USDA-APHIS Biotechnology Regulatory Services
User Guide

Notification

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

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

Language implying that guidance is mandatory (e.g., "shall," "must," "required," or "requirement") should not be construed as binding unless the terms are used to refer to a statutory or regulatory requirement. Throughout the document, sections from applicable statutes and regulations are clearly identified in grey-shaded text boxes.

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

Notification

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Quick Guide to Notification

Notification is an administratively streamlined alternative to the permit process to allow the introduction of a certain subset of genetically engineered plants.

The goal of the notification procedure is the same as the permit system: preventing the unintended release of the regulated article.

- The notification procedure for introduction of genetically engineered plants may be used if:
  - The introduced plant meets **all** of the six eligibility criteria, AND,
  - The introduction (the importation, interstate movement, or environmental release) will meet **all** of the six performance standards.
- By submitting 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.
  - The submission document contains information that helps APHIS determine the appropriateness of the notification process for the proposed introduction.
  - The notification should be submitted to APHIS:
    - 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 the introduction has been proposed.
- If APHIS agrees that the application is complete, the article meets eligibility criteria, and the introduction meets performance standards, APHIS will send a letter of acknowledgement to the applicant:
  - 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.
- Design protocols articulate how the introduction meets the required performance standards.
- Introductions may not proceed without a letter of acknowledgement from APHIS.
- Applicants must promptly notify APHIS of any unusual occurrences that happen during the introduction.
- All introductions are subject to inspection by Federal and/or State inspectors.
- All activities under notification must be terminated on or before the expiration date of the notification.
- A planting report must be submitted to APHIS on or before the 15th of the month that follows the release (planting) date.
- A field test report must be submitted to APHIS within six months of the termination of an environmental release.

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, 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.

***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).

The ultimate goal of both the notification and permit systems is identical: preventing the unintended release of the regulated article. At first, notifications were limited to six crops: corn, cotton, potato, soybean, tobacco, and tomato. In 1997, APHIS expanded the notification process to include many other plant species.

Notification is an administratively streamlined procedure for the introduction (interstate movement, importation, or environmental release) of certain genetically engineered plants that are regulated articles. Importation means moving regulated articles from a foreign country into the United States; interstate movement means moving the regulated articles from one U.S. State to another. A release is the use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure.

APHIS reviews the notification for appropriateness of the proposed introduction under the notification process. If APHIS agrees that the introduction does not require a permit, APHIS will acknowledge receipt of a complete notification within 10-30 days, depending upon the type of introduction. 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. Further, although a pathogen-resistant plant variety may be eligible for introduction under the notification procedure,

introduction of the 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. For more information on Federal quarantine laws, visit APHIS Plant Protection and Quarantine:
http://www.aphis.usda.gov/plant_health/index.shtml

The National Plant Board provides information about State-level quarantine laws:
http://nationalplantboard.org/laws/index.html.

Qualifying for the Notification Process

Only introductions certain genetically engineered plants are eligible for the notification process. Genetically engineered insects, nematodes, bacteria, viruses, and other regulated organisms 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 date of acknowledgement, 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 date the notification is acknowledged. All activities must be completed on or before the expiration date of the notification.

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

In order 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 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. Introduction of plant species listed as noxious weeds in 7 CFR part 360 (http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/7cfr360-06.pdf) are not eligible for notification. Plants being considered for release into the environment are not eligible under notification if they are considered to be 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, contact APHIS as far in advance of the proposed introduction as possible.

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 to be a stable transformation. Crosses designed to mobilize, alter, or replicate (i.e., increase copy number) stably inserted cloned genetic material are not eligible for notification. However, regulated articles that contain these constructs in their stable form do meet this eligibility requirement.

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. The criterion also excludes experiments in which random clones of unknown function have been inserted (e.g., cosmid or cDNA library screening experiments).

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 genetically engineered (GE) 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 GE plants that are likely to be toxic to organisms living or feeding on the plants. GE plants that are designed to be toxic to some organisms— the 'target organisms'—are not excluded (e.g., plants producing Bt toxins). The introduction of GE plants that may be toxic to nontarget organisms that are not likely to feed or live on the introduced plant, i.e., organisms that are not associated with the plant during the field trial, may be allowed under notification.

