flow is controlled by placing bags around the corn tassels there will be no other corn within 2,640 feet of the field test site and the pharmaceutical corn must be planted no less than 28 days before or 28 days after any corn growing in a zone extending from 2,640 to 5,280 feet from the field test site ensuring there is no overlap in anthesis.

B. With the establishment of isolation distances of 1 mile for open pollinated corn and one-half mile for controlled pollination corn field tests, APHIS will not allow the use of border rows to reduce these isolation distances. APHIS believes that other methods are available and do not pose the difficulties inherent in using border rows. For example, by eliminating the use of border rows/buffer strips there will be a reduction in the amount of plant material that must be disposed of after the field test is terminated (border rows are handled the same as the regulated article as their proximity to the plots make them possible pollen recipients). This should reduce the possibility of inadvertent mixing of regulated articles with nonregulated plant material. 68 FR 11337-11340 (II)(2)(A)

APHIS requires greater confinement measures for pharmaceutical and industrial corn.

### Perimeter Fallow Zone

APHIS will increase the size of the perimeter fallow zone (not in production) around the field test site from 25 to 50 feet. This measure is designed to ensure that test plants are not inadvertently commingled with plants to be used for food or feed. APHIS currently prohibits the use of the field test site and its perimeter fallow zone to be used to produce food or feed crops during the tests. APHIS increased the size of the perimeter fallow zone around the test site to allow farm machinery to move around the site and yet still prevent physical mixing of the regulated plants with surrounding plants that may be used for food or feed. 68 FR 11337-11340 (II)(1)(A)

## **Appendix - Pharmaceutical, Industrial and Phytoremediation Permits**

To prevent regulated plants from inadvertently commingling with plants to be used for food or feed, a perimeter fallow zone of at least 50 ft. must be maintained around the release site in which no crops are grown to be harvested or used for food or feed. Plants may be grown in the 50 ft. fallow zone, as long as they are not used for food or feed.

### **SOPs and Cleaning of Field Equipment and Seed Cleaning and Drying Equipment**

APHIS will require cleaning procedures to be submitted and approved to minimize the risk of seed movement by field operations or equipment (movement of seed on tires of tractors, etc.) from the authorized test site.

APHIS will require procedures to be submitted and approved for seed cleaning and drying in order to confine the plant material and minimize the risk of seed loss or spillage. 68 FR 11337-11340 (II)(1)(E-F)

Submit Standard Operating Procedures (SOPs) that describe how a particular task or operation will be carried out. Processes described in the SOPs should be followed for the duration of the permit and post-harvest monitoring period. If the permit is a renewal, indicate what changes were made and what additional equipment was added to the SOP. SOPs must be dated or have a version number. SOPs must be submitted and approved by APHIS for equipment cleaning.

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

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

### **SOPs and Restrictions for Dedicated Planting and Harvesting Equipment**

APHIS will require that planters and harvesters be dedicated to use in the permitted test site(s) for the duration of the tests. In addition, while tractors and tillage attachments, such as disks, plows, harrows, and subsoilers, do not have to be dedicated, they must be cleaned in accordance with protocols approved by APHIS (see item II.1.E). To ensure the regulated articles are not inadvertently removed from the site, APHIS authorization will be required before the machinery is used elsewhere. 68 FR 11337-11340 (II)(1)(C)

## **Appendix - Pharmaceutical, Industrial and Phytoremediation Permits**

To prevent the regulated article from being inadvertently removed from the site, planting and harvesting equipment must be dedicated for use in the permitted release site(s) from the time of planting through the end of harvesting. After use in the pharma release(s) is complete, dedicated planters and harvesters must be thoroughly cleaned and inspected by APHIS before being returned to general use.

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

Permission must be granted by APHIS (with a determination made by the APHIS inspector) before planting and harvesting equipment can be used on any sites planted to crops not included under this permit. The permittee must submit a notice to APHIS and the State Regulatory Official at least 21 calendar days in advance of cleaning this equipment so that APHIS can complete an inspection to ensure that the equipment has been cleaned appropriately. This is done by submitting a Cleaning notice (Return to General Use Notice) through ePermits, email, FAX or mail.

### **In addition to the information required for Cleaning of Field Equipment and Seed Cleaning and Drying Equipment SOPs, provide the following information in the SOPs for dedicated equipment (i.e., planters and harvesters):**

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

### **Dedicated Storage Facilities for Equipment and Regulated Articles**

APHIS will require the use of dedicated facilities for the storage of equipment and regulated

## **Appendix - Pharmaceutical, Industrial and Phytoremediation Permits**

articles for the duration of the field test. Facilities must be cleaned according to APHIS approved protocols prior to general use of the facilities. 68 FR 11337-11340 (II)(1)(D)

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

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

### **Post Harvest Land Use Restrictions**

APHIS will restrict the production of food and feed crops at the field test site and perimeter fallow zone in the following season in cases where there is a potential for volunteer plants to be inadvertently harvested with the following crop. 68 FR 11337-11340 (II)(1)(B)

Production of food and feed crops at the release site and the perimeter fallow zone is restricted during one or more growing seasons following harvest or termination of the release. This is done to ensure that volunteer plants are adequately monitored for and controlled to prevent mixing with other commodities and persistence in the environment. The same release site may be used in subsequent years for pharma production (for pharmaceutical or for industrial use) under permit. Authorization must be obtained from APHIS prior to planting any food or feed crop at the release site and perimeter fallow zone during the post-harvest monitoring period. Requests for such authorization are not encouraged and will not be granted in cases where there is a reasonable potential for the regulated articles to become mixed with the proposed food or feed crop during harvesting.

### **Personnel Training Program**

APHIS will require the permittee to implement an approved training program to ensure that personnel are prepared to successfully implement and comply with permit conditions. 68 FR 11337-11340 (II)(1)(G)

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

## Appendix - Pharmaceutical, Industrial and Phytoremediation Permits

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

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

- The regulations at 7 CFR 340 for release, interstate movement, and importation as applicable to the permittee's activities:
  - sections 7 CFR 340.4 (a)-(f), 7 CFR 340.7 and 7 CFR 340.8
    - <http://www.aphis.usda.gov/biotechnology/regulations.shtml>
  - FR Notice (68 FR 11337-11340) on Field Testing of plants Engineered to Produce Pharmaceutical and Industrial Compounds
    - [http://www.aphis.usda.gov/brs/fedregister/BRS\\_20030310a.pdf](http://www.aphis.usda.gov/brs/fedregister/BRS_20030310a.pdf)
  - Plant Protection Act [7 U.S.C. 7734 (Sec. 424)] that address the consequences of noncompliance
    - <http://www.aphis.usda.gov/biotechnology/regulations.shtml>
- The training should include all aspects related to permit activities including those described in the permit, the standard permit conditions, the supplemental permit conditions and the SOPs.
- The training should include methods for inspecting, monitoring, and recording activities that are undertaken to meet the conditions of the permit. For example, this could include monitoring or reporting forms, seed inventory and transport forms, third party auditing, or witness verification that critical procedures were performed according to SOPs and/or permit conditions.
- The training program should be applicable to all personnel who handle, store, perform field activities with, or transport regulated articles, or who are responsible for regulatory affairs, or those who manage these activities.
- Personnel should know who has authorized access to the release site and other restricted areas. Persons having access should receive training that addresses site security and how to prevent unauthorized access to regulated articles.
- Personnel should be made aware of reporting requirements for accidental or unauthorized releases and appropriate remedial measures to address spills or loss of containment of regulated articles.

### Compliance and Inspections

In order to ensure compliance with the regulations as well as all permit conditions APHIS will increase the number of field site inspections during the upcoming growing season to correspond with critical times relevant to the confinement measures. Examples might include inspection at the preplanting stage to evaluate the site location; at the planting stage to verify site coordinates

## Appendix - Pharmaceutical, Industrial and Phytoremediation Permits

and adequate cleaning of planting equipment; at midseason to verify reproduction isolation protocols and distances; at harvest to verify cleaning of equipment and appropriate storage; at post-harvest to verify cleanup at the field site; and for the following growing season inspections will be timed to ensure that regulated articles do not persist in the environment. For example a field test may have five inspections during the growing season and two additional inspections postharvest; however APHIS may inspect more frequently in some cases.

The permittee must as always maintain records of activities related to meeting the permitting conditions. APHIS will increase the auditing of the permittee's records to verify that required permit conditions were accomplished. APHIS will continue to require permittees to regularly inspect sites and maintain accurate records that will be available for APHIS auditing. The permittee will be required to record all efforts undertaken to meet the confinement protocols and other permit conditions. Some of this information will be related to agronomic information (i.e. detasseling, pollination time of test crop, pollination time of surrounding crops, etc.). Frequent APHIS audits will enable the Agency to identify any discrepancies and mitigate any potential adverse effects. 68 FR 11337-11340 (III)

To ensure compliance with regulations and permit conditions, APHIS's policy for pharmaceutical and industrial releases is to conduct inspections at critical control points in the production cycle of the regulated article. Generally, seven inspections of the release are performed. These inspections usually occur prior to planting/microbe inoculation, during planting/microbe inoculation, during active growth (generally at mid-season), at harvest, and after harvest. Two inspections are conducted at the same site the following season to monitor for volunteer plants.

