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

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Notification User Guide

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

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

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

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

Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
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GUIDE INFORMATION

ISSUING AGENCY/OFFICE:	Animal and Plant Health Inspection Service (APHIS) BiotechnologyRegulatory Services (BRS)
TITLE OF DOCUMENT:	Notification User Guide with Reference To 7 CFR Part 340 – Movement of Organisms Modified or Produced Through Genetic Engineering
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SUMMARY:	The Notification Guide aids APHIS stakeholders (responsible persons, their agents and the general public) on preparation of a notification application to move (import, move interstate, or release into the environment) organisms developed through genetic engineering (modified organisms).
DISCLAIMER:	The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Agency regulations.

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INTRODUCTION

A notification is an administratively streamlined alternative to the permit process to allow the introduction of a certain subset of genetically engineered plants (modified plants). The Notification Guide aids APHIS stakeholders (responsible persons, their agents and the general public) on preparation of a notification application to move (import, move interstate, or release into the environment) organisms developed through genetic engineering (modified organisms).

QUICK GUIDE TO NOTIFICATION

The goal of the notification procedure is the same as the permit system: preventing the dissemination and establishment of plant pests.

You may use the notification procedure for introduction (interstate movement, importation, environmental release) for modified plants if:

- The introduced plant meets **all** of the six eligibility criteria, AND;
- The introduction (the importation, interstate movement, or environmental release) will meet **all** six performance standards.

Please note, however, that certain plants do not qualify for notification because they require specific supplemental permit conditions to ensure they remain confined. Examples include wheat, sorghum, camelina, and any species that have sexually compatible weed species near the release site. Also, the environmental release under notification may only occur for one year. A release involving a perennial plant can occur under notification if the release is limited to one year.

- By submitting an application for a notification to APHIS, the applicant certifies to APHIS that the regulated article and introduction will meet the specified eligibility criteria and performance standards, respectively.
  - Your application and supporting standard operating procedure help APHIS determine the appropriateness of the notification process for the proposed introduction.
    - Standard Operating Procedures (SOP) describe how the introduction meets the required performance standards. You may use APHIS' voluntary template or your own SOP so long as it describes how you will meet the six performance standards.
  - Please submit your application for notification to APHIS via APHIS eFile:
    - At least 10 days prior to an interstate movement of a regulated article, or
    - At least 30 days prior to an importation or environmental release of a regulated article

- APHIS sends copies of the notification to State regulatory officials for review in each State where a proposed introduction may occur.

- If APHIS agrees that the application is complete, the regulated article meets eligibility criteria, and the introduction meets performance standards, APHIS will send an acknowledgement letter to the applicant to authorize the introduction:
  - Within 10 days of receipt of a complete notification of interstate movement, or
  - Within 30 days of receipt of a complete notification of importation or environmental release.

- Introductions may not proceed without an acknowledgment letter from APHIS.
- Responsible persons must notify APHIS of any unusual occurrences that happen during the introduction in writing by email at BRSCompliance@usda.gov as soon as possible but not later than within 5 working days.
- Responsible persons must notify APHIS of any accidental or unauthorized release of the regulated article orally immediately upon discovery and in writing by email at BRSCompliance@usda.gov within 24 hours.
- All introductions are subject to inspection by Federal and/or State inspectors.
- You must complete all activities (e.g., all shipments must arrive at their destination, plants must be harvested, and remaining plants and plant parts must be destroyed or contained) related to this introduction by the expiration date. After the expiration date, you must continue to manage volunteers to prevent persistence in the environment. APHIS requests that responsible parties submit a Planting Report no later than 30 days following the date of the environmental release.
- Under notification, you must submit a Field Test Report to APHIS within six months of the expiration date of the notification.

NOTIFICATION FOR THE INTRODUCTION OF CERTAIN REGULATED ARTICLES

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).

Beginning with the Coordinated Framework in 1986[1], APHIS oversaw introductions of regulated articles by granting permits. In 1993, APHIS introduced the notification procedure as a streamlined alternative to permitting for crops with which APHIS had developed experience.

This experience gives APHIS confidence that the regulated article will not be released beyond the proposed introduction (both in time and space) if the responsible party certifies that specified performance standards will be met.

[1] To view the 1986 framework, go to *https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf*.

> ***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).

Importation is the movement of regulated articles from a foreign country into the United States; interstate movement is the movement of the regulated articles from one U.S. State, Territory, or District to another. A release is the use of a regulated article outside a structure that provides physical confinement constraints that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure, designed to prevent dissemination and establishment of the organism.

APHIS reviews the application for notification for appropriateness of the proposed introduction under the notification process. If APHIS agrees that the introduction qualifies for notification, APHIS will authorize the activities in a notification by issuing acknowledgement letter within 10 days (interstate movement) or 30 days (importation, Release, or Interstate Movement and Release). Introductions may not proceed without a letter of acknowledgement from APHIS.

Please note that other Federal and State plant quarantine laws may restrict or prohibit the interstate movement, importation, or release of the regulated article. Additional information for such restriction can be found from "Additional Federal and State Regulatory Requirements That may Apply to APHIS BRS Authorizations" Document located at https://www.aphis.usda.gov/biotechnology/biotechnology-permits-notifications. For example, although a pathogen-resistant plant variety may be eligible for introduction under the notification procedure, use of an unmodified pathogen may still require additional permits (e.g., challenge-inoculation experiments of resistant plants). It is the applicant's responsibility to obtain any additional permits required by Federal and State law.

QUALIFYING FOR THE NOTIFICATION PROCESS

Only introductions of certain modified plants are eligible for the notification process. Modified insects, nematodes, bacteria, viruses, and other regulated microorganisms do not qualify for notification; a permit application must be submitted for introductions of these organisms. Further, because the duration of a release under notification is limited to one year from the effective date listed in the acknowledgement letter, environmental releases of most perennial and biennial plant species must be authorized under a permit, unless the release will be fully terminated within one year from the effective date of notification authorization.

To qualify for the notification process, the applicant must certify that: 1) the regulated article meets specific eligibility criteria, and 2) the introduction will meet specified performance standards.

ELIGIBILITY CRITERIA

To introduce a regulated article under the notification procedure, the regulated article must meet all of the six eligibility criteria described below. Eligibility criteria are characteristics of the regulated article (i.e., the plant) and the introduced genetic material.

If you have questions about whether a proposed regulated article will meet all six eligibility criteria, contact APHIS brspermits@usda.gov as far in advance of the proposed introduction as possible. Regulated articles that do not meet all six eligibility criteria may still be eligible for introduction under a permit, but the approval of a permit may take longer than a notification.
The eligibility criteria are:

1. **Recipient organism is not listed as a noxious weed nor considered by APHIS to be a weed in the area of release**

> "The regulated article is any plant species that is not listed as a noxious weed in regulations at 7 CFR part 360 under the Plant Protection Act (7 U.S.C. 7712), and, when being considered for release into the environment, the regulated article is not considered by the Administrator to be a weed in the area of release into the environment." (§ 340.3(b)(1)).

Most common crops meet this eligibility criterion. Introductions of plant species listed as noxious weeds in 7 CFR § 360 are not eligible for notification. Plants being considered for release into the environment are not eligible under notification if they are considered weeds in the area of release. If there is any question that the plant species could be considered a weed in the area of release, we encourage you to contact state plant board.

2. **Stable integration of genetic material**

> "The introduced genetic material is 'stably integrated' in the plant genome, as defined in Sec. 340.1." (§ 340.3(b)(2)).

> **Stably Integrated.** The cloned genetic material is contiguous with elements of the recipient genome and is replicated exclusively by mechanisms used by recipient genomic DNA (§ 340.1).