Finally, the GE plant must not express compounds intended for pharmaceutical or industrial use. These GE 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 which are to be used 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). Under a separate statutory authority, APHIS cannot acknowledge notifications involving select agents, genes from select agents, or toxins produced by select agents. For more information on select agents, visit: http://www.aphis.usda.gov/programs/ag_selectagent/index.shtml

Performance Standards

The performance standards are a set of six conditions that must be met in order 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 persist in the environment. The applicant is given flexibility in developing protocols appropriate to the introduction. However, in the notification the applicant certifies that the performance standards will be met (see **Information to Include in a Notification: 9. Certification** below), and is legally responsible for meeting those standards regardless of the methods selected. Applicants submit documents for releases, such as Design Protocols, that address how the performance standards will be met. See section on **Design Protocols** below.

If you have questions about whether a proposed introduction will meet all six performance standards, please contact APHIS before beginning the notification process. Applicants are encouraged 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 the notification procedure 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.

APHIS does not regulate the use of GE organisms 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 are a violation of APHIS regulations. APHIS strongly encourages applicants to ensure that destination facilities follow containment guidelines established by the National Institutes of Health or other similar guidelines.

For more information about contained facilities see:

- Guidelines for Research Involving Recombinant DNA Molecules (National Institutes of Health): http://oba.od.nih.gov/rdna/nih_guidelines_oba.html
- Practical Guide to Containment— Greenhouse Research with Transgenic Plants and Microbes (Information Systems in Biotechnology, Virginia Tech): http://www.isb.vt.edu/cfdocs/greenhouse_manual.cfm

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 cross pollination of sexually compatible crops that may be within pollination distance of the release. The issue of pollen movement is discussed more fully under Performance Standard 5.

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 that is sexually compatible with 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.

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 such as wheat, barley, and sorghum. Likewise, APHIS recommends increased distances when cultured insect-pollinators are used for seed production for crops such as almond. 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," which is only available online to members. However, seed isolation distances based upon AOSCA standards for most common crops are published in 7 CFR 201.76 (http://edocket.access.gpo.gov/cfr_2003/7CFR201.76.htm), Federal Seed Act Regulations.

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 GE 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.
- In the case of woody perennial species, trees, and vines, removal of the plants to a contained facility, cutting and mulching, chipping, 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 monitoring protocols. For example, some hard seeds may not be destroyed by fumigation.

Plant materials that are not destroyed should be removed 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 FR 17044, 17049).

The fifth performance standard is the test that 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.

Introductions of plant species that may escape and persist in the environment may not be able to meet this performance standard. These plants may have characteristics that include: abundant seed production and dispersal, seed dormancy or long term seed viability in the soil, reproduction via vegetative structures, rapid population establishment, adaptation for long-distance dispersal (wind, water, animals, etc.), and existence of feral populations of non-transgenic plants.

In most cases, pollen movement from the regulated plants to nearby cultivated sexually compatible crop species does not strictly meet the definition of "persistence in the environment," because the resulting hybrid progeny would not reproduce without human intervention. However, hybridization of the regulated article with nonregulated plants does violate Performance Standard 2. Therefore, the guidelines in this section to limit pollen movement to wild relatives should also be applied to prevent pollen movement to cultivated relatives.

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 security 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.

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 of the plant species to produce viable, fertile progeny with sexually compatible wild, weedy, or feral relatives, and their distribution within the range of pollination.
- Synchrony of the flowering cycle of the regulated plants with other sexually compatible relatives within the range of pollination.
- The ability of hybrid progeny to persist in the environment.

- Any precautions that may be taken to minimize pollen movement (such as flower bagging, 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).

6. No 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 the GE 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 the GE plants were grown may help in identifying volunteers for later elimination. Applicants should have monitoring protocols of adequate 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, notification must be submitted at least ten days prior to the proposed day of movement. To notify APHIS of an importation or environmental release of a regulated article, notification must be submitted at least 30 days prior to the proposed day of importation or release.