For perennial plants, inspections may be different than that of annual plants depending on the biology of the species. Generally, sites are inspected prior to planting/release and during planting/release. The release is usually inspected during the period when volunteer plants usually emerge or when flowering is expected each year. Harvest and post-harvest inspections are performed in the year in which these activities occur. Site inspections for volunteer monitoring occur in year one or year two following the harvest of the regulated plants to ensure they do not persist in the environment.

As part of a government-wide effort to increase transparency, APHIS posts to its website redacted notices of inspection findings summarizing the results of permit inspections for Pharmaceutical, Industrial, and Phytoremediation permits, see [http://www.aphis.usda.gov/brs/ph\\_permits.html](http://www.aphis.usda.gov/brs/ph_permits.html).

### **Records and Record Audits**

## Appendix - Pharmaceutical, Industrial and Phytoremediation Permits

The permittee must, as always, maintain records of activities related to meeting the permitting conditions. APHIS will increase the auditing of the permittee's records to verify that required permit conditions were accomplished. APHIS will continue to require permittees to regularly inspect sites and maintain accurate records that will be available for APHIS auditing. The permittee will be required to record all efforts undertaken to meet the confinement protocols and other permit conditions. Some of this information will be related to agronomic information (i.e., detasselling, pollination time of test crop, pollination time of surrounding crops, etc.). Frequent APHIS audits will enable the Agency to identify any discrepancies and mitigate any potential adverse effects. 68 FR 11337-11340 (III)

APHIS audits records and verifies compliance with the conditions imposed in permits. See the section on Compliance and Inspections in the Permit Guidance for further information. Records of who has been trained, for what activity, and when they were trained should be maintained.

### Reports and Notices

Additional Reports and Notices are required for permits designed for pharmaceutical and industrial intent. A report is the submission of required information; a notice is the alert of some action to occur in the near future.

- For information on what reports must be submitted, when and where and how to submit the reports, refer to the permit conditions.
- For additional information on submitting planting/environmental reports refer to **Appendix –Planting/Environmental Reports and Appendix - Consolidated Monthly Planting/Release Report Submission Formats for Applicable Organizations**
- 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](https://epermits.aphis.usda.gov/epermits/xml_schema/BRS_Reports_and_Notices_User_Guide.pdf) )

### **Version**

7/9/2008	“Guidance for APHIS Permits for Field Testing or Movement of Organisms Intended for Pharmaceutical or Industrial Use”
12/7/2011	“USDA-APHIS-BRS User’s Guide Permit, Appendix - Pharmaceutical, Industrial and Phytoremediation Permits” supersedes “Guidance for APHIS Permits for Field Testing or Movement of Organisms Intended for Pharmaceutical or Industrial Use” Version 7/9/2008

## Appendix – Planting and Environmental Release Reports

### Introduction

This appendix clarifies and describes the planting/release information APHIS requires for environmental releases conducted under the permit process. Planting/release information (i.e., location, size and date) must be provided when a permit is submitted to APHIS prior to planting/release or outdoor placement of plants or environmental subject to these regulations.

A report is the submission of required information; a notice is the alert of some action to occur in the near future.

- For information on what, when and how to submit all reports and notices, refer to the permit conditions.
- For information on reports and notices submitted through ePermits, also consult “ePermits BRS Reports and Notices User Guide” (see [https://epermits.aphis.usda.gov/epermits/xml\\_schema/BRS\\_Reports\\_and\\_Notices\\_User\\_Guide.pdf](https://epermits.aphis.usda.gov/epermits/xml_schema/BRS_Reports_and_Notices_User_Guide.pdf)).
- If CBI is involved, submit both a CBI and CBI-deleted version.

APHIS allows planting/release information to be provided in two stages in order to meet the permit requirements as stated in 7 CFR 340.4. At the time of submission of a permit, certain general information about each planting/release location is allowed. However, specific information must be provided in one or more subsequent planting/release reports.

The information in this appendix is intended for all applicants, especially those who do not include specific planting/release location information in their original permit.

### Submission of Planting/Release or Other Environmental Release Information

For plants, there are three types of environmental releases under permit: plantings of seed, transplanting of plants, and the outdoor placement or transplanting of plants grown in containers. For each of these releases, defined here as “planting” events, a planting report is required so that the location, size, and duration of all plant environmental releases are known. An historical synonym for a planting report is a “post-planting report.”

For microbes or insects, an environmental release (release) occurs each time the regulated article is released into the environment.

Environmental release information supports three critical APHIS regulatory functions. It is used to (1) evaluate the permit and other analyses for the planned environmental release, (2) verify compliance through inspections, and (3) monitor and respond to regulatory incidents, and emergency management situations, such as severe weather events.

As stated in the regulation, APHIS requires three types of information related to the environmental releases under permit. They are the location, size of planting/release, and date of the environmental release. This information must be provided when the permit is submitted to APHIS prior to environmental release. However, a permit is typically submitted many months

## Appendix – Planting and Environmental Release Reports

prior to the expected date of release, which has made it difficult for the responsible person to predict, and for APHIS to know, the exact release site, size, and release date at the time the permit was submitted. In order to meet this requirement, APHIS allows this information to be provided in two stages.

In the first stage, the State and County of each location, at least one GPS coordinate, a maximum planted area, and the proposed start and end dates of the release are provided with the permit application. This information shall be sufficient for APHIS permit review and TES and NEPA analysis.

In the second stage, following permit issuance, the actual location (which must be situated within the State and County authorized), size of the planting/release and planting/release date must be submitted in a planting/release report within the required time frame. Each of these planting/release reports must be submitted according to the permit conditions and must include the data described below. Note, however, that the permit applicant may define a planting/release and its associated start date in ways that are meaningful, convenient, or important to their processes. Regardless of how each planting/release is defined, its corresponding planting/release report must include the required information.

Submit the information requested to APHIS as in the Supplemental Permit Conditions. Below is additional information on what to submit and when to submit the planting/release reports.

### **Planting/Release Reports: What to Submit**

**1. Location.** The location must be assigned, by the applicant, a Location Unique ID that exclusively identifies one release site for the location described in the permit. The Location Unique ID is used, among other reasons, to link all reports for the same release site. If this Unique ID has been assigned previously as part of the permit submitted via ePermits, then the same Unique ID must be used in the planting/release report. The Unique ID may be meaningful words or a coded string of alphanumeric characters. The same Unique ID may be used for the same location on different permits (or notifications), but must be unique within each permit (or notification).

The location must be described either in the form of at least one (and no more than six) GPS coordinate(s) for the release site. If only one required GPS coordinate is provided, it must define the northwest corner, or the northwestern-most point, of the planting/release.

**2. Planting/Release Unique ID.** If more than one planting/release is to be made at this location (e.g., different times or different release sites within the same location) under this permit, provide a planting/release Unique ID. This identifier typically will be used to designate different release sites planted/released at different times within temperate locations, or for different planting/release times on the same release sites within tropical locations. A single planting/release may span several days. An extended planting/release period—planned or unplanned (e.g., poor weather)—may be divided into two or more plantings/releases that each

## Appendix – Planting and Environmental Release Reports

have a different planting/release Unique ID. The planting/release Unique ID may be meaningful words or a coded string of alphanumeric characters, such as “P1” or “planting\_n” or “release\_n”.

**3. Planting/release start date.** The date of each planting/release occurrence in the relevant release site (i.e., with this Location Unique ID) must be provided.

**4. Size of release.** The applicant must report the amount of regulated material planted or otherwise released in acres. In most cases, the applicant must provide the area occupied only by the regulated article(s) for the planting/release occurrence on the planting/release date. Border rows may optionally be included in the reported area; however, the acres planted/released over all planting/release occurrences must sum to be equal to or less than the authorized area provided in the issued permit. Consequently, it is possible to exceed the allowable acreage if border rows are included in the reported area.

Note that total area planted/released (regulated plus border rows, etc.) may be provided optionally in addition to area planted/released only to the regulated article(s).

### Report Only New Information

When providing a planting/release report, submit only previously unreported planting information; do not submit previously reported plantings/releases on the same site unless it is a new planting/release.

### Report Sites Not to be Planted or Released

Identify in planting/release reports any release sites included in the permit that will not be planted at all under the permit. Identify these sites as soon as you know that they will not be planted.

Do not identify sites as “not planted” or “not released” if they will be, or are likely to be, planted/released later under the permit. Only note a site as “not planted” or “not released” in a planting/release report if you are certain no planting/release will occur at a given site before the permit expires. All sites must be accounted for in the Final Planting/Release Report that is submitted within 6 months after the end of the release.

### Planting/Release Reports: Due Date

All required planting/release information must be provided in a report, preferably as an electronic file according to the permit conditions. When multiple plantings/releases are made under a single permit, a planting/release report must be submitted for each planting/release; however, the permit holder may actually define these as one or more plantings/releases, depending on factors that are meaningful, convenient, or important to their processes. For example, if two plantings/releases are made during the month of May, the planting/release information may be submitted in either one or two reports.

In general, APHIS currently uses the date of submission stated on a planting/release report as the date of receipt. This is the practice for both electronically and conventionally mailed reports.

## **Appendix – Planting and Environmental Release Reports**

Consequently, if the date on a planting/release report, or its attached cover letter, memorandum, email, or postmarked envelope is no later than the date provided in the permit conditions, the report will be deemed on time unless there is reason to believe the date is not accurate. If no date of submission appears on or with the report, then a verifiable tracking report from the delivery service will be used to determine the actual date of submission (i.e., the date sent). When there is no date on or with the planting/release report and no tracking record available, APHIS will use the actual date the report was received by APHIS as the date of receipt.