The DNA may be inserted into any part of the genome of the plant including nuclear, mitochondrial or chloroplast genomes. The method of transformation must result in a stable integration. Vectors that can mobilize or replicate would not be considered a stable transformation. For instance, extrachromosomal maintenance of the genetic material is not considered as stably integrated (e.g. novel genetic material maintained on plasmids or transposons, extrachromosomal replication of viral vectors).

3. **Known function of genetic material that does not result in plant disease**

> "The function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease." (§ 340.3(b)(3)).

The intent of this criterion is to exclude the use of introduced genetic material that would result in plant disease. This criterion excludes many sequences expressing pathogenesis-related proteins. This also requires that the applicant knows enough about the function of the genetic material to assert that it does not cause plant disease.

To make the assertion that an inserted sequence is unlikely to result in plant disease, the function of the inserted material in the plant must have been determined by empirical observation or inferred from a high degree of sequence similarity to sequences with an empirically determined function. This criterion excludes, for example, nucleotide sequences whose sole identification or characterization is based upon expression in response to a particular chemical or physical stimulus.

4. Characteristics of the gene and gene product

> "The introduced genetic material does not: (i) Cause the production of an infectious entity, or (ii) Encode substances that are known or likely to be toxic to nontarget organisms known or likely to feed or live on the plant species, or (iii) Encode products intended for pharmaceutical or industrial use." (§ 340.3(b)(4)).

This criterion has three components. The first ensures that the modified plant has not been modified to produce an infectious entity, such as a plant virus, an animal virus, a human virus, or other infectious entities. This criterion does not exclude the use of genetic materials from infectious entities per se, so long as a complete infectious entity cannot be produced.

The second component prevents introductions of modified plants that are likely to be toxic to nontarget organisms living or feeding on the plants.

Finally, the modified plant must not express compounds intended for pharmaceutical or industrial use. These modified plants always require a permit.

Plants are considered to express compounds intended for pharmaceutical use if commercialization of the compound would require approval of one of the following agencies:
1. FDA's Center for Biologics Evaluation and Research (human biologics),
2. FDA's Center for Drug Evaluation and Research (human drugs),
3. FDA's Center for Veterinary Medicine (animal drugs), or
4. USDA's Center for Veterinary Biologics (animal biologics).

Plants that meet all of the following three criteria are considered to produce industrial compounds:
1. The plants are engineered to produce compounds that are new to the plant,
2. The new compound has not been commonly used in food or feed, and
3. The new compound is being expressed for non-food, non-feed industrial uses. Industrial uses include, but are not limited to, detergent manufacturing, paper production, and mineral recovery.

Plants engineered for tolerance to heavy metals and use in agricultural production are not excluded from the notification process by this criterion. However, plants that accumulate or detoxify soil contaminants require a permit, even if not intended for food or feed use.

5. Does not pose significant risk of creating new plant viruses

> "To ensure that the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, plant virus-derived sequences must be: (i) Noncoding regulatory sequences of known function, or (ii) Sense or antisense genetic constructs derived from viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species, and that do not encode a functional noncapsid gene product responsible for cell-to- cell movement of the virus." (§ 340.3(b)(5)).

The intent of this criterion is to prevent the creation of new plant viruses that might result from recombination of the introduced genetic material with genetic material from endemic viruses. Introduced sequences derived from plant viruses must be either noncoding sequence or sequences that are 1) from viruses prevalent and endemic in the proposed area of introduction, and 2) do not encode a functional cell-to-cell movement protein. Eligible non-coding sequences include promoters, enhancers, introns, upstream activating sequences, polyadenylation signals, transcription terminators, or other known regulatory sequences. In addition to anti-sense constructs, eligible constructs also include those using other mechanisms of RNA-mediated gene silencing of virus genes.

6. Does not contain sequences from human or animal pathogens

> "The plant has not been modified to contain the following genetic material from animal or human pathogens: (i) Any nucleic acid sequence derived from an animal or human virus, or (ii) Coding sequences whose products are known or likely causal agents of disease in animals or humans." (§ 340.3(b)(6)).

Plants containing any nucleic acid sequence derived from an animal or human virus are not eligible for notification (e.g., hemagglutinin derived from human influenza virus). In addition, plants containing coding sequences whose products are known or likely causal agents of disease in humans or nontarget animals are not eligible (e.g., cholera toxin A). APHIS cannot authorize notifications involving select agents, or toxins produced by select agents.

PERFORMANCE STANDARDS

The performance standards are a set of six conditions that must be met to ensure that the regulated article is introduced in such a way that it is not inadvertently released beyond the proposed introduction, allowing it to persist in the environment.

The goal of performance standards is to manage the introduced regulated article such that it or its offspring are unlikely to escape or persist in the environment. The applicant is given flexibility in developing protocols appropriate to the introduction. However, as part of the application for notification, the applicant must certify that the introduction will meet the performance standards (see **Information to Include in a Notification: Certification** below). Applicants submit documents for releases, such as SOP, that address how the performance standards will be met. See section on **SOP** below.

If you have questions about whether a proposed introduction will meet all six performance standards, please contact APHIS before applying for a notification. We encourage applicants to discuss with APHIS any

relevant biological considerations associated with particular plant species that may affect the ability to meet performance standards.

Introductions that do not meet all of the performance standards may still be eligible for introduction under a permit.

The required performance standards are:

1. Shipping and maintenance at destination

> "If the plants or plant materials are shipped, they must be shipped in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment." (§ 340.3(c)(1)).

Plant materials shipped under notification must be packaged to ensure that plant material is unlikely to be released from the shipping container in transit. The shipping container requirements described in 7 CFR § 340.8 or similar shipping methods are sufficient to meet this performance standard. The packaging should generally include redundant layers to prevent loss of regulated material, and, at a minimum, such packaging must include a layer comprised of a solid container (cardboard box, hard plastic tote, etc.) and a layer comprised of secure material (super sac, paper, plastic, or fiber bag, etc.). Both layers must be adequately sealed. Although not mandatory, it is prudent to label all packages clearly with their contents and prominently display the authorization number on the package.

APHIS does not regulate the use of modified plants in contained facilities and does not evaluate the adequacy of research and storage facilities to prevent release into the environment. However, unauthorized releases of regulated articles from such facilities will result in noncompliance with APHIS regulations. APHIS strongly encourages applicants to ensure that destination facilities follow containment guidelines established by the National Institutes of Health or other similar guidelines.

For more information about contained facilities see:

- Guidelines for Research Involving Recombinant DNA Molecules (National Institutes of Health)
- Practical Guide to Containment— Greenhouse Research with Transgenic Plants and Microbes (Information Systems in Biotechnology, Virginia Tech)

2. Inadvertent mixing of materials in environmental releases

> "When the introduction is an environmental release, the regulated article must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release." (§ 340.3(c)(2)).

This performance standard minimizes the likelihood of mixing of regulated and non-regulated material through physical comingling.

Inadvertent mixing of regulated material and nonregulated material can usually be prevented by planting the regulated article in a defined area with an unplanted alley or other easily distinguishable zone between

it and any other material. These areas should not be planted with a species that will be harvested or with a sexually compatible species of the regulated article. All species planted within the release area must be morphologically distinct from the regulated article. Alleys between the regulated field plot and neighboring plots should be sufficient to allow movement of planting 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 plant species that are not part of the release. Farm implements that can retain viable seed or other propagules should be cleaned on the release site or otherwise treated to meet the performance standards. Persons granted access to the release site should be made aware of any protocols used to meet the performance standards to ensure that their actions at the site will be consistent with those requirements.