> In April 2006, APHIS introduced the e-Permits system for electronic submission of notification. Applicants are encouraged to send notification to APHIS electronically using this method. For instructions, visit: http://www.aphis.usda.gov/permits/brs_epermits.shtml

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 notify APHIS about introductions of more than one crop species, send separate notifications for each species.

One notification may also include more than one introduction. More specifically, 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. Notification should be submitted at least 10 days prior to the first movement and 30 days prior to the first release. Multiple importations also may be described in one notification. However, all importations in a single notification must be shipped from the same origin and to the same destination. 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 a notification to help APHIS staff determine if the regulated article and proposed introduction meets eligibility criteria and performance standards. To facilitate APHIS review of this information, follow the guidelines below for organizing your information. For examples of notifications submitted via ePermits see Appendix C.

1. Applicant. 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 **9. 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 responsible parties.

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. Introduction Type. Identify whether the introduction is an importation, interstate movement, environmental release, or a combination of interstate movement and environmental release.

3. Applicant Reference Number. An applicant-supplied reference number for the applicant's own use. It should not be used to communicate with APHIS regarding the status of a notification. An official APHIS BRS notification number will be assigned to the application after it is certified and submitted.

4. Confidential Business Information (CBI) Verification. Identify whether the submission contains CBI. If so, a CBI justification Statement must be included. For more information about submission of documents containing CBI, see guidance document on Document Submission Guidelines (http://www.aphis.usda.gov/brs/pdf/Doc_Prep_Guidance.pdf). Please note that the

ePermits system uses square brackets '[ ]' to identify CBI content. If you are submitting a notification using ePermits, do not use square brackets in your submission unless it denotes CBI content.

5. Regulated Article. Provide the common name, scientific name, and cultivar name(s) for the recipient plant.

6. Phenotypic Designation. 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 Phenotype Designation if they were genetically engineered with the same DNA, regardless of where the DNA was inserted into the recipient plant DNA. See sample applications provided in the appendix.

Phenotypic designation name. A unique designation given to a transformed line or lines that all contain the same construct. 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. The designation does not have to contain information that might reveal parentage or valued characteristics. The phenotypic designation should be consistently used to identify the transformed line in all future documents submitted to APHIS, e.g., planting reports, other notifications, petitions to grant nonregulated status, etc.

Identifying lines. List all of the variety designations or identifiers for those lines to be introduced which carry a given construct.

Construct. An identifier of the genetic construct transformed into all of the lines identified above.

Mode(s) of transformation. The method used to insert the construct into the plant genome (e.g., biolistic transformation, disarmed *Agrobacterium*-mediated transformation).

Phenotype category. Please select one or more of the appropriate two-letter codes.

VR = Virus resistant
HT = Herbicide tolerant
IR = Insect resistant
FR = Fungus resistant
BR = Bacteria resistant
NR = Nematode resistant
PQ = Product quality
AP = Agronomic properties
MG = Marker genes
OO = Other

"Product quality" includes modifications such as delayed ripening of fruit, altered amino acid profile, modified seed storage proteins, enhanced floral characteristics (ornamentals), increased solids in fruit, etc.

"Agronomic properties" includes modifications such as drought tolerance, cold tolerance, tolerance to specific environmental stresses, enhanced nitrogen use, male sterility, etc.
"Other" is for modifications that do not clearly fall into one of the other categories. For example, control lines transformed with empty vectors.

Phenotype(s). The specific trait created by the genetic modification, and is a subset of "phenotype category." For example, if the category is HT, then the phenotype is resistance to a specific herbicide. If the category is VR, then the phenotype is resistance to a specific virus.

Genotype(s) and brief summary of construct elements. The summary of the genetic components inserted into the genome of the recipient organism, including the construct name(s) and list of construct elements. For each element in a construct, in the order in which they occur in the construct, provide the following information: i) element type (e.g., promoter, gene, terminator), ii) name of the element (e.g., 35S, extensin, catalase), iii) the organism from which the element is derived (plant species or virus strain) and, iv) a brief description of the element's function. A single notification may include multiple constructs. See sample applications provided.