### **For Multiple Plantings (Plants) or Releases (Microbes)**

If the plantings/releases occur with more than 30 days in between, these should appear on separate planting/release reports; however, for reporting purposes, the permit holder may define separate plantings/releases that occur at intervals shorter than 30 days.

### **Examples of Non-Compliance**

#### **1. Required report “late”**

If APHIS does not receive a planting/release report containing the required information by the date in the permit conditions the report will be deemed late.

#### **2. Required report “not provided”**

If APHIS does not receive a planting/release report containing the required information 31 or more days after the due date, the requirements specified in 7 CFR 340.4(b) have not been met, and the absent report will be considered a compliance infraction. APHIS identifies as “not provided” any planting/release report that is submitted 31 or more calendar days following the due date.

#### **3. Required report “incomplete”**

If APHIS receives a planting/release report that does not contain required information, then the requirement specified in 7 CFR 340.4(b) have not been met. An incomplete report will be considered a compliance infraction.

Late and/or missing reports are subject to enforcement actions including the issuance of a notice of non-compliance and/or a warning letter, and the potential assessment of a civil penalty.

12/13/2011 “USDA-APHIS-BRS User’s Guide Permit, Appendix – Planting and Environmental Release Reports” updates USDA-APHIS-BRS User’s Guide Notification and Appendix A Planting/Environmental Release Report Requirements” Version 3/28/11 to be specific to Permits

## Appendix - Consolidated Monthly Planting and Release Reports

Information that must be submitted in a planting/release report is described in Appendix - Planting/Environmental Reports; some organizations release at many locations under multiple permits and may prefer to submit consolidated monthly reports. In this appendix, APHIS provides to these organizations guidance for (1) the data elements to be provided, (2) the formatting of those data elements, and (3) the methods of report submission. All required information must be reported for each environmental release. If a planting/release made during a calendar month is not included in the consolidated report that is due for that month, then permit holders must include those plantings/releases in the consolidated planting/release report due the following month.

### **Data Elements to be Provided**

In general, the data elements needed to satisfy the planting/release report requirements in a consolidated monthly planting/release report must be arranged in a tabular, spreadsheet format. The data elements described below are consistent with the ePermits module that allows the web form entry or XML uploading of planting/release information into the system. For consolidated monthly planting/release reports APHIS is requesting that the same data elements be provided as follows:

- 1. Permit Number.** Report the permit number.
- 2. State.** Report the name of the State in which the planting/release occurs.
- 3. County.** Depending on the State or territory, report the name of the County, parish, borough or municipality in which the planting/release occurs.
- 4. Location Name.** Report the release site's Location name (farm level) the same as it is listed in the issued permit.
- 5. Location Unique ID.** This is an alphanumeric code that more specifically identifies the release site of the planting/release, typically at the field level and is used, among other reasons, to link all reports for the same field location. It can be any combination of letters or numbers that you choose, but it must be unique for each release site within each permit. If a Unique ID was provided for this release site in the issued permit, the applicant must use the same Unique ID in the planting/release report.
- 6. Planting/Release occurred.** Indicate whether or not a planting/release has occurred at this release site. There are three possible entries: Use a "Y" if a planting/release occurred or an "N" if the release site will never be planted/released under this permit. Leave the entry blank if no planting/release was made but the site will be, or may be, planted/released later under this permit.
- 7. Planting/Release Unique ID.** For this permit and unique release site, use a unique alphanumeric term or code to identify this planting/release at a specific field, plot or time. Use a simple planting/release identifier even if there will be only one planting/release at the site. Provide this identifier only if you entered "Y" for "planting/release occurred" (#6 above).

## Appendix - Consolidated Monthly Planting and Release Reports

**8. Planting/Release start date.** Report the beginning date on which the release was planted/release occurred. Provide this date only if you entered “Y” for “planting/release occurred” (#6 above).

**9. Size.** Report the total size of the planting/release, including only the area planted/released with the regulated article(s). This quantity must be submitted in acres; use no more than three decimal places. APHIS prefers that border rows not be included in this figure, even though they usually are treated as regulated during the release. For complex field designs that involve plantings/releases under multiple permits and notifications at one field location, report the planting/release size separately for each permit or notification, excluding border rows. Provide the planting/release size only if you entered “Y” for “planting/release occurred” (#6 above).

**10. Latitude coordinate.** Report a latitude coordinate for the planting/release in degree decimal format. Up to six decimal places can be provided. Provide this coordinate only if you entered “Y” for “planting/release occurred” (#6 above). Example: 39.123456.

**11. Longitude coordinate.** Report the corresponding longitude coordinate in degree decimal format. Up to six decimal places can be provided. Each value is reported as a negative number. Provide this coordinate only if you entered “Y” for “planting/release occurred” (#6 above). Example: -101.123456.

**NOTE:** Up to six latitude/longitude pairs may be provided to define the perimeter of each planting/release location. However, if you report only one pair of coordinates, the latitude and longitude coordinates must be for the northwest corner, or northwestern-most point, of the field or plot planted/released.

**GENERAL NOTE:** Submit only new (not previously reported) planting/release information in each monthly report. Do not submit previously reported plantings/releases at the same location unless it is a new planting/release (e.g., a new plot, field or time with a new planting/release identifier).

### Other Data Elements that May be Provided (Optional)

#### Elements aligning with ePermits

A new ePermits module is now available and allows for the electronic reporting of planting/release information. The module contains additional data elements that applicants may optionally include in consolidated monthly reports. Although their use will not be required, applicants who plan to use these elements in ePermits may want to establish some continuity in their planting/release report submissions prior to using ePermits by using one or more of these elements. They are described below.

**1. Site cooperator contact information.** Provide the name and contact information for the person responsible for conducting the release at this specific location. Provide this contact

## Appendix - Consolidated Monthly Planting and Release Reports

information only if you entered “Y” for “planting/release occurred” (#6 above). Note: After the new ePermits module becomes available, the system will automatically bring forward this information from the permit into the planting/release report.

**2. Anticipated harvest/destruct date.** Provide the date on which the regulated article(s) planted/release is expected to be harvested or to be terminated prior to harvest.

**3. Comments.** Provide as text any comments or miscellaneous information relating to the planting/release. Examples of such information include data elements that the applicant has provided in the past or desires to add to the ePermits record (e.g., total acres planted, including borders, cumulative acres planted). Note that multiple comments and data elements may be provided for each planting/release, but they may be entered only into one open “Comments” text field in ePermits.

**4. Phenotypic designation.** The applicant may provide the constructs involved with this planting/release. Note that the phenotypic designations must be provided in the final field test report even if they have been provided earlier in planting/release reports.

### Other Optional Elements

An applicant may voluntarily provide in a consolidated planting/release report other information not listed above. However, with the availability of the ePermits reporting, an applicant may continue to submit all such voluntary information to ePermits, but these additional elements will need to be submitted either in the single “Comments” text field that will be available for each planting/release, or in a separate attachment.

### Formatting of Data Elements

APHIS requests this information as an Excel spreadsheet file containing the above information in the columnar format shown on the next page, or in another format that allows for data extraction. Formats such as the portable document file (pdf) do not allow for data extraction and processing. However, a second file in a non-extractable format may be submitted with the extractable spreadsheet. APHIS is requesting this information in an extractable format due to the large volume of records received on a monthly basis, and due to the varying formats of reports being received. An example of a consolidated monthly planting/release report table is shown on the final page of this appendix. This example includes only data elements that are required by the ePermits reporting module. It does not include optional data elements. APHIS requests receiving the report in the format shown, but applicants may include optional fields. Columns may be arranged in any order the applicant desires. In either instance, these column headings are requested to facilitate accurate data processing.

If CBI is involved, please submit both a CBI and CBI-deleted version.

## Appendix - Consolidated Monthly Planting and Release Reports

### Example: Consolidated Planting/Release Report

Consolidated Planting/Release Report for June 2010

Notification Number	State Name	County Name	Location Name	Location Unique ID	Release Site planted? (Y/N)	Planting Unique ID	Planting Start Date	Quantity Planted (acres)	Latitude coordinates for field or plot planted	Longitude coordinates for field or plot planted	Site cooperators name & contact information (optional)
10-999-101n	AK	Nome	Fred's Farms	Fred0010	Y	F1	6/1/10	2	123.456789	-987.654321	Fred Smith 515-555-5555
10-999-101n	AK	Nome	Fred's Farms	Fred0010	Y	F2	6/8/10	2.5	123.456772	-987.654321	Fred Smith 515-555-5555
10-999-101n	AK	Nome	Fred's Farms	Fred0022							
10-801-104n	AK	Bethel	Shortseason Ranch	SR001	N						
10-801-104n	AK	Bethel	Shortseason Ranch	SR002	Y	S1	6/25/10	1.333	120.456789	-987.054321	Bill Seward 515-555-9900

Note: This report would be due on the date provided in the permit conditions.

### Version

12/7/2011 "USDA-APHIS-BRS User's Guide Permit Appendix - Consolidated Monthly Planting and Release Reports" updates "USDA-APHIS-BRS User's Guide Notification, Appendix B Consolidated Monthly Planting Report Submission Formats for Applicable Organizations" Version 3/28/11 to be specific to Permits.

The collection of this information is authorized by the Plant Protection Act of 2000. The information will be used to determine eligibility to receive all types of permits. No permit will be issued until this application has been approved.