3. Maintaining identity and devitalization

> "The plants and plant parts must be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use." (§ 340.3(c)(3)).

This performance standard stipulates that the regulated articles are clearly identified at all times so that they are not inadvertently confused with other plant materials, and that they are either destroyed or moved to contained facilities prior to the expiration date of the notification.

Identity of regulated articles should be maintained with adequate labeling, record keeping, and by planting modified plants in distinct plots. See also Performance Standard 2 for more guidelines on preserving the identity of regulated material in the field.

Methods of final disposition and devitalization might include:

- Harvest of all seed, ears, tubers, or other reproductive material for transport to devitalization or containment facilities.
- Incorporation of all remaining vegetative material at the release site into the soil for decomposition or above-ground composting.
- Treatment of the remaining vegetative material with an appropriate registered herbicide.
- Removal of the plants to a contained facility, cutting and mulching, exposing the plants to high temperature treatment (i.e., autoclaving, oven baking, or incineration, in accordance with local regulations), or ensuring that any underground plant parts capable of reproduction are removed and likewise destroyed.
- For plants allowed to set seed during the field trial, the occurrence and duration of seed dormancy are factors that should also be considered in the design of proper post termination monitoring protocols.

Plant materials that are not destroyed must be moved to a contained facility to prevent further unauthorized release prior to the expiration date of the notification. The identity of stored seeds and propagative plant parts must be maintained in such a way that persons handling these regulated articles will know that subsequent introductions require APHIS authorization. All materials must be securely stored in a contained facility or devitalized according to the above no later than the expiration date of the notification, or when all research activities at the release site are terminated if prior to the notification's expiration date. See Performance Standard 1 for guidelines on contained facilities.

4. Elimination of viable vector agents

> "There must be no viable vector agent associated with the regulated article." (§ 340.3(c)(4)).

When the transformation vector agent involved is a live microorganism, such as *Agrobacterium tumefaciens*, the transformed tissue should be free of the bacterium at the time of introduction. Acceptable elimination of the bacterium can be accomplished by treatment of the plant material with appropriate antibiotics.

5. Persistence in the environment

> "The field trial must be conducted such that: (i) The regulated article will not persist in the environment, and (ii) No offspring can be produced that could persist in the environment." (§ 340.3(c)(5)).

> ***Persistence in the environment.*** Producing feral or sustained populations of the regulated article or its offspring that can persist in agricultural or nonagricultural habitats without human intervention. (58 Fed. Reg. 17044, 17049 (Mar. 31, 1993).

The fifth performance standard most often determines whether APHIS will allow an introduction under the notification procedure. Plant species having characteristics that make them more likely to persist without human intervention are less likely to be eligible for notification but may still be eligible for release under a permit.

Pollen movement must be prevented between the regulated article and wild relatives or non-regulated sexually compatible relatives (SCRs). If viable pollen may be produced by the regulated plants, the applicant should consider the following:

- Whether the plant is self-pollinating or outcrossing.
- The extent and distance of pollen dissemination by wind and/or pollinating insects, birds, or other species, and the occurrence of these species in the area.
- The ability for the plant species to produce viable, fertile progeny with sexually compatible wild, weedy, or feral relatives, and their distribution.
- Synchrony of the flowering cycle of the regulated plants with other sexually compatible relatives.
- The ability of hybrid progeny to persist in the environment.
- Any precautions that may be taken to minimize pollen movement (such as flower bagging, flower removal, border rows, male sterility, etc.).
- Any precautions that may be taken to prevent persistence of hybrids in the environment (such as removal or destruction of wild relatives in the area, provided they are not threatened and endangered species).

In general, the isolation distances for foundation seed production published by the Association of Official Seed Certifying Agencies (AOSCA) should be considered the minimum acceptable distance between the

regulated plants and any sexually compatible species. The foundation seed production distances can be different depending on certain situations for some crops, e.g., depending on the size of the field and whether hybrid seeds are being produced. For example, greater isolation distances are sometimes specified for production of hybrid seeds for crops with male sterility. Likewise, APHIS recommends increased distances when cultured insect-pollinators are used for seed production. Local seed certification rules may also impose greater distances. More stringent methodologies may be necessary for the applicant to ensure that no progeny will be produced that can persist in the environment.

Isolation distance standards are published in AOSCA's "Yellow Book." For a few common crops BRS has published minimum separation distances to conduct field trials on its website.

To minimize the likelihood that seed or vegetative propagules are dispersed from an environmental release and create persistent populations, the applicant should consider the following:

- Dispersal mechanisms of seed or vegetative propagation (natural or accidental).
- Whether the release site is near waterways or in an area prone to flooding.
- Range of possible dispersal.
- Likelihood of seed or propagule survival within the range of possible dispersal.
- Methods adequate to prevent such dispersal, including appropriate confinement measures if appropriate.
- Ability to monitor for, identify, and destroy any dispersed plants or their progeny.

If seeds or propagules are likely to be dispersed long distances (such as by wind or animals), it may be necessary to prevent seed set or to use bagging, netting, or other methods sufficient to prevent dispersal.

6. Preventing and managing volunteer plants

> "Upon termination of the field test: (i) No viable material shall remain which is likely to volunteer in subsequent seasons, or (ii) Volunteers shall be managed to prevent persistence in the environment." (§ 340.3(c)(6)).

Volunteers should be minimized by growing modified plants in defined areas in the field and by using adequate termination protocols (see Performance Standard 3). The use of stakes, markers, or GPS coordinates, to define the area where modified plants were grown help in identifying volunteers for later elimination. Responsible persons should have monitoring protocols of adequate frequency and duration to ensure that all volunteers have been eliminated by the methods described in the sections above, including those volunteers that may emerge outside of the field plot (e.g., in fallow zones or adjacent fields). See also Performance Standard 5 above.

PROCEDURAL REQUIREMENTS FOR NOTIFYING APHIS

To notify APHIS of an interstate movement of a regulated article, you must submit an application for notification to APHIS via APHIS eFile at least ten days prior to the proposed day of movement. To notify APHIS of an importation or environmental release of a regulated article, you must submit an application for notification to APHIS via APHIS eFile at least 30 days prior to the proposed day of importation or release.

One notification may include multiple plant lines derived from more than one transformation event and/or multiple constructs. However, all lines described in a single notification must be of the same crop or plant species. If you wish to introduce more than one crop species, send separate applications for notification for each species.

One notification may include more than one introduction.

- Multiple interstate movements and/or multiple environmental releases (i.e., multiple field trial locations) may be described in the same notification. Notification of interstate movement and environmental release may be combined in the same document.
- Multiple importations may be described in one notification. Notification of importation cannot be combined with notification of interstate movement or release.

INFORMATION TO INCLUDE IN A NOTIFICATION

"The notification shall include the following:
(i) Name, title, address, telephone number, and signature of the responsible person;
(ii) Information necessary to identify the regulated article(s), including:
(A) The scientific, common, or trade names, and phenotype of regulated article,
(B) The designations for the genetic loci, the encoded proteins or functions, and donor organisms for all genes from which introduced genetic material was derived, and
(C) The method by which the recipient was transformed;
(iii) The names and locations of the origination and destination facilities for movement or the field site location for the environmental release; and the size of the introduction,
(iv) The date and, in the case of environmental release, the expected duration of the introduction (release); and
(v) A Statement that certifies that introduction of the regulated article will be in accordance with the provisions of this section." (§ 340.3(d)(2)).