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

Where the 'type of plant material' introduced is required, be as specific as possible (e.g., seeds, tubers, tissue cultures, whole plants, leaves, slips, cutting, seed potatoes, etc.).

All locations must list both County and State to facilitate information sharing with State regulatory officials and compliance with the Endangered Species Act.

Importation. Notifications of importation must have one point of origin and one destination:

POINT OF ORIGIN: Location name and complete address, including country of origin, from which the regulated article will be imported.
DESTINATION: Location name and complete address, including County and State, into which the regulated article will be imported.
DATES: The proposed dates of shipment from point of origin to destination.
QUANTITY: Type of plant material to be imported and an estimate of maximum quantity (e.g., tubers, 15 lbs.).
CONTACT PERSON(S) (optional): Name, phone number, and other contact information of a responsible person at the point of origin, destination, or both.

Interstate Movement. Notification of interstate movements may have multiple origins and destinations:

ORIGIN(S): Location name and complete address, including County and State, from which the regulated article will be moved.

DESTINATION(S): Location name and complete address, including County and State, to which the regulated article will be moved.
DATES: The proposed dates of shipment from origin to destination.
QUANTITY: Type of plant material to be moved and an estimate of maximum quantity per movement (e.g., tubers, 15 lbs.).
CONTACT PERSON(S) (optional): Name, phone number, and other contact information of a responsible person at any or all origins or destinations.

Environmental Release. Notification of environmental release may have multiple locations:

RELEASE LOCATION: Location name and complete address, including County and State, of the planting site. The location name must uniquely identify and distinguish the location from all other field sites to facilitate inspection. Applicant should assign a Location unique ID. See **Appendix A and B** for more details.
GPS COORDINATES: Provide GPS coordinates for the planting site in decimal format. If only one coordinate pair is provided, it should be located at the northwest corner of the planting site. Latitude values may range from -90.0 to 90.0 degrees. Longitude values may range from -180.0 to 180.0 degrees.
RELEASE SITE HISTORY: Specify the type of agricultural activity (e.g., cropping, pasture, orchard, managed forest) and approximate length of time that the release site and area to be monitored has been under managed agricultural production.[1]
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.
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.
SIZE OF RELEASE: Proposed total size of the release at a given site in acres. Give area planted with GE crops. Area should exclude any sexually compatible border rows of non-GE crops, if planted.
NUMBER OF PLANTINGS: Some crops and locations can be planted several times per year. Enter the number of plantings that will occur at this location. This is the number

[1] 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 http://www.aphis.usda.gov/brs/pdf/BRS_critical_hab_guide_notif.pdf

of times the total proposed quantity is planted in a year. For example, if the total proposed quantity is one acre and the full acre is harvested and replanted, the number of proposed plantings is two. If the one acre is planted over several weeks and a total of one acre is harvested, the number of proposed plantings is one. If plantings occur with more than 30 days in between, these should appear on separate planting reports. If there will be multiple plantings at a given site during the proposed release period, list the number of plantings.

CONTACT PERSON(S) (optional): Name, phone number, and other contact information of a responsible person at one or more release locations.

8. 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.

9. 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 party whose contact information appears in **1. Applicant** above. If a paper copy is submitted, the certification must not stand alone on a page. 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 _____

Design Protocols

To facilitate the APHIS review, applicants are encouraged to submit design protocols that describe the specific cultivation and management practices to be used in the proposed environmental release in order to meet each of the required performance standards (see **Performance Standards** above). For many crops, typical cultivation practices may not be sufficient to meet the performance standards. However, by detailing in design protocols how the applicant proposes to alter cultivation and management practices, the applicant may be able to demonstrate that the performance standards can be met for the proposed introduction. Design protocols are not typically developed for interstate movement or importation, but may be required under certain circumstances.

APHIS may be less likely to acknowledge a notification—and thus require a permit—if, based on experience, APHIS concludes that the cultivation practices typically employed for the crop would not meet the performance standards. The applicant is responsible for meeting the

performance standards described in 7 CFR 340(c); failure to follow proposed design protocols may suggest that the applicant is also not meeting performance standards.