U.S. DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
BIOTECHNOLOGY REGULATORY SERVICE  
**APPLICATIONS FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340**  
(Genetically Engineered Organisms or Products)

**1. NAME, ADDRESS, TELEPHONE, AND EMAIL OF APPLICANT**

**Name:** Dr. Maisy Cornwall  
**Position:** Associate Professor  
**Organization:** Research University  
**Organization Unique ID:**  
**Address:** 111 Agriculture Lane  
Farmington, NE 68714  
**County/Province:** NOTE: THE APPLICANT AND CONTACT  
INFORMATION MAY  
**Township/Island:** NOT BE DECLARED AS CBI  
**Day Telephone:** 301-555-5555  
**FAX:**  
**Alternate:** 301-555-5555  
**Email 1:** maisy@researchu.edu  
**Email 2:**

**2. INTRODUCTION TYPE**

- Importation  
 Interstate Movement  
 Interstate Movement and Release  
 Release

**3. PERMIT TYPE**

- Standard Permit  
 Courtesy Permit

**4. PURPOSE OF PERMIT**

- Industrial Product  
 Pharmaceutical Product  
 Phytoremediation  
 Traditional  
 test purpose

**5. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)**

Does this application contain CBI?  Yes  No

**CBI Justification:**

NOT A VALID PERMIT

APHIS EXAMPLE PERMIT (RELEASE - Corn - Permit contains Confidential Business Information (CBI))

**Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the release of protected information would likely cause substantial financial competitive harm.

Identification of the country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed, and produced; and the collaborators at the release site, the release site location, and acreage.

Providing location where the regulated organism was developed, and the location of the release, the size of the release and our collaborators at the release site would unfairly jeopardize the time and expense spent in developing these collaborative partnerships and could substantively put at financial risk the time and expense to set up the business partnership.

Phenotype description, phenotype, and genetic material (promoters, genes & terminators).

Providing the phenotype description, phenotype, and genetic material inserted and the donors would compromise the time and expense spent in developing the technology to produce the desired trait. This particular genetic combination is unique because the arrangement is novel and the genetic constructs are themselves novel.

If this information was disclosed, replication by a competitor would cause the loss on many dollars in developing our technology. Furthermore, the competitors would have access to this technology for free at our expense.

**6. REQUEST TYPE**

New  Amendment  Renewal  Variance  Amendment, Renewal and/or Variance

**Amendment/Renewal Description:****Previous Permit Number(s):****7. MEANS OF MOVEMENT**

N/A

**8. VARIANCE VERIFICATION**

**WARNING:** Any use of ePermits to make materially false, fictitious, or fraudulent statements or representations is subject to civil penalties of up to \$250,000 (7 U.S.C. § 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C. §1001).

Have you previously applied for variance(s) that you wish to apply to this permit?  Yes  No

Variance Number(s):

If so, describe in a brief summary how the variance will be applied:

N/A

#### 9. REGULATED ARTICLE

Scientific Name: Zea mays

Common Name: Corn

Cultivar and/or Breeding Line:

Any biological material (e.g., culture medium, or host material) accompanying the regulated Article during movement:

N/A

Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed, and produced:

The genetically engineered lines covered in this permit were constructed at [CornyGene, 222 Boulder Way, Stoneybrooke NE]

#### Processes, Procedures, and Safeguards Description:

The facility where the genetically engineered corn was constructed is a controlled-access building. The greenhouse facilities used to produce seed are also accessible by personnel with security badges. Regulated seed is kept separated from non-engineered seed by the use of labels.

#### 10. ARTICLE SUPPLIER AND/OR DEVELOPER

<u>Name</u>	<u>Location</u>	<u>Contact Information</u>
[Fred] [Flintrock]	[CornyGene] [222 Boulder Way] NOTE: SUPPLIER MAY NOT BE CLAIMED AS CBI IF THE APPLICANT AND SUPPLIER AND/OR DEVELOPER ARE THE SAME. [Stoneybrooke], NE [68301]	Day Telephone: [555]-[555]-[5555] FAX: Email: [flintrock@cornygene.com]

#### 11. PHENOTYPES/GENOTYPE

1) Phenotypic Designation Name: PopRight

Identifying Line(s):

Construct(s): XX-1234

Mode of Transformation: Agrobacterium tumefaciens, disarmed

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.

[The intended phenotype is to increase starch production in endosperm to enhance popping corn. The Waxy gene (Granule Bound Starch Synthase) is regulated by the endosperm specific maize granule-bound starch synthase gene promoter.]

Phenotype(s)

PQ - [Starch level increased]

Genotype(s)

Gene(s) of Interest

Promoter: [zmGBS] **from** [Zea mays] - [Tissue specific promoter for granule-bound starch synthase (Waxy) gene]

Gene: [Granule Bound Starch Synthase] **from** [Pisum sativum] - [Granule Bound Starch Synthase is involved in amylose synthesis and the intent is to increase the amylose content to around 20 % of starch weight for the transgenic lines.]

Terminator: [NOS] **from** [Agrobacterium tumefaciens] - [Nopaline synthase (NOS) terminator is a very common stop signal for gene transcription.]

## Screenable Marker

Promoter: [35S] **from** [Cauliflower mosaic caulimovirus] - [The 35S promoter is a very strong constitutive promoter, causing high levels of gene expression in dicot plants, less so in monocots, but is still a very effective promoter]

Gene: [GFP] **from** [Aequorea victoria] - [green fluorescent protein (GFP) from Jellyfish. The green fluorescent protein (GFP) is a protein that exhibits bright green fluorescence when exposed to blue light. See Prendergast F, Mann K (1978). Biochemistry 17 (17): 3448- 53. In this case it is used to confirm successful integration of the construct in the transgenic plants]

Terminator: [NOS] **from** [Agrobacterium tumefaciens] - [Nopaline synthase (NOS) terminator is a very common stop signal for gene transcription.]

## 12. INTRODUCTION

## Release Site

Location Name & Description	Location Address	Contact(s)
<b>1)</b> [McGregor Farm] - NOTE: RELEASE SITE LOCATION MAY NOT BE CLAIMED AS CBI, IF IT IS THE SAME AS THE APPLICANT'S ADDRESS.	Peter County IA [10125] <b>Proposed Release Start Date:</b> 4/15/2012 <b>Proposed Release End Date:</b> 4/15/2013 <b>No. of Releases:</b> 1 <b>Quantity:</b> [50] acres	<b>1)</b> [Bea] [Potter] <b>Day Telephone:</b> [555-555-5555]
<b>Location Unique ID:</b> BRS002 <b>Location GPS Coordinates:</b> [30.882236], [-83.805507] <b>Release Site History:</b> This has been an agricultural research farm for over 5 years and has been in agricultural cropping during that time. The farm consists of agricultural fields that include corn, cotton and soybean plantings. There is other transgenic corn grown at this location. All the surrounding land is agricultural land or mixed-use pastures. <b>Critical Habitat Involved?:</b> ___ Yes <u>X</u> No		
<b>2)</b> [Breezy Wood Farm]	Marshall County IN [55555] <b>Proposed Release Start Date:</b> 4/15/2012 <b>Proposed Release End Date:</b> 4/15/2013 <b>No. of Releases:</b> [1] <b>Quantity:</b> [15] acres	<b>1)</b> Rodney Crow <b>Day Telephone:</b> [555-555-5555]
<b>Location Unique ID:</b> BRS005 <b>Location GPS Coordinates:</b> [41.344336], [-86.153554] <b>Release Site History:</b> This has been an agricultural research farm for over 5 years and has been in agricultural cropping during that time. The farm consists of agricultural fields that include corn, cotton and soybean plantings. There is other transgenic corn grown at this location. All the surrounding land is agricultural land or mixed-use pastures. <b>Critical Habitat Involved?:</b> ___ Yes <u>X</u> No		

## 13. DESIGN PROTOCOLS

## Production Design

A detailed description of the purpose for the introduction of the regulated article including detailed description of the proposed experimental and/or production design:

NOTE: THE INFORMATION IN THIS SECTION IS NOT CLAIMED AS CBI IN THIS SAMPLE PERMIT APPLICATION, HOWEVER, IT MAY BE CLAIMED AS CBI AS LONG AS APPROPRIATE CBI JUSTIFICATION IS PROVIDED.

The purpose of the introduction is to produce PopRight seed for research and product development. Plants will be grown to evaluate the performance of plants and production of grains [with increased starch yield]. The field sites will be isolated by no less than 660 feet from any non-regulated corn. Planting, harvesting equipment and other field equipment will be cleaned on site. Field equipment will be cleaned (using shovels, brushes, water, or compressed air, etc.) at the field site. Harvested grain will be labeled and stored in secure grain bins. All employees who handle the regulated material will follow the management practices, as specified in the permit and permit conditions, to confine the regulated material to the field site.

WARNING: Any use of ePermits to make materially false, fictitious, or fraudulent statements or representations is subject to civil penalties of up to \$250,000 (7 U.S.C. § 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C. §1001).

**Destination or Release Description**

**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):**

NOTE: THE INFORMATION IN THIS SECTION IS NOT CLAIMED AS CBI IN THIS SAMPLE PERMIT APPLICATION, HOWEVER, IT MAY BE CLAIMED AS CBI AS LONG AS APPROPRIATE CBI JUSTIFICATION IS PROVIDED.