Certain information must be present in your application for notification to help APHIS determine if the regulated article and proposed introduction meet eligibility criteria and performance standards. To facilitate APHIS review of this information, follow the guidelines below for organizing your information. The following application sections are listed in the order they appear in the .pdf format of the application. For instructions on completing details in APHIS eFile, see "Application Details Chevrons" Section of Permit User Guide. You can find additional help from APHIS 2000 Permit Application and Compliance Reporting Job Aid or USDA APHIS eFile Training.

1. **APPLICANT INFORMATION.** The "applicant" is the person responsible for the information provided in the notification who has control and will maintain control over the introduction of the regulated article to ensure that Federal Regulations are met, and who certifies the notification (see **Certification** below). A responsible person representing the organization must provide their name and sign the notification.

   The responsible person must 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 the responsible person.

Name, title, full address, email address, and telephone number of the primary person responsible for the introduction of the regulated article should be provided.

2. **PURPOSE OF PERMIT.** You do not need to complete this detail if you are applying for notification.

3. **MOVEMENT TYPE.** Identify whether the introduction is an importation, interstate movement, environmental release, or a combination of interstate movement and environmental release.

4. **APPLICANT REFERENCE NUMBER (optional).** An applicant-supplied reference number for the applicant's own use only (e.g., for internal tracking). An official APHIS BRS authorization number will be assigned to the application after it is submitted.

5. **CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI).** Identify whether the submission contains CBI. If so, a CBI justification statement must be included. For more information about submission of documents containing CBI, including drafting a CBI justification statement, see CBI Document Submission Guidelines. Please note that the APHIS eFile system uses square brackets '[ ]' to identify CBI content. If you are submitting a notification using APHIS eFile, do not use square brackets in your submission unless they denote CBI content.

6. **REQUEST TYPE.** Select **"**new" when applying for a notification.

7. **MEANS OF MOVEMENT.** Indicate whether you transport the regulated material under notification via commercial carrier or by hand carrier.

8. **ORGANISM.** Provide the common name, scientific name, and cultivar name(s) for the recipient plant.

9. **ORGANISM SUPPLIERS OR DEVELOPERS.** Indicate the supplier or developer of the regulated plant.

10. **CONSTRUCTS.** The information in this section identifies each group of plant lines having the same inserted DNA construct(s) (added genetic element(s) expected to be identical within a genetically engineered plants). Multiple plant lines would be classified as a single construct if they were genetically engineered with the same DNA, regardless of where the DNA was inserted into the recipient plant DNA.

    CONSTRUCT(S) CHEVRON
    For APHIS, a construct is the DNA that is incorporated into the recipient genome of the plant(s) listed in the application, or the edits to the genome of the plants. A single plant or a line with multiple constructs (stacks) would be considered a single construct.

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

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

- Construct Details
- Intended Trait(s)
- Genotypes

Additional information about these sections is detailed below.

Construct Details

Construct Name (required). Provide a unique name to identify 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. The designation can be a name, number, short phrase, or any other unique identifier provided by the applicant to assist both the applicant and APHIS in tracking the transformed line. When necessary, APHIS uses this information to communicate with applicants about constructs.

Organism (required). Select the plant modified with your construct. APHIS eFile provides a construct cloning tool that can be used to reduce data input. APHIS uses this information, in conjunction with other construct information, to evaluate the modified plant's potential to escape containment/confinement.

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

- If the material inserted into the genome is itself expected to create further alterations, the modification method should refer only to the method of construct insertion into the genome (e.g., if disarmed Agrobacterium tumefaciens is used to insert genome editing mechanisms such as Cas9, the modification method selected should be "Agrobacterium tumefaciens, disarmed").
- You should select "Direct Injection" when enzymes, templates, or plasmids are injected into a cell for the purpose of altering the genome (e.g., injection of plasmids with PiggyBac transposable elements, injection of Cas9).
- If you select "Other", you should use the Transformation Events/Construct Description field to describe the modification method and provide references as necessary. APHIS uses this information to evaluate the intended trait(s).

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

Intended Trait(s):
In general, a construct can have one or more expression cassettes, and each expression cassette can have an associated intended trait.

An intended trait is composed of three characteristics:

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

Traits can be classified into 10 distinct categories:

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

Phenotype (required). Provide your phenotype. A phenotype is a set of observable characteristics of an organism resulting from the interaction of its genotype with the environment. The phenotype expands on the Trait category. It is important to note the directionality of your phenotype when entering your specific phenotype information (e.g., increased leaf blight resistance as opposed to leaf blight resistance or early flowering time as opposed to altered flowering time). APHIS uses this information to confirm eligibility.

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

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

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

- “Empty Transformation Vector”
- “Gene Knock-Out”
- “Gene Silencer”
- “Gene(s) of Interest”

- "RNA Interference (RNAi)"
- "Screenable Marker"
- "Selectable Marker"
- "Virus Genome"
- "Wild Type"
- "Recombination Site"
- "Other"

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

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

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

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

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

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

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

APHIS uses this information to contribute to the understanding of the function of a component.

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

Previously Submitted Constructs (PSCs) Section

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

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

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

11. **LOCATIONS.** This section includes details specific to each type of introduction: importation, interstate movement, and/or environmental release. Notification for interstate movement may be combined with notification for environmental release (include both sections separately), but notification for importation must be provided in a separate request.

Location Information

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

- "Origin" location. This represents where regulated material is shipped from.
- "Destination" location. This represents where regulated material is received.

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

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

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

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

Location Section (Origin, Destination, Origin & Destination, and Release Location Types)
These fields are common across all location types: Location Name (required), Street Address 1 (required), Street Address 2 (optional), Street Address 3 (optional), Street Address 4 (optional), City (required), Country (required), State/Province (required), County (required), Zip (required), and Location Description (optional). APHIS uses this information to identify locations and verify the address of a location if an inspection is required. APHIS also uses the County and State information to verify the provided GPS coordinates for each Release location.

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

APHIS uses this information to determine if the location is a contained facility and determine notification eligibility.

Location Unique ID (required). This field is unique to the "Release" location type. Use only alphanumeric characters in this field. A location unique ID must be unique within each application. APHIS uses this information to assist in identifying release locations[1].
Materials Section (Destination and Origin & Destination location types)

Quantity (required), Material Type (required), and Unit of Measure (required). These fields are unique to "Destination" and "Origin & Destination" location types. The quantity entered in this field should represent the maximum total (cumulative) amount of material you plan to ship under the notification. For example, if you list 50 pounds of seed in this field, you could ship 10 pounds of seed 5 times, or 50 pounds of seed 1 time.

Release Details Section (Release location type)
The following fields are unique to "Release" location types:

Number of Proposed Releases (required). The Number of Proposed Releases indicates how many times you anticipate releasing your modified plant into the environment within the notification's duration[2].

- For multiple plantings, enter the number of plantings that will occur at a location. This is the number of times the listed Number of Acres (or the actual acreage, if your planted acreage is less than the value listed in that field) is planted under the notification. For example, if the Number of Acres 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.
- One release may span several days. However, if there is a gap of more than 30 days when no releases take place, the next release date will constitute the beginning of a new release. In this scenario, the number of proposed releases is greater than one.
- You may propose a greater number of plantings/releases than will be released to cover unexpected release needs. Please refer to **Appendices A and B** for more specific requirements and information on submitting planting reports.

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

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

Is Location within Critical Habitat (required). Use this field to indicate if the proposed release location is within Critical Habitat for Threatened and Endangered Species[2].

Proximity to critical habitat: Identify whether the proposed release site and/or area to be monitored are within, or in close proximity, to 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 of 1973, as amended). If so, provide 1) the species and common names for all species that have designated critical habitat or habitat proposed for designation within the release site and monitoring area, 2) an analysis of the effects of the proposed release on designated critical habitat or 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[1], and 3) measures that are being taken so that there is no disturbance of critical habitat.