After acknowledgement, applicants must provide inspectors access to on-site documentation that demonstrates that an introduction is meeting performance standards (see **Inspections** below). Applicants are encouraged to have design protocols or similar documentation available for inspectors to help demonstrate that the introduction meets Federal regulations.

Use the following as guidance for information to include in design protocols:

Performance Standard 1. Briefly describe how movements of the regulated material will be conducted to prevent dissemination during transit, and how the regulated material will be stored at the destination facility to prevent unintended release. Include, for example, a description of packaging materials, how the materials will be identified or labeled in transit and in storage, storage location, and description of the destination facilities, methods of segregation, etc. If the materials will be moved from storage to the field for release, describe how the material will be moved to prevent release in transit.

Performance Standard 2. If the article is to be released into the environment, briefly describe how the regulated material will be planted in order to prevent inadvertent mixing with other nonregulated materials. Include, for example, descriptions of how the release location is separated from adjacent plots to prevent mechanical mixing, and how planting, harvesting, and other equipment will be segregated or cleaned. If seed or fruit will be produced, describe how the regulated material will be prevented from entering the food or feed supply.

Performance Standard 3. Briefly describe how the identity of the regulated materials will be maintained at all times. Include, for example, descriptions of labeling and packaging of the regulated materials, and how the release site will be identified and separated from other planting areas, using flags, stakes, markers, fallow zones, etc. Additionally, describe methods to be used to destroy or devitalize the regulated material after use (e.g., autoclaving, composting, chemical treatment), or how the regulated material will be returned to and maintained in a contained facility. Destruction/devitalization of plant and plant material remaining at the release site must occur on or before the expiration date of the notification.

Performance Standard 4. Briefly describe how the applicant can ensure that no viable vector agent is associated with the regulated material (e.g., antibiotic or other chemical treatment of tissues/cells during transformation/regeneration or of seeds, or no vector agents were used).

Performance Standard 5. If the article is to be released into the environment, briefly describe the methods used to ensure that the regulated materials and any possible offspring remain confined to the release site and do not persist in the environment. Include, for example, descriptions of isolation distances, use of border rows or fallow zones, use of temporal isolation, cages, flower removal or bagging, male sterility, etc. In addition, describe any special circumstances that may increase the likelihood that regulated materials or offspring could persist in the environment, such as: proximity to sexually compatible wild or weedy relatives, whether

the location is prone to flooding, high winds, animal incursion, or public access. If such circumstances should occur, please provide measures that will be taken to avoid such situations.

Performance Standard 6. If the article is to be released into the environment, briefly describe how the release will be terminated to minimize the likelihood of volunteers in subsequent seasons (e.g., disking, chemical treatment), and how volunteers will be managed to prevent persistence in subsequent seasons (e.g., frequency, timing, and area of monitoring, methods of removal, other crops to be planted in the field in subsequent seasons that can be readily differentiated from the regulated material). Destruction/devitalization of plant and plant material remaining at the field release site must occur on or before the expiration date of the notification.

Confidential Business Information in Notifications

General instructions for inclusion of confidential business information (CBI) in submissions to APHIS are presented in the guidance document, **Document Submission Guidelines** (http://www.aphis.usda.gov/brs/pdf/Doc_Prep_Guidance.pdf). If a notification contains CBI, two versions of the document should be submitted to APHIS: one containing CBI and the other a CBI-deleted version. All CBI claims must be justified in the application.

When sending a notification using the ePermits system, only the CBI version is necessary; the ePermits system generates the CBI-deleted version automatically. Please note that the ePermits system uses square brackets '[ ]' to identify CBI content. Do not use square brackets in your submission unless it denotes CBI content.

Only the CBI-deleted version is shared with State regulatory officials (see **APHIS Review and Acknowledgement** below). For this reason, applicants are strongly encouraged not to claim 'County' as CBI in notifications, because State regulatory officials may question the location of the introduction. In this event, the applicant may have to contact State officials directly, without APHIS' assistance, to resolve the issue. Further, any CBI claims may require FOIA office review prior to submission of the notification to the State officials.

How to Submit a Notification

To submit a notification via ePermits log onto:
http://www.aphis.usda.gov/permits/learn_epermits.shtml and fill out the application online.