While in storage the corn seeds will be kept in a locked storage facility with limited access. Storage containers are identified by barcode labels that specify the line number. At least one sign stating "Authorized Personnel Only" will be posted in each area where the regulated article is stored. The greenhouse facilities used to produce seed are also only accessible by personnel with security badges. Seeds will be labeled with unique identifiers. Field equipment will be cleaned at the field site (using shovels, brushes, water, or compressed air, etc.).

**Confinement Protocols**

**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:**

NOTE: THE INFORMATION IN THIS SECTION IS NOT CLAIMED AS CBI IN THIS SAMPLE PERMIT APPLICATION, HOWEVER, IT MAY BE CLAIMED AS CBI AS LONG AS APPROPRIATE CBI JUSTIFICATION IS PROVIDED.

Regulated corn will be planted only at the field site specified in the permit. Field sites will be well-defined with stakes. An unplanted alley of no less than 15 feet will separate corn regulated under this permit and any other planted agricultural material.

The field site, border rows and alleys will be monitored for volunteers for one year after harvest. Volunteers will be removed prior to pollen release and turned into the soil. Monitoring will be done once in every 4 weeks until the last freeze. The following growing season, monitoring will occur every 4 weeks. Any volunteer plants found will be destroyed by any one of the following methods: discing or other methods to incorporate the plant into the soil or chemical treatment. The following growing season, the field will be planted to a crop that is morphologically distinct unless the field site is covered under another permit or notification.

Fields will not be replanted with corn unless the corn is regulated and is planted under an APHIS permit or notification.

**Final Disposition Method:**     Destruction/Devitalization     Other     Storage in Contained Facility

**Final Disposition Description:**

NOTE: THE INFORMATION IN THIS SECTION IS NOT CLAIMED AS CBI IN THIS SAMPLE PERMIT APPLICATION, HOWEVER, IT MAY BE CLAIMED AS CBI AS LONG AS APPROPRIATE CBI JUSTIFICATION IS PROVIDED.

Seed or other material capable of propagation will be devitalized by incineration, grinding or discing, herbicide treatment or composting at the field test site. Seed not used in the field trial will be returned to CornyGene (supplier) for storage or destruction.

**14. ATTACHMENTS****15. ADDITIONAL INFORMATION****16. COURTESY JUSTIFICATION**

I, *Maisy Cornwall*, hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

I acknowledge this is not an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents, as described in 9 CFR 121.

I will not introduce the regulated articles described in this application until APHIS has deemed the application complete and has granted the permit. By signing this permit, I agree to comply with any and all state, local, and tribal laws and regulations that may apply to the introduction of the articles described in this applications.

If there are any changes to the information disclosed in this application, I will contact APHIS.

**17. SIGNATURE OF RESPONSIBLE PERSON**

Maisy Cornwall

**18. DATE**

November 1, 2011

The collection of this information is authorized by the Plant Protection Act of 2000. The information will be used to determine eligibility to receive all types of permits. No permit will be issued until this application has been approved.

U.S. DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
BIOTECHNOLOGY REGULATORY SERVICE  
**APPLICATIONS FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340**  
(Genetically Engineered Organisms or Products)

**1. NAME, ADDRESS, TELEPHONE, AND EMAIL OF APPLICANT**

**Name:** Dr. Maisy Cornwall  
**Position:** Associate Professor  
**Organization:** Research University  
**Organization Unique ID:**  
**Address:** 111 Agriculture Lane  
Farmington, NE 68714  
**County/Province:** NOTE: THE APPLICANT AND CONTACT  
INFORMATION MAY  
**Township/Island:** NOT BE DECLARED AS CBI  
**Day Telephone:** 301-555-5555  
**FAX:**  
**Alternate:** 301-555-5555  
**Email 1:** maisy@researchu.edu  
**Email 2:**

**2. INTRODUCTION TYPE**

- Importation  
 Interstate Movement  
 Interstate Movement and Release  
 Release

**3. PERMIT TYPE**

- Standard Permit  
 Courtesy Permit

**4. PURPOSE OF PERMIT**

- Industrial Product  
 Pharmaceutical Product  
 Phytoremediation  
 Traditional  
 test purpose

**5. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)**

Does this application contain CBI?  Yes  No

**CBI Justification:**

NOT A VALID PERMIT

APHIS EXAMPLE PERMIT (RELEASE - Corn - Permit contains Confidential Business Information (CBI))

**Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the release of protected information would likely cause substantial financial competitive harm.

Identification of the country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed, and produced; and the collaborators at the release site, the release site location, and acreage.

Providing location where the regulated organism was developed, and the location of the release, the size of the release and our collaborators at the release site would unfairly jeopardize the time and expense spent in developing these collaborative partnerships and could substantively put at financial risk the time and expense to set up the business partnership.

Phenotype description, phenotype, and genetic material (promoters, genes & terminators).

Providing the phenotype description, phenotype, and genetic material inserted and the donors would compromise the time and expense spent in developing the technology to produce the desired trait. This particular genetic combination is unique because the arrangement is novel and the genetic constructs are themselves novel.

If this information was disclosed, replication by a competitor would cause the loss on many dollars in developing our technology. Furthermore, the competitors would have access to this technology for free at our expense.

**6. REQUEST TYPE**

New  Amendment  Renewal  Variance  Amendment, Renewal and/or Variance

**Amendment/Renewal Description:****Previous Permit Number(s):****7. MEANS OF MOVEMENT**

N/A

**8. VARIANCE VERIFICATION**

**WARNING:** Any use of ePermits to make materially false, fictitious, or fraudulent statements or representations is subject to civil penalties of up to \$250,000 (7 U.S.C. § 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C. §1001).

Have you previously applied for variance(s) that you wish to apply to this permit?  Yes  No

Variance Number(s):

If so, describe in a brief summary how the variance will be applied:

N/A

**9. REGULATED ARTICLE**

Scientific Name: Zea mays

Common Name: Corn

Cultivar and/or Breeding Line:

Any biological material (e.g., culture medium, or host material) accompanying the regulated Article during movement:

N/A

Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed, and produced:

The genetically engineered lines covered in this permit were constructed at [ ]

**Processes, Procedures, and Safeguards Description:**

The facility where the genetically engineered corn was constructed is a controlled-access building. The greenhouse facilities used to produce seed are also accessible by personnel with security badges. Regulated seed is kept separated from non-engineered seed by the use of labels.

**10. ARTICLE SUPPLIER AND/OR DEVELOPER**

Name	Location	Contact Information
[ ] [ ]	[ ] [ ] NOTE: SUPPLIER MAY NOT BE CLAIMED AS CBI IF THE APPLICANT AND SUPPLIER AND/OR DEVELOPER ARE THE SAME. [ ], NE [ ]	Day Telephone: [ ]-[ ]-[ ] FAX: Email: [ ]

**11. PHENOTYPES/GENOTYPE**

1) Phenotypic Designation Name: PopRight

Identifying Line(s):

Construct(s): XX-1234

Mode of Transformation: Agrobacterium tumefaciens, disarmed

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.

**Phenotype(s)**

PQ - [ ]

**Genotype(s)**

Gene(s) of Interest

Promoter: [ ] from [ ] - [ ]

Gene: [ ] from [ ] - [ ]

Terminator: [ ] from [ ] - [ ]

Screenable Marker  
 Promoter: [ ] from [ ] - [ ]  
 ]  
 Gene: [ ] from [ ] - [ ]  
 ]  
 Terminator: [ ] from [ ] - [ ]  
 ]

**12. INTRODUCTION**

**Release Site**

Location Name & Description	Location Address	Contact(s)
<b>1)</b> [ ] - NOTE: RELEASE SITE LOCATION MAY NOT BE CLAIMED AS CBI, IF IT IS THE SAME AS THE APPLICANT'S ADDRESS.	Peter County IA [ ] <b>Proposed Release Start Date:</b> 4/15/2012 <b>Proposed Release End Date:</b> 4/15/2013 <b>No. of Releases:</b> 1 <b>Quantity:</b> [ ] acres	<b>1)</b> [ ] [ ] <b>Day Telephone:</b> [ ]
<b>Location Unique ID:</b> BRS002 <b>Location GPS Coordinates:</b> [ ], [ ] <b>Release Site History:</b> This has been an agricultural research farm for over 5 years and has been in agricultural cropping during that time. The farm consists of agricultural fields that include corn, cotton and soybean plantings. There is other transgenic corn grown at this location. All the surrounding land is agricultural land or mixed-use pastures. <b>Critical Habitat Involved?:</b> ___ Yes <u>X</u> No		
<b>2)</b> [ ]	Marshall County IN [ ] <b>Proposed Release Start Date:</b> 4/15/2012 <b>Proposed Release End Date:</b> 4/15/2013 <b>No. of Releases:</b> [ ] <b>Quantity:</b> [ ] acres	<b>1)</b> Rodney Crow <b>Day Telephone:</b> [ ]
<b>Location Unique ID:</b> BRS005 <b>Location GPS Coordinates:</b> [ ], [ ] <b>Release Site History:</b> This has been an agricultural research farm for over 5 years and has been in agricultural cropping during that time. The farm consists of agricultural fields that include corn, cotton and soybean plantings. There is other transgenic corn grown at this location. All the surrounding land is agricultural land or mixed-use pastures. <b>Critical Habitat Involved?:</b> ___ Yes <u>X</u> No		

**13. DESIGN PROTOCOLS**

**Production Design**

A detailed description of the purpose for the introduction of the regulated article including detailed description of the proposed experimental and/or production design:

NOTE: THE INFORMATION IN THIS SECTION IS NOT CLAIMED AS CBI IN THIS SAMPLE PERMIT APPLICATION, HOWEVER, IT MAY BE CLAIMED AS CBI AS LONG AS APPROPRIATE CBI JUSTIFICATION IS PROVIDED.