Site Specific Information Section (Release location type)

[2] This information is necessary to facilitate assessment of the proposed release's possible impacts on threatened and endangered species. For additional guidance on assessment of these impacts, see Guidance for Critical Habitat Analysis, available online at National Environmental Policy Act.

Release Site History (required). This field is only present on "Release" location types. Use this field to describe the land use history of the release location and its adjacent areas. Indicate if the land has been in agricultural production. Specify the type of agricultural activity (e.g., cropping, pasture, orchard, managed forest). Describe the areas around the location. For example, is this an agricultural research farm surrounded by other agricultural research or production; are there sexually compatible species in the surrounding area; is this area used for breeding studies of the same species that is in the application?[2]

Duration. The proposed dates of release/planting and final harvest/destruction (devitalization) of the crop. Note: destruction/devitalization of plant and plant material remaining at the field release site must occur on or before the expiration of the notification. The latter date does not include any post-harvest monitoring period. Duration may be no longer than one year from the date of acknowledgement of the notification.

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

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

APHIS uses this information to help verify other information provided about the Release location, including **State/Province (required), County (required), Location Description (optional), and Release Site History (required)**.

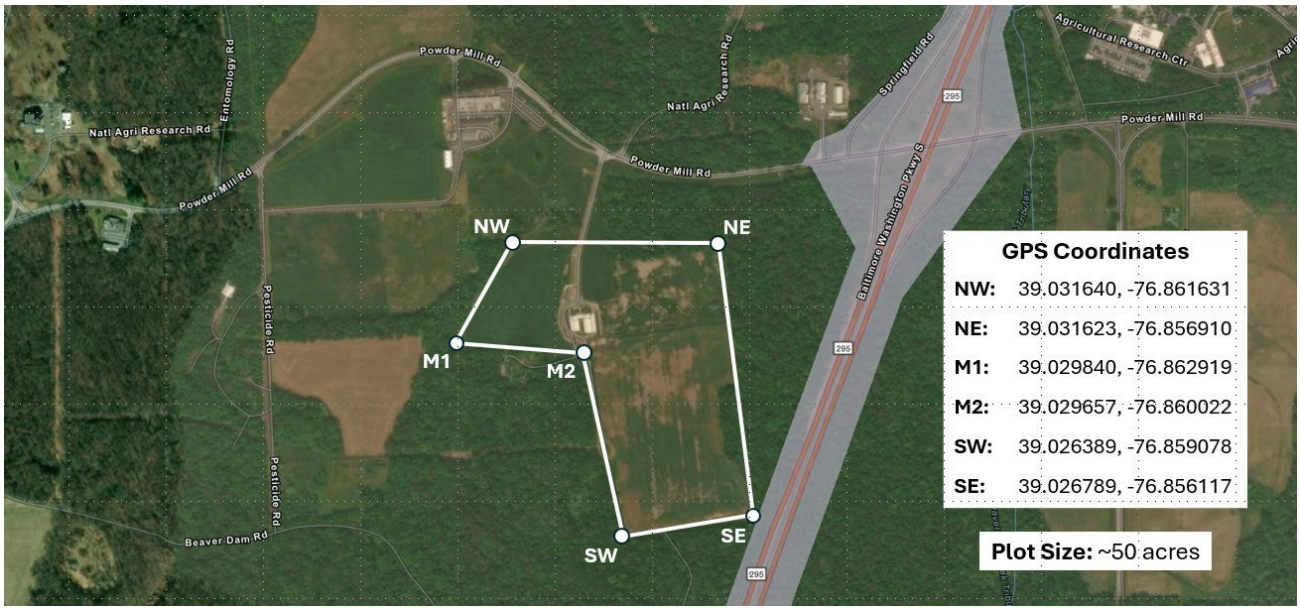

Figure 1. Use GPS coordinates to identify the Release location. You can submit coordinate pairs for a larger area than the Number of Acres you propose to plant to encompass the isolation distance to be monitored.

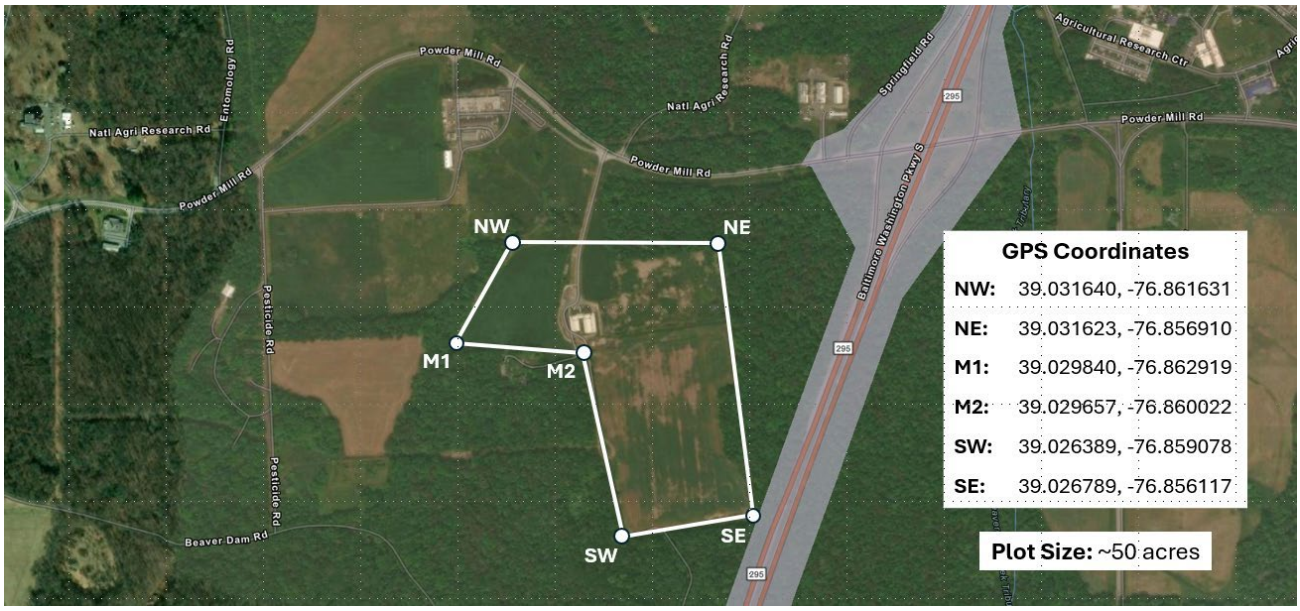

Figure 2. Use GPS coordinates to identify the boundaries of a Release location. You can enter up to six coordinates pairs to delineate boundaries and limit the release location to agricultural land. NW: northwest. NE: northeast. SW: southwest. SE: southeast. M1, M2: middle 1, middle 2.

Agents Section (Origin, Destination, Origin & Destination, and Release location types)
These fields are common across all location types:

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

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

12. **ATTACHMENTS.** Use this section to include SOP and other documents.

13. **ADDITIONAL INFORMATION.** Use this section to include any additional information that may support the applicants' certification that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR § 340.3.

14. **CERTIFICATION.** The notification must contain a signed certification that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR § 340.3. The certification must be signed and dated by the responsible person whose contact information appears in **1. APPLICANT INFORMATION** above. A portion of at least the previous section must appear with it such that the certification can be identified as belonging to a particular notification.

    An acceptable example of the certification statement is as follows:

    I certify that the regulated article(s) described in this document will be introduced in accordance with the eligibility criteria and performance standards set forth in 7 CFR § 340.3. Information contained in this document is true to the best of my knowledge. If there are any changes, I will contact APHIS promptly.