If you are unable to submit the notification using the ePermits system, mail it to:

Permits and Program Services Branch
Biotechnology Regulatory Services
USDA-APHIS, Unit 91
4700 River Road
Riverdale, MD 20737

Because the certification statement on a notification must have an original signature, faxes and e-mail notifications are not accepted. In the ePermits system, an electronic version of a signature is collected.

Please note that submission of a hard copy could delay the process as the information needs to be entered into ePermits. Using ePermits is strongly encouraged.

Changes to a Notification after Submission or Acknowledgment

All notifications must be submitted in a complete and accurate manner. After APHIS has received a notification, changes to the notification are not accepted. An applicant may, however, withdraw a notification prior to acknowledgement.

In the event that the responsible person has changed, promptly submit the revised information to APHIS in writing to:

Branch Chief
Permits and Program Services Branch
Biotechnology Regulatory Services
USDA-APHIS, Unit 91
4700 River Road
Riverdale, MD 20737

If, after submitting a notification to APHIS the applicant decides not to introduce the regulated article, the applicant must send a letter to APHIS stating that the regulated article was not planted, as soon as possible (see also **Field Test Reports** below). This allows APHIS to document that there was no introduction and to cancel any scheduled inspections.

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. Please note that the notification number is not the same as the reference number assigned to the applicant by ePermits; this number is assigned before submission.

> "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)).

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.

> "(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. 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 to120 days or longer depending on the need for an environmental assessment.

Effective Dates of Acknowledged Notification

By default, an acknowledged 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 have arrived 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 an acknowledged notification becomes effective on a specified date, such as the first proposed date of introduction. This encourages applicants to send notification to APHIS earlier. 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. Applicants may not request effective dates that are sooner than the required 10- or 30-day notice periods. If a desired effective date is not specified, the default effective date is the date of acknowledgement.

Notification of Unusual Occurrences

> "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)).

> "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)).

After the applicant receives APHIS acknowledgement of notification and the regulated article has been introduced, the applicant is required to notify APHIS of any unusual occurrences associated with the introduction. This is the same requirement as for introductions under permit.

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

If the GE 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, a written report of the unusual occurrence needs to be submitted to APHIS in accordance with 7

CFR 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 or in writing, as required):

Compliance Evaluation and Enforcement Branch
Biotechnology Regulatory Services
USDA-APHIS, Unit 91
4700 River Road
Riverdale, MD 20737
(301) 734-0670
brscompliance@aphis.usda.gov

Failure to notify APHIS of unusual occurrences in the required time frames can result in legal action, civil penalties, or even criminal charges.

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.

Notifications are selected randomly for inspection. However, combination of other risk-related factors may be considered, including: type of regulated article, size of the introduction (volume shipped or acreage), number of sites, and experience and compliance history of the applicant. Also, APHIS may conduct an inspection at any site and/or facility under notification regardless of routine selection procedures.

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 starndards 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 Federal requirements, and documentation that these protocols are being followed (see also **Design Protocols** above).

For more information on inspections of introductions under notification, please contact the appropriate APHIS-BRS regional office.

Eastern Region
Eastern Compliance Assurance Branch
USDA /APHIS Biotechnology Regulatory Services
920 Main Campus Dr. Suite 200
Raleigh, NC 27606
(919) 855-7622
brscompliance@aphis.usda.gov

Western Region
Western Compliance Assurance Branch
USDA /APHIS Biotechnology Regulatory Services
NRRC Building B
Ft. Collins, CO 80526
(970) 494-7513
brscompliance@aphis.usda.gov

Planting Report

APHIS has developed further clarification for submitting notification planting information as stipulated in 7 CFR 340. **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 electronically 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 termination of the field test. Because APHIS does not always know the actual termination date in advance, APHIS considers the field test report to be due no later than six months after the expiration of the 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.
- 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:
  1. A report on the accidental or unauthorized release of the regulated article,
  2. A report that characteristics of the permitted species are substantially different from those listed in the application, or
  3. 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 applicant 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, after a notification has been acknowledged by APHIS, the applicant decides not to introduce the regulated article, APHIS requests that the applicant send a letter to APHIS stating this as soon as possible. This allows APHIS to document that the introduction did not proceed and to cancel any scheduled inspections. APHIS accepts this letter in lieu of the required field test report in the case of introductions that are acknowledged but that did not take place.