The purpose of the introduction is to produce PopRight seed for research and product development. Plants will be grown to evaluate the performance of plants and production of grains [ ]. The field sites will be isolated by no less than 660 feet from any non-regulated corn. Planting, harvesting equipment and other field equipment will be cleaned on site. Field equipment will be cleaned (using shovels, brushes, water, or compressed air, etc.) at the field site. Harvested grain will be labeled and stored in secure grain bins. All employees who handle the regulated material will follow the management practices, as specified in the permit and permit conditions, to confine the regulated material to the field site.

**Destination or Release Description**

**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):**

NOTE: THE INFORMATION IN THIS SECTION IS NOT CLAIMED AS CBI IN THIS SAMPLE PERMIT APPLICATION, HOWEVER, IT MAY BE CLAIMED AS CBI AS LONG AS APPROPRIATE CBI JUSTIFICATION IS PROVIDED.

While in storage the corn seeds will be kept in a locked storage facility with limited access. Storage containers are identified by barcode labels that specify the line number. At least one sign stating "Authorized Personnel Only" will be posted in each area where the regulated article is stored. The greenhouse facilities used to produce seed are also only accessible by personnel with security badges. Seeds will be labeled with unique identifiers. Field equipment will be cleaned at the field site (using shovels, brushes, water, or compressed air, etc.).

**Confinement Protocols**

**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:**

NOTE: THE INFORMATION IN THIS SECTION IS NOT CLAIMED AS CBI IN THIS SAMPLE PERMIT APPLICATION, HOWEVER, IT MAY BE CLAIMED AS CBI AS LONG AS APPROPRIATE CBI JUSTIFICATION IS PROVIDED.

Regulated corn will be planted only at the field site specified in the permit. Field sites will be well-defined with stakes. An unplanted alley of no less than 15 feet will separate corn regulated under this permit and any other planted agricultural material.

The field site, border rows and alleys will be monitored for volunteers for one year after harvest. Volunteers will be removed prior to pollen release and turned into the soil. Monitoring will be done once in every 4 weeks until the last freeze. The following growing season, monitoring will occur every 4 weeks. Any volunteer plants found will be destroyed by any one of the following methods: discing or other methods to incorporate the plant into the soil or chemical treatment. The following growing season, the field will be planted to a crop that is morphologically distinct unless the field site is covered under another permit or notification.

Fields will not be replanted with corn unless the corn is regulated and is planted under an APHIS permit or notification.

**Final Disposition Method:**     Destruction/Devitalization     Other     Storage in Contained Facility

**Final Disposition Description:**

NOTE: THE INFORMATION IN THIS SECTION IS NOT CLAIMED AS CBI IN THIS SAMPLE PERMIT APPLICATION, HOWEVER, IT MAY BE CLAIMED AS CBI AS LONG AS APPROPRIATE CBI JUSTIFICATION IS PROVIDED.

Seed or other material capable of propagation will be devitalized by incineration, grinding or discing, herbicide treatment or composting at the field test site. Seed not used in the field trial will be returned to CornyGene (supplier) for storage or destruction.

**14. ATTACHMENTS****15. ADDITIONAL INFORMATION****16. COURTESY JUSTIFICATION**

I, *Maisy Cornwall*, hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

I acknowledge this is not an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents, as described in 9 CFR 121.

I will not introduce the regulated articles described in this application until APHIS has deemed the application complete and has granted the permit. By signing this permit, I agree to comply with any and all state, local, and tribal laws and regulations that may apply to the introduction of the articles described in this applications.

If there are any changes to the information disclosed in this application, I will contact APHIS.

**17. SIGNATURE OF RESPONSIBLE PERSON**

Maisy Cornwall

**18. DATE**

November 1, 2011

The collection of this information is authorized by the Plant Protection Act of 2000. The information will be used to determine eligibility to receive all types of permits. No permit will be issued until this application has been approved.

U.S. DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
BIOTECHNOLOGY REGULATORY SERVICE  
**APPLICATIONS FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340**  
(Genetically Engineered Organisms or Products)

**1. NAME, ADDRESS, TELEPHONE, AND EMAIL OF APPLICANT**

**Name:** Dr. John Jefferson  
**Position:**  
**Organization:** Land Grant University  
**Organization Unique ID:**  
**Address:** 123 Main Street  
Anytown, MD 20202  
**County/Province:**  
**Township/Island:** NOT A VALID PERMIT. APHIS  
SAMPLE PERMIT.  
**Day Telephone:** 301-555-1212  
**FAX:**  
**Alternate:** 555-555-5555  
**Email 1:** **Email 2:**  
JRJefferson@landgrantuniversity.edu

**2. INTRODUCTION TYPE**

- Importation  
 Interstate Movement  
 Interstate Movement and Release  
 Release

**3. PERMIT TYPE**

- Standard Permit  
 Courtesy Permit

**4. PURPOSE OF PERMIT**

- Industrial Product  
 Pharmaceutical Product  
 Phytoremediation  
 Traditional  
 test purpose

**5. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)**

Does this application contain CBI?  Yes  No

**CBI Justification:**

N/A

**6. REQUEST TYPE**

New  Amendment  Renewal  Variance  Amendment, Renewal and/or Variance

**Amendment/Renewal Description:**

**Previous Permit Number(s):**

**7. MEANS OF MOVEMENT**

Common carrier.

**8. VARIANCE VERIFICATION**

Have you previously applied for variance(s) that you wish to apply to this permit?  Yes  No

**Variance Number(s):**

**If so, describe in a brief summary how the variance will be applied:**

N/A

**9. REGULATED ARTICLE**

**Scientific Name:** Vitis vinifera

**Common Name:** grape

**Cultivar and/or Breeding Line:**

**Any biological material (e.g., culture medium, or host material) accompanying the regulated Article during movement:**

No additional biological material will be included with regulated material during movement.

**Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed, and produced:**

The recipient organism was from a vineyard collection in Anytown, MD. Lines were transformed at Land Grant University in Maryland.

**Processes, Procedures, and Safeguards Description:**

The facility where the genetically engineered grape was constructed is a controlled-access building. The greenhouse facilities used to produce seed are only accessible by personnel with security badges. Regulated seed is kept separated from non-engineered seed by the use of labels.

**10. ARTICLE SUPPLIER AND/OR DEVELOPER**

**WARNING:** Any use of ePermits to make materially false, fictitious, or fraudulent statements or representations is subject to civil penalties of up to \$250,000 (7 U.S.C. § 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C. §1001).

<u>Name</u>	<u>Location</u>	<u>Contact Information</u>
Dr. Abigail Adams	Land Grant University 123 Main Drive Anytown, MD 20202	<b>Day Telephone:</b> 301-555-1213 <b>FAX:</b> <b>Email:</b>

**11. PHENOTYPES/GENOTYPE**

- 1) Phenotypic Designation Name:** Herbicide Tolerant
- Identifying Line(s):** Al-111, Al-122, Al-133
- Construct(s):** pAlfalfa
- Mode of Transformation:** Agrobacterium tumefaciens, disarmed
- Phenotype Description:** glyphosate tolerant  
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.
- Phenotype(s)**
- HT - Glyphosate tolerant
- Genotype(s)**
- Gene(s) of Interest  
Promoter: 35S **from** Cauliflower mosaic caulimovirus - Full length 35S
- Gene: EPSPS **from** Agrobacterium tumefaciens - 5-Enolpyruvylshikimate-3-phosphate
- Terminator: Rubisco **from** Brassica oleracea - 3' terminator region from the Brassica Q10 subunit of Ribulose-1,5-bisphosphate carboxylase oxygenase
- 2) Phenotypic Designation Name:** Fungal Resistant
- Identifying Line(s):**
- Construct(s):** FR-04, FR-09
- Mode of Transformation:** Agrobacterium tumefaciens, disarmed
- Phenotype Description:** Fungal Resistance to Powdery Mildew  
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.
- Phenotype(s)**
- FR - Powdery mildew resistant
- Genotype(s)**
- Gene(s) of Interest  
Promoter: 35S **from** Cauliflower mosaic caulimovirus - 35S enhanced expression
- Gene: PWresist **from** Cucurbita pepo - PWresist gene
- Terminator: NOS **from** Agrobacterium tumefaciens - NOS terminator from Agrobacterium tumefaciens
- Selectable Marker  
Promoter: 35S **from** Cauliflower mosaic caulimovirus - enhanced 35s promoter

Gene: EPSPS **from** Agrobacterium tumefaciens - 5-Enolpyruvylshikimate-3-phosphate (EPSP) synthase conferring glyphosate tolerance

Terminator: NOS **from** Agrobacterium tumefaciens - Nopaline synthase from Agrobacterium

**3) Phenotypic Designation Name:** Yield Increase  
**Identifying Line(s):** YI-3456, YI-5678  
**Construct(s):** pAlfalfaYield  
**Mode of Transformation:** Agrobacterium tumefaciens, disarmed  
**Phenotype Description:** Yield Increase

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.