    Signature _____ Date _____
    Printed Name _____

STANDARD OPERATING PROCEDURE

To facilitate the APHIS review, applicants should submit an SOP that describe the specific cultivation and management practices they will use for any proposed environmental release that describes how the release will meet each of the required performance standards (see **Performance Standards** above).

After receiving an acknowledgement letter from APHIS authorizing an introduction, the responsible persons must provide inspectors access to on-site documentation that demonstrates that an introduction is meeting performance standards (see **Inspections** below).

Responsible persons are encouraged to have SOP or similar documentation available for inspectors to help demonstrate that the introduction meets the required performance standards.

CONFIDENTIAL BUSINESS INFORMATION IN NOTIFICATIONS

Only the CBI-deleted version is shared with State regulatory officials (see **APHIS Review and Acknowledgement** below). General instructions for inclusion of confidential business information (CBI) in submissions to APHIS are presented in Guide for Claiming Confidential Business Information.

NOTIFICATION AFTER SUBMISSION OR ACKNOWLEDGMENT

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

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

- Authorization number(s)
- Current Responsible Person Name
- Current Responsible Person Username (login.gov User ID) – if available, for verification purposes
- Requested New Responsible Person Username (login.gov User ID)

Email BRSpermits@usda.gov to change local agent. Changes to the other sections of acknowledged notification are generally not allowed once notification is acknowledged.

If your plans change and you do not intend to proceed with an introduction after submitting an application for a notification or receiving a letter from APHIS acknowledging a notification, please write to APHIS (BRSpermits@usda.gov) and request to withdraw your application or notification.

WHAT TO EXPECT AFTER NOTIFYING APHIS

APHIS REVIEW AND ACKNOWLEDGEMENT

Shortly after APHIS receives a notification, APHIS assigns a notification number to the submission and a biotechnologist reviews it to determine if it meets eligibility criteria and performance standards, APHIS sends a copy of the notification to the appropriate State regulatory officials for review and comment. APHIS does not have a formal CBI-sharing arrangement with State governments; therefore, APHIS will send the CBI-deleted copy of the notification to State regulatory officials. If State officials request access to CBI contained in a notification, APHIS encourages them to contact the applicant directly to request disclosure of the CBI. APHIS works collaboratively with the State regulatory officials using the wealth of knowledge of their environments to meet regulatory conditions; APHIS considers their input before acknowledgement of a notification involving a proposed importation or release into the environment.

> "(2) The Administrator, will provide acknowledgement within 10 days of receipt that the interstate movement is appropriate under notification.
> (3) The Administrator, will provide acknowledgement within 30 days of receipt that the importation is appropriate under notification.
> (4) APHIS will provide acknowledgment within 30 days of receipt that the environmental release is appropriate under notification. Such acknowledgment will apply to field testing for 1 year from the date of introduction, and may be renewed annually by submission of an additional notification to APHIS." (**§** 340.3(e)(2-4)).

After review of the notification, if APHIS agrees that the regulated article and proposed introduction meets required eligibility criteria and performance standards, APHIS will issue a letter to the applicant acknowledging the appropriateness of the introduction under the notification process.

Acknowledgement letters for notification of interstate movement will be sent within 10 days of receipt of the complete notification. APHIS will send acknowledgement letters for notification of proposed importations and environmental releases within 30 days of receipt of the complete notification.

The applicant must receive an acknowledgement letter that has been issued by APHIS before introducing the regulated article.

> "A person denied permission for introduction of a regulated article under notification may apply for a permit for introduction of that regulated article without prejudice." (§ 340.3(e)(5)).

If an applicant has any question about whether a proposed introduction is appropriate for notification, the applicant is encouraged to contact APHIS as far in advance of the proposed introduction as possible. Please do not wait until 30 days before your desired planting date to notify APHIS of your introduction. If APHIS determines that the proposed introduction is not appropriate for the notification process, the applicant may submit an application for an introduction permit without prejudice. Issuance of a permit could take up to 120 days or longer depending on the need for an environmental assessment.

EFFECTIVE DATES OF AUTHORIZATION NOTIFICATION

By default, an authorized notification is valid for one year from the date of acknowledgement. The introduction cannot proceed until on or after the date of acknowledgement, and all activities associated with the introduction (excluding any monitoring periods) must be completed by the expiration date of the notification. For interstate movements and importations, all shipments must depart from the date of authorization and arrive at their destination before the expiration date. Environmental releases must be completely terminated by the expiration date (i.e., plants harvested, and all remaining plants and plant parts, are either destroyed (devitalized) or moved into contained facilities).

In some cases, the applicant may wish to request that a notification becomes effective on a specified date, such as the first proposed date of introduction. Applicants should clearly state in their notification that a specific effective date is desired. In most cases this request will be granted, as long as APHIS has adequate

time to acknowledge by that date. If a desired effective date is not specified, the default effective date is the date of acknowledgement.

NOTIFICATION OF UNUSUAL OCCURRENCES

After the responsible person receives APHIS acknowledgement of notification and the regulated article has been introduced, the responsible person is required to notify APHIS of any unusual occurrences associated with the introduction.

> "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)).

In the event of any accidental or unauthorized release of the regulated article, the responsible person must orally notify APHIS immediately upon discovery by phone to (301) 851-3935, and in writing within 24 hours to BRSCompliance@usda.gov. Events that require immediate notification include but are not limited to: potential dispersal of modified plant material outside the approved area of introduction by high winds or flooding or other incidents; accidental planting of the regulated article in an unauthorized location; planting a variety with an unauthorized construct; damaged packaging materials; animal incursion; or materials lost in shipping.

If modified plants are observed to have any characteristics that are different from those described in the notification—particularly those characteristics related to persistence or the presence of plant pests or disease—the applicant must notify APHIS in writing within five working days.

Any unexpected changes in the plant's phenotype that could compromise the introduction's ability to meet the performance standards should be reported. Additionally, any unexplained effects on plant heath such as crop failure or significant plant death, or unexpected impacts on non-target organisms, should be reported.

If a field trial is damaged or destroyed to the extent that the release is prematurely terminated, the responsible person must submit written report of the unusual occurrence APHIS in accordance with 7 CFR §

> "APHIS will provide copies of all notifications to appropriate State regulatory official(s) for review within 5 business days of receipt. Comments to APHIS from appropriate State regulatory officials in response to notifications for interstate movement of regulated articles will not be required by APHIS prior to acknowledgment, although States may provide their reviews to APHIS at their discretion." (§ 340.3(e)(1)).

340.3(d)(5). Further, APHIS recommends that the damage or destruction be included with the required field test report (see **Field Test Report** below). Indicate clearly that the report is both a notification of the event and the final field test report.
In the event of any of these unusual occurrences, contact (orally and/or in writing, as required):

Compliance Evaluation and Enforcement Branch
Biotechnology Regulatory Services USDA APHIS, Unit 78
4700 River Road
Riverdale, MD 20737
Phone: (301) 851-3935
Email: brscompliance@usda.gov
Fax: (301) 734-8910

Failure to notify APHIS of unusual occurrences in the required time frames may result in noncompliance with 7 CFR part 340.

> "The Administrator, shall be notified of any unusual occurrence within the time periods and in the manner specified in Sec. 340.4(f)(10)." (§ 340.3(d)(5)).

INSPECTIONS

> "Access shall be allowed for APHIS and State regulatory officials to inspect facilities and/or the field test site and any records necessary to evaluate compliance with the provisions of paragraphs (b) and (c) of this section." (§ 340.3(d)(6)).

All introductions under the notification process are subject to inspection by trained Federal and State inspectors. Access to field sites and related facilities (i.e., buildings for equipment, seed storage, processing, disposal, etc.) must be provided when requested by authorized personnel. Authorized inspectors may include personnel from APHIS' Biotechnology Regulatory Services (BRS) or Plant Protection and Quarantine (PPQ), and/or State regulatory officials.

In addition to allowing access to facilities and release sites associated with the introduction, the responsible party is required to provide records that demonstrate that performance standards are being met. Note that this normally requires documentation beyond the information submitted to APHIS in the notification. Applicants are encouraged to keep written field trial protocols to ensure that the introduction meets the required performance standards and document that these protocols are being followed (see also **Standard Operating Procedure** above).

For more information on inspections of introductions under notification, please contact APHIS:

By Phone at: (301) 851-3935

By Email at: brscompliance@usda.gov

By Mail at:
Regulatory Operations Programs

Biotechnology Regulatory Services
USDA-APHIS, Unit 78
4700 River Road
Riverdale, MD 20737

By Fax at: (301) 734-8910

Planting Report

APHIS has developed further clarification for submitting notification planting information. **Appendix A** describes the regulatory policy for submitting required planting location, size, and date information so as to meet regulatory requirements. **Appendix B** provides information to applicable large organizations for submitting planting location, size, and date information in consolidated monthly reports. Please refer to **Appendices A and B** for more specific requirements and information on submitting planting reports.

Field Test Report

> "Field test reports must be submitted to APHIS within 6 months after termination of the field test. Field test reports shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment." (§340.3 (d) (4)).

All environmental releases of regulated articles under notification require the submission of a field test report within six months of the expiration of the notification. APHIS uses this report for two purposes: 1) to have a record that the introduction was carried out and terminated according to Federal regulations, and 2) to collect data about any observed unanticipated impacts the field trial may have had, if any. Note that this reporting requirement only applies to environmental releases under notification (not importations or interstate movements).

The following information should be included in the field test report:

- APHIS Notification number
- Location Name
- Location Unique ID
- County
- State
- Indicate if any of the planted material was destroyed before harvest
  - If so, provide the Pre-Harvest destruction completion date and describe how the pre- harvested material was destroyed
- Indicate if any of the planted material was harvested
  - If so, provide the harvest completion date

Describe how the harvested material was terminated

- If the material was terminated in the field and not removed from the field, provide the date the field test was completely terminated and describe the method of termination
- If material was removed from the field and terminated off site describe how it was disposed and provide the date of offsite destruction

- If material was removed from the field and placed in storage, provide the amount of material that was stored and provide a description of the storage location
- Describe any other disposition methods that may be applicable
- Describe any deleterious effects on plants, non-target organisms, or the environment
- Describe methods of observations and resulting data and analyses
    - Indicate if you have submitted any of the following:
    - A report on the accidental or unauthorized release of the regulated article,
    - A report that characteristics of the acknowledged species are substantially different from those listed in the application, or
    - A report of any unusual occurrence

Unusual occurrences during an introduction may require immediate notification to APHIS, particularly when related to possible accidental release or if plant characteristics are found to be different from those described in the original notification (see **Notification of Unusual Occurrences** above). The field test report, however, requires the responsible person to report any additional deleterious effects observed 'on plants, nontarget organisms, or the environment,' with a description of data collection and analytical methods used to characterize those effects.

If your plans change and you do not intend to proceed with an introduction after submitting an application for a notification or receiving a letter from APHIS acknowledging a notification, please write to APHIS (BRSpermits@usda.gov) and request to withdraw your application or notification. This allows APHIS to document that the introduction did not proceed and to cancel any scheduled inspections.

If APHIS makes a determination of nonregulated status for all lines in an ongoing release under notification, APHIS requests the responsible person submit a 'change in status notice' to APHIS via email to the address below. The report should state that the environmental release has been administratively terminated due to the determination of nonregulated status and include the petition number, the crop, the event(s), and the date of the determination. In addition, the notice should include:

- APHIS Notification number
- Location Name
- Location Unique ID
- County
- State

All applicable notifications may be submitted in one notice. The environmental release may still be subject to inspection until the 'change in status notice' has been received. Further, if the environmental release contains any additional lines that are still regulated, the environmental release is still subject to all regulations in 7 CFR § 340.3.
APHIS requests that field test reports be submitted via APHIS eFile using the link under "My Reports and Notices."

APHIS provides instructions for submitting via APHIS eFile on the eFile website.

Other options are to submit reports and notices via email however, we strongly encourage submission via APHIS eFile. If submitting using any other method, then both CBI and CBI-deleted or non-CBI copies should be submitted to:

BRS E-mail: BRSCompliance@usda.gov

HOW TO FIND MORE INFORMATION

If you would like more information about introductions using the notification procedure, please email APHIS at biotechquery@usda.gov.

For information about a specific notification that you have already submitted to APHIS, please email APHIS at brspermits@usda.gov.

VERSION HISTORY

Date	Version Updates
2/7/25	Update to new template, formatting, and broken link corrections.
1/21/25	Update to reflect APHIS eFile terms.
3/28/11	Addition of 'change in status notice'.
3/21/11	Clarification of "quantity" for importation and movement and "size of release" for environmental release.
2/09/11	Updated document, added instructions for submitting reports via APHIS eFile, added examples of compliant report submissions.
11/10/2009	Clarification of Monthly Planting Report policy; addition of Appendix B 8/4/2010 Updated document, modified Appendix A, Appendix B, and Appendix C – sample notifications.
2/5/2008	Removal of word "draft" from document.
11/20/2007	Reformatting to remove references to chapter organization of *BRS User's Guide*.
9/7/2007	Reformatting to match APHIS eFile (p. 16-20). Addition of guidance on TES data requirements (p. 19). Addition of guidance on Standard Operating Procedure (p. 21-22). Addition of sample notifications.
1/16/2007	Original draft.

APPENDIX A - PLANTING/ENVIRONMENTAL RELEASE REPORT

Purpose
APHIS requests that responsible parties submit a Planting Report no later than 30 days following the date of the environmental release. This report provides APHIS with details about the releases that occurred under this notification and generates a final field trial report for these releases, which must be submitted no later than 180 days after the expiration date of this notification. The report should include: the Notification number; name of the regulated article

The information in this appendix is intended for all responsible persons, especially those who do not include specific planting location information in their original notification. This appendix primarily clarifies and describes the planting information APHIS requests for environmental releases conducted under the notification procedure.

Submission of Planting or Other Environmental Release Information
There are three types of environmental releases under an acknowledged notification: 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 requested so that the location, size, and duration of all environmental releases are known. An historical synonym for a planting report is a "post-planting report."

Environmental release information supports three critical APHIS regulatory functions. It is used to (1) perform a risk assessment 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.

1. **Location.** The location must be assigned, by the responsible person, a Location Unique ID that exclusively identifies one release site for the location described in the notification. The Location Unique ID is used, among other reasons, to link all reports for the same field location If this Unique ID has been assigned previously as part of the notification submitted via APHIS eFile, then the same Unique ID must be used in the planting 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 notifications (or permits) but must be unique within each notification.

   The location must be described either in the form of at least one (and no more than six) GPS coordinate for the field or release site. If only one required GPS coordinate is provided, it must define the northwest corner, or the northwestern-most point, of the planting. (At a minimum the northwest corner should be easier to access and identify than the center point).