#### Phenotype(s)

AP - Yield increased

#### Genotype(s)

Gene(s) of Interest

Promoter: 35S **from** Bean common mosaic virus - enhanced 35S promoter

Gene: Yielder exons 1-5 **from** Glycine max - High yielding gene regions involved in stress tolerance and biomass production

Terminator: NOS **from** Agrobacterium tumefaciens - Nopaline synthase sequence

Selectable Marker

Promoter: 35S **from** Cauliflower mosaic caulimovirus - enhanced 35S activity

Gene: EPSPS **from** Agrobacterium tumefaciens - 5-Enolpyruvylshikimate-3-phosphate (EPSP) synthase conferring glyphosate tolerance

Terminator: NOS **from** Agrobacterium tumefaciens - NOS 3' terminator

## 12. INTRODUCTION

### Point of Origin

<u>Location Name &amp; Description</u>	<u>Location Address</u>	<u>Contact(s)</u>
1) Land Grant University	123 Main Street Adams Anytown, MD 55555	1) James Monroe <b>Day Telephone:</b> 301-555-1212
2) Land Grant University	Tyler OH	

### Destination

<u>Location Name &amp; Description</u>	<u>Location Address</u>	<u>Contact(s)</u>
1) Land Grant University	123 Main Drive Rascal MD 55555 <b>Proposed Start Date:</b> 08/01/2010 <b>Proposed End Date:</b> 08/01/2011 <b>Quantity:</b> 15 Lbs Plant parts <b>Inspected by BRS or PPQ?</b> Yes <b>Previous Permit No.:</b> 08-000-000-rm	1) Dolly Madison <b>Day Telephone:</b> 301-555-1213

**WARNING:** Any use of ePermits to make materially false, fictitious, or fraudulent statements or representations is subject to civil penalties of up to \$250,000 (7 U.S.C. § 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C. §1001).

<b>2)</b> Land Grant University	1122 Agriculture Lane Smith Smith, OH 44044 <b>Proposed Start Date:</b> 08/01/2010 <b>Proposed End Date:</b> 08/01/2011 <b>Quantity:</b> 5 Lbs Plant Parts <b>Inspected by BRS or PPQ?</b> Yes <b>Previous Permit No.:</b> 08-000-000-rm	<b>1)</b> Elizabeth Monroe <b>Day Telephone:</b> 555-555-1245
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**Release Site**

<b>Location Name &amp; Description</b>	<b>Location Address</b>	<b>Contact(s)</b>
<b>1)</b> Polk Research Farm	Polk MD 20202 <b>Proposed Release Start Date:</b> 11/01/2011 <b>Proposed Release End Date:</b> 08/01/2014 <b>No. of Releases:</b> 10 <b>Quantity:</b> 10 acres	<b>1)</b> James Madison <b>Day Telephone:</b> 555-55-5555
<b>Location Unique ID:</b> WilliamsFarm1 <b>Location GPS Coordinates:</b> 39.464564, -77.757351 <b>Release Site History:</b> Over 30 years in agricultural cropping <b>Critical Habitat Involved?:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		

**13. DESIGN PROTOCOLS****Production Design**

**A detailed description of the purpose for the introduction of the regulated article including detailed description of the proposed experimental and/or production design:**

The purpose of the release to accumulate information on the reaction of the engineered lines to infection with Powdery Mildew, to assess yield and to determine the efficacy of the herbicide tolerance gene (glyphosate). This release is a continuation of plants that are already in the ground. New lines may also be added to the field trial site. Training of vines and control of pests and disease will be according to standard industry practices. Powdery mildew is endemic to the area of release and there will be no artificial inoculations.

**Destination or Release Description**

**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):**

The tissue culture derived grapes were grown in pots in the Greenhouse at 100 Jefferson Dr. Anytown, MD. The greenhouse is kept locked at all times. Individual pots are labeled with a plastic stick. Plants will be transported in an enclosed vehicle to the field test site.

The site of release is on university owned agricultural research farm. Access is restricted by a locked gate. The material will be used for research only.

Some of the engineered lines are already in the ground (under permit 08-000-000rm). New lines will be released under this permit.

**Confinement Protocols**

**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:**

Grape (*Vitis vinifera*) is primarily a self-pollinating species; and the pollen is heavy that does not drift far (6 - 20 ft.). There will be at least 50 ft. separation distance to grapes surrounding the field test. There will be no *Vitis* species within 50 ft of the field test.

The plot is located off the main road and is accessible only through a locked gate.

The plot will be monitored monthly from June to October to ensure the separation distance is maintained and scout for any unintended effects (unusual disease or insect pressure, or other unusual unanticipated phenotype).

During the fall harvest, fruits will be collected in a box transported in an enclosed vehicle back to Land Grant University.

**Containment During Shipment:**

Plant parts will be shipped interstate according to 340.8. No seed will be shipped. Plants will be packed in sealed plastic bags of at least 5 mil thickness, inside a sturdy, sealed,

**WARNING: Any use of ePermits to make materially false, fictitious, or fraudulent statements or representations is subject to civil penalties of up to \$250,000 (7 U.S.C. § 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C. §1001).**

leak-proof, outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood or other material of equivalent strength.

**Final Disposition Method:**  Destruction/Devitalization  Other  Storage in Contained Facility

**Final Disposition Description:** At the termination of the field trial, the regulated grape plants will be treated with a systemic foliar herbicide, mechanically removed 2-3 months following the herbicide treatment and incinerated on site.

The field site will be monitored on a monthly basis for volunteer grapevine plants over 1 year. No other grapevines will be planted on site during the one year monitoring after termination of the trial.

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#### 14. ATTACHMENTS

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#### 15. ADDITIONAL INFORMATION

NOT A VALID PERMIT. APHIS SAMPLE PERMIT.

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#### 16. COURTESY JUSTIFICATION

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I, *John Jefferson*, hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

I acknowledge this is not an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents, as described in 9 CFR 121.

I will not introduce the regulated articles described in this application until APHIS has deemed the application complete and has granted the permit. By signing this permit, I agree to comply with any and all state, local, and tribal laws and regulations that may apply to the introduction of the articles described in this applications.

If there are any changes to the information disclosed in this application, I will contact APHIS.

**17. SIGNATURE OF RESPONSIBLE PERSON**

John Jefferson

**18. DATE**

November 2, 2011

The collection of this information is authorized by the Plant Protection Act of 2000. The information will be used to determine eligibility to receive all types of permits. No permit will be issued until this application has been approved.

U.S. DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
BIOTECHNOLOGY REGULATORY SERVICE  
**APPLICATIONS FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340**  
(Genetically Engineered Organisms or Products)

<b>1. NAME, ADDRESS, TELEPHONE, AND EMAIL OF APPLICANT</b> <b>Name:</b> Mr. James Smith <b>Position:</b> CEO <b>Organization:</b> Premier Enzymes <b>Organization Unique ID:</b> <b>Address:</b> 1 State Street Middletown, IA 00000 <b>County/Province:</b> NOTE: THE APPLICANT AND CONTACT INFORMATION MAY <b>Township/Island:</b> NOT BE DECLARED AS CBI <b>Day Telephone:</b> 914-555-1212 <b>FAX:</b> <b>Alternate:</b> <b>Email 1:</b> JSmith@email.com <b>Email 2:</b>	<b>2. INTRODUCTION TYPE</b> <input checked="" type="checkbox"/> Importation <input type="checkbox"/> Interstate Movement <input type="checkbox"/> Interstate Movement and Release <input type="checkbox"/> Release	<b>3. PERMIT TYPE</b> <input checked="" type="checkbox"/> Standard Permit <input type="checkbox"/> Courtesy Permit
<b>4. PURPOSE OF PERMIT</b> <input type="checkbox"/> Industrial Product <input type="checkbox"/> Pharmaceutical Product <input type="checkbox"/> Phytoremediation <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> test purpose		

**5. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)**

Does this application contain CBI?  Yes  No

**CBI Justification:**

NOT A VALID PERMIT

APHIS EXAMPLE PERMIT (Importation - Multiple Species - Permit contains Confidential Business Information (CBI))

**Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the release of protected information would likely cause substantial financial competitive harm.

The genetic material (promoters, genes & terminators).

Providing the phenotype description, phenotype, and genetic material inserted and the donors would compromise the time and expense spent in developing the technology to produce the desired trait.

This particular genetic combination is unique because the arrangement is novel and the genetic constructs are themselves novel.

If this information was disclosed, replication by a competitor would cause the loss on many dollars in developing our technology. Furthermore, the competitors would have access to this technology for free at our expense.

**6. REQUEST TYPE**

New  Amendment  Renewal  Variance  Amendment, Renewal and/or Variance

**Amendment/Renewal Description:**

**Previous Permit Number(s):**

**7. MEANS OF MOVEMENT**

Common carrier

**8. VARIANCE VERIFICATION**

Have you previously applied for variance(s) that you wish to apply to this permit?  Yes  No

**Variance Number(s):**

**If so, describe in a brief summary how the variance will be applied:**

N/A

**WARNING:** Any use of ePermits to make materially false, fictitious, or fraudulent statements or representations is subject to civil penalties of up to \$250,000 (7 U.S.C. § 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C. §1001).

**9. REGULATED ARTICLE****Scientific Name:** Aspergillus niger, Fusarium solani**Common Name:****Cultivar and/or Breeding Line:****Any biological material (e.g., culture medium, or host material) accompanying the regulated Article during movement:**

No additional biological material included with regulated material during movement.

**Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed, and produced:**

Paris, France

NOTE: SUPPLIER MAY NOT BE CLAIMED AS CBI IF THE APPLICANT AND SUPPLIER AND/OR DEVELOPER ARE THE SAME.

**Processes, Procedures, and Safeguards Description:****10. ARTICLE SUPPLIER AND/OR DEVELOPER**

<u>Name</u>	<u>Location</u>	<u>Contact Information</u>
Mr. Richard Smith	00 Rue de Merveilleux Paris 000 France <b>County:</b> Ile de France	<b>Day Telephone:</b> 00+000+123456 <b>FAX:</b> <b>Email:</b>

**11. PHENOTYPES/GENOTYPE****1) Phenotypic Designation Name:****Identifying Line(s):** Aspergillus niger or Fusarium solani NOTE: Construct components may be used in different combinations.**Construct(s):** 1-0-1**Mode of Transformation:** Protoplast

**Phenotype Description:** The fungal strains produce [lipases that hydrolyze fatty acids and produce green fluorescent protein. The GFP is a selectable marker for transformation.]

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.

**Phenotype(s)**

00 - Fatty acid degrading enzyme

**Genotype(s)**

Gene(s) of Interest

Promoter: [lipase] **from** [Aspergillus oryzae] - native promoterPromoter: [lipase] **from** [Aspergillus nidulans] - native promoterGene: [lipase] **from** [Aspergillus oryzae] - Degrades fats.Terminator: [lipase] **from** [Aspergillus oryzae] - native terminator

Screenable Marker

Promoter: [35s] **from** Cauliflower mosaic caulimovirus - [enhanced 35s function]Gene: [GFP] **from** Aequorea victoria - [green fluorescent protein used to monitor protein transport in plants]Terminator: [NOS] **from** [Agrobacterium tumefaciens] - [nopaline synthase from agrobacterium]

WARNING: Any use of ePermits to make materially false, fictitious, or fraudulent statements or representations is subject to civil penalties of up to \$250,000 (7 U.S.C. § 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C. §1001).

**12. INTRODUCTION****Point of Origin**

<u>Location Name &amp; Description</u>	<u>Location Address</u>	<u>Contact(s)</u>
1) Institute de Recherche	France	1) Mr. Jean Boulanger Day Telephone: 33+235+12345

**Destination**

<u>Location Name &amp; Description</u>	<u>Location Address</u>	<u>Contact(s)</u>
1) American Institute of Science	NOTE: DESTINATION MAY NOT BE CLAIMED AS CBI, IF IT IS THE SAME AS THE APPLICANT'S ADDRESS. NY County: Jefferson Proposed Start Date: 11/1/2011 Proposed End Date: 11/1/2012 Quantity: 10 Individual Petri dishes Inspected by BRS or PPQ? Yes Previous Permit No.: 08-258369rm, 08-1472589m	1) John Doe Day Telephone: 000-000-000

**13. DESIGN PROTOCOLS****Production Design**

A detailed description of the purpose for the introduction of the regulated article including detailed description of the proposed experimental and/or production design:

N/A

**Destination or Release Description**

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):

NOTE: THIS INFORMATION MAY BE CLAIMED AS CBI.

Microbial cultures will be moved to the research and manufacturing facility for storage and subsequent growth in culture. There will be no plant inoculation. The cultures will be grown for enzyme extraction and commercial sale.

**Confinement Protocols**

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:

NOTE: THIS INFORMATION MAY BE CLAIMED AS CBI.

Cultures will be shipped according to 7 CFR 340.8 (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:

Volume not exceeding 50 ml (petri plates) will be placed in a securely closed durable plastic box and enclosed in a second, durable watertight container plastic box. The space between the primary and secondary containers contain sufficient nonparticulate absorbent material to absorb the entire contents of the primary container(s). Each set of primary and secondary containers will be enclosed in an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, or other material of equivalent strength.

**Final Disposition Method:**  Destruction/Deactivation  Other  Storage in Contained Facility

**Final Disposition Description:**

NOTE: THIS INFORMATION MAY BE CLAIMED AS CBI.

All cultures will be autoclaved or stored in secured storage (limited access, locked storage) for future use.

**14. ATTACHMENTS**

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**15. ADDITIONAL INFORMATION**

NOT A VALID PERMIT. APHIS EXAMPLE PERMIT FOR THE IMPORTATION OF MULTIPLE ORGANISMS.

---

**16. COURTESY JUSTIFICATION**

---

I, *James Smith*, hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

I acknowledge this is not an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents, as described in 9 CFR 121.

I will not introduce the regulated articles described in this application until APHIS has deemed the application complete and has granted the permit. By signing this permit, I agree to comply with any and all state, local, and tribal laws and regulations that may apply to the introduction of the articles described in this applications.

If there are any changes to the information disclosed in this application, I will contact APHIS.

**17. SIGNATURE OF RESPONSIBLE PERSON**

James Smith

**18. DATE**

April 14, 2011

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U.S. DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
BIOTECHNOLOGY REGULATORY SERVICE  
**APPLICATIONS FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340**  
(Genetically Engineered Organisms or Products)

**1. NAME, ADDRESS, TELEPHONE, AND EMAIL OF APPLICANT**

**Name:** Mr. James Smith  
**Position:** CEO  
**Organization:** Premier Enzymes  
**Organization Unique ID:**  
**Address:** 1 State Street  
Middletown, IA 00000  
**County/Province:** NOTE: THE APPLICANT AND CONTACT  
INFORMATION MAY  
**Township/Island:** NOT BE DECLARED AS CBI  
**Day Telephone:** 914-555-1212  
**FAX:**  
**Alternate:**  
**Email 1:** JSmith@email.com  
**Email 2:**

**2. INTRODUCTION TYPE**

- Importation  
 Interstate Movement  
 Interstate Movement and Release  
 Release

**3. PERMIT TYPE**

- Standard Permit  
 Courtesy Permit

**4. PURPOSE OF PERMIT**

- Industrial Product  
 Pharmaceutical Product  
 Phytoremediation  
 Traditional  
 test purpose

**5. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)**

Does this application contain CBI?  Yes  No

**CBI Justification:**

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APHIS EXAMPLE PERMIT (Importation - Multiple Species - Permit contains Confidential Business Information (CBI))

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If this information was disclosed, replication by a competitor would cause the loss on many dollars in developing our technology. Furthermore, the competitors would have access to this technology for free at our expense.

**6. REQUEST TYPE**

New  Amendment  Renewal  Variance  Amendment, Renewal and/or Variance

**Amendment/Renewal Description:**

**Previous Permit Number(s):**

**7. MEANS OF MOVEMENT**

Common carrier

**8. VARIANCE VERIFICATION**

Have you previously applied for variance(s) that you wish to apply to this permit?  Yes  No

**Variance Number(s):**

**If so, describe in a brief summary how the variance will be applied:**

N/A

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**Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed, and produced:**

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<u>Name</u>	<u>Location</u>	<u>Contact Information</u>
Mr. Richard Smith	00 Rue de Merveilleux Paris 000 France County: Ile de France	Day Telephone: 00+000+123456 FAX: Email:

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**Phenotype(s)**

00 - Fatty acid degrading enzyme

**Genotype(s)**

Gene(s) of Interest

Promoter: [ ] from [ ] - native promoter

Promoter: [ ] from [ ] - native promoter

Gene: [ ] from [ ] - Degrades fats.

Terminator: [ ] from [ ] - native terminator

Screenable Marker

Promoter: [ ] from Cauliflower mosaic caulimovirus - [ ]

Gene: [ ] from Aequorea victoria - [ ]

Terminator: [ ] from [ ] - [ ]

**12. INTRODUCTION****Point of Origin**

<u>Location Name &amp; Description</u>	<u>Location Address</u>	<u>Contact(s)</u>
1) Institute de Recherche	France	1) Mr. Jean Boulanger Day Telephone: 33+235+12345

**Destination**

<u>Location Name &amp; Description</u>	<u>Location Address</u>	<u>Contact(s)</u>
1) American Institute of Science	NOTE: DESTINATION MAY NOT BE CLAIMED AS CBI, IF IT IS THE SAME AS THE APPLICANT'S ADDRESS. NY County: Jefferson Proposed Start Date: 11/1/2011 Proposed End Date: 11/1/2012 Quantity: 10 Individual Petri dishes Inspected by BRS or PPQ? Yes Previous Permit No.: 08-258369rm, 08-1472589m	1) John Doe Day Telephone: 000-000-000

**13. DESIGN PROTOCOLS****Production Design**

A detailed description of the purpose for the introduction of the regulated article including detailed description of the proposed experimental and/or production design:

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**Final Disposition Method:**     Destruction/Devitalization     Other     Storage in Contained Facility

**Final Disposition Description:**    NOTE: THIS INFORMATION MAY BE CLAIMED AS CBI.

All cultures will be autoclaved or stored in secured storage (limited access, locked storage) for future use.

**14. ATTACHMENTS**

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**15. ADDITIONAL INFORMATION**

NOT A VALID PERMIT. APHIS EXAMPLE PERMIT FOR THE IMPORTATION OF MULTIPLE ORGANISMS.

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**16. COURTESY JUSTIFICATION**

---

I, *James Smith*, hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

I acknowledge this is not an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents, as described in 9 CFR 121.

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If there are any changes to the information disclosed in this application, I will contact APHIS.

**17. SIGNATURE OF RESPONSIBLE PERSON**

James Smith

**18. DATE**

April 14, 2011