2. **Planting Unique ID.** If more than one planting is to be made at this location (e.g., different times or different fields within the same location) under this notification, provide a Planting Unique ID. This identifier typically will be used to designate different fields or plots planted at different times within temperate locations, or for different planting times on the same fields within tropical locations. A single planting may span several days. An extended planting period—planned or unplanned (e.g., poor weather)—may be divided into two or more plantings that each have a different Planting Unique ID. The Planting Unique ID may be meaningful words or a coded string of alphanumeric characters, such as "P1" or "Planting_n".

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

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

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

Other Submission Requirements

1. **Type and Due Date of Report**
   When multiple plantings are made under a single notification, we request that you submit a planting report for each planting. For example, if two plantings are made during the month of May, the planting information may be submitted, or be postmarked, in either one or two reports within 30 days from the date of planting.

   The requested uniform planting/environmental release due date (i.e., within 30 days from the first date of release) establishes a predictable deadline for the regulated community and BRS.

   Holders of multiple notifications may submit one consolidated monthly report listing in tabular form the information for all notifications in which plantings have occurred during a calendar month (see **Appendix A**). As stated above, we request that you submit planting information in the consolidated report, preferably as an electronic file in tabular format be submitted or be postmarked to APHIS, within 30 days from the date of planting.

2. **Report Only New Information**
   When providing a planting report, submit only previously unreported planting information. Do not submit previously reported plantings on the same site unless it is a new planting.

3. **Report Sites Not to be Planted**
   Identify in planting reports any release sites included in the notification that will not be planted at all under the notification. Identify these sites as soon as you know that they will not be planted. Do not identify sites as “not planted” if they will be, or are likely to be, planted later under the notification.

Method of Report Submission

APHIS requests that planting reports be submitted via APHIS eFile using the "View Reports/Notices" button on the Authorization Detail Page. You can view instructions for submitting via APHIS eFile in our Guide for Submitting Data for Reports and Notices.

Another option is to submit electronic reports via email. However, we strongly encourage submission via APHIS eFile. If submitting using any other method, then both CBI and CBI-deleted or non-CBI copies should be submitted to: BRSCompliance@usda.gov.

Examples of Planting Report Submissions

1. **Single interrupted release that spans two months**
   A responsible person begins planting at an authorized release site on June 30, is interrupted for five days, and finishes planting the planting on July 14. The timeframe(s) for receiving the associated planting report(s) depends on how he or she defines the planting(s). If the planting is defined as the entire period from June 30 to July 14, then we request that you submit all planting report information within 30 days from the start date of release. If the entire period is instead split into two plantings due to the interruption, then only the information from planting on June 30 is due within 30 days from the start date of release, and the remaining information from planting on July 6 through July 14 is due within 30 days from the start date of release.

2. **Single non-interrupted release that spans two months**
   A responsible person plants at an authorized release site on August 31 and September 1. The timeframe(s) for submitting the associated planting report(s) depends on how he or she defines the planting(s). If the planting is defined as both days spanning two months, then APHIS requests that you submit one planting report containing all information within 30 days from the start date of release. If the two days are instead separated to define two plantings, then please submit the information from the August 31 planting within 30 days from August 31, and the corresponding information for the September 1 planting within 30 days from September 1.

3. **Plantings on discontinuous days at one release site**
   A notification holder plants at an authorized release site on three days—June 3, June 15, and June 25. He or she could define these actions as one, two, or three plantings, depending on other factors that may be meaningful or convenient, and submit one, two, or three planting reports with the associated information. APHIS requests that you submit the planting report(s) within 30 days from the start date of release on the report(s).

APPENDIX B - CONSOLIDATED MONTHLY PLANTING REPORT SUBMISSION FORMATS FOR APPLICABLE ORGANIZATIONS

Some organizations plant many locations under multiple acknowledged notifications and may prefer to submit consolidated monthly reports. In this appendix, APHIS provides to these organizations suggestions for (1) the data elements to be provided, (2) the formatting of those data elements, and (3) the methods of report submission.

Data Elements to be Provided

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

1. **Notification Number.** Report the notification number.

2. **State.** Report the name of the State in which the planting occurs.

3. **County.** Depending on the State or territory, report the name of the County, parish, borough or municipality in which the planting occurs.

4. **Location Name.** Report the release site's Location name (farm level) the same as it is listed in the acknowledged notification.

5. **Location Unique ID.** This is an alphanumeric code that more specifically identifies the release site of the planting, 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 Notification. If a Unique ID was provided for this release site in the acknowledged notification, the responsible person must use the same Unique ID in the planting report.
6. **Planting occurred.** Indicate whether or not a planting has occurred at this release site. There are three possible entries: Use a "Y" if a planting occurred or an "N" if the release site will never be planted under this notification. Leave the entry blank if no planting was made but the site will be, or may be, planted later under this notification.

7. **Planting Unique ID.** For this notification and unique release site, use a unique alphanumeric term or code to identify this planting at a specific field, plot or time. Use a simple planting for "Planting occurred" (**#6** above).

8. **Planting start date.** Report the beginning date on which the trial was planted. Provide this date only if you entered "Y" for "Planting occurred" (**#6** above).

9. **Size.** Report the total size of the planting, including only the area planted with the regulated article(s). Please use acres and 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 under multiple notifications at one field location, report the planting size separately for each notification, excluding border rows. Provide the planting size only if you entered "Y" for "Planting occurred" (**#6** above).

10. **Latitude coordinate.** Report a latitude coordinate for the planting in degree decimal format. Up to six decimal places can be provided. Provide this coordinate only if you entered "Y" for "Planting 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 occurred" (**#6** above). Example: -101.123456.

NOTE: Up to six latitude/longitude pairs may be provided to define the perimeter of each planting 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.

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

Other Data Elements that May be Provided (Optional) Elements aligning with APHIS eFile

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

1. **Agent or site cooperator contact information.** Provide the name and contact information for the person given responsibility for conducting the trial at this specific location. Provide this contact information only if you entered "Y" for "Planting occurred" (**#6** above). Note: After the new APHIS eFile module becomes available, the system will automatically bring forward this information from the notification into the planting report.

2. **Anticipated harvest/destruct date.** Provide the date on which the regulated article(s) planted 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. Examples of such information include data elements that the responsible person has provided in the past or desires to add to the APHIS eFile record (e.g., total acres planted, including borders, cumulative acres planted). Note that multiple comments and data elements may be provided for each planting, but they may be entered only into one open "Comments" text field in APHIS eFile.

4. **Phenotypic designation.** The responsible person may provide the constructs involved with this

planting. Note that the phenotypic designations must be provided in the final field test report even if they have been provided earlier in planting reports.

Other Optional Elements

A responsible person may voluntarily provide in a consolidated planting report other information not listed above. However, with the availability of the APHIS eFile reporting, a responsible person may continue to submit all such voluntary information to APHIS eFile, but these additional elements will need to be submitted either in the single "Comments" text field that will be available for each planting, or in a separate file attached to the environmental release report.

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 spread sheet. 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 report table is shown on the final page of this appendix. This example includes only data elements that are required by the APHIS eFile reporting module. It does not include optional data elements. APHIS requests receiving the report in the format shown, but responsible persons may include optional fields. Columns may be arranged in any order the responsible person 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.

Method of Report Submission
APHIS requests that these consolidated planting reports be submitted:

By email at: BRSCompliance@usda.gov

OR

By mail, with an explanatory cover letter, memorandum, or note to: Permits and Program Services Branch
USDA, APHIS, Biotechnology Regulatory Services
4700 River Road, Unit 78
Riverdale, MD 20737

Example: Consolidated Monthly Report

Consolidated Planting 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 cooperator 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 or postmarked by July 1, 2010 (i.e., within 30 days from the start date of release on the report which the plantings were made).