If all lines in an ongoing release under notification are granted nonregulated status, the applicant must submit a field test report covering the period from introduction to the date that nonregulated status is granted. In addition to the information required by 7 CFR 340.3(d)(4), the report should state that the environmental release has been administratively terminated due to the granting of nonregulated status (include petition number). The environmental release may still be subject to inspection until the final field test report has been received. Further, if the environmental release contains any additional lines that have not been granted nonregulated status, the environmental release is still subject to all regulations in 7 CFR 340.3.

The field test reports should be submitted by one of the following methods:

Email: BRSCompliance@aphis.usda.gov

Or

Mail to:
Permit and Program Services Branch
Biotechnology Regulatory Services
USDA-APHIS, Unit 91
4700 River Road
Riverdale, MD 20737

How to Find More Information

If you would like more information about introductions using the notification procedure, please contact biotechquery@aphis.usda.gov

For information about a specific notification you have already submitted to APHIS, please contact:

Permit and Program Services Branch
Biotechnology Regulatory Services
USDA-APHIS, Unit 91
4700 River Road
Riverdale, MD 20737
(301) 734-5690

Version History

1/16/2007	Original draft.
9/7/2007	Reformatting to match ePermits (p. 16-20). Addition of guidance on TES data requirements (p. 19). Addition of guidance on design protocols (p. 21-22). Addition of sample notifications.
11/20/2007	Reformatting to remove references to chapter organization of *BRS User's Guide*
2/5/2008	Removal of word "draft" from document
11/10/2009	Clarification of Monthly Planting Report policy; addition of Appendix A
8/4/2010	Updated document, modified Appendix A, Appendix B, and Appendix C - sample notifications.

7 CFR 340.3

"Sec. 340.3 Notification for the introduction of certain regulated article.[5]

(a) *General.* Certain regulated articles may be introduced without a permit, provided that the introduction is in compliance with the requirements of this section. Any other introduction of regulated articles require a permit under Sec. 340.4, with the exception of introductions that are conditionally exempt from permit requirements under Sec. 340.2(b) of this part.

(b) *Regulated articles eligible for introduction under the notification procedure.* Regulated articles which meet all of the following six requirements and the performance standards set forth in paragraph (c) of this section are eligible for introduction under the notification procedure.

(1) 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.

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

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

(4) 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.

(5) 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.

(6) 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.

(c) *Performance standards for introductions under the notification procedure.* The following performance standards must be met for any introductions under the notification procedure.

(1) 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.

(2) 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.

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

Sec. 340.3 Notification for the introduction of certain regulated article (cont'd)

(c) *continued…*

"(3) 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.

(4) There must be no viable vector agent associated with the regulated article.

(5) 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.

(6) 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.

(d) *Procedural requirements for notifying APHIS.* The following procedures shall be followed for any introductions under the notification procedure:

(1) Notification should be directed to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biotechnology and Scientific Services, Biotechnology Permits, 4700 River Road, Unit 147, Riverdale, Maryland 20737-1237.

(2) 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.

(3) Notification must be submitted to APHIS:

(i) At least 10 days prior to the day of introduction, if the introduction is interstate movement.

(ii) At least 30 days prior to the day of introduction, if the introduction is an importation.

(iii) At least 30 days prior to the day of introduction, if the introduction is an environmental release.

(4) 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.

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

(6) 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.

(e) *Administrative action in response to notification.*

(1) 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.

Sec. 340.3 Notification for the introduction of certain regulated article (cont'd)

(e) *continued…*

(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 a notification to APHIS.

(5) 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."

Appendix A
Planting/Environmental Release Report Requirements

Purpose

Planting information (i.e., location, size and date) must be provided when a notification is submitted to APHIS prior to planting or outdoor placement of plants subject to these regulations.

APHIS allows planting information to be provided in two stages in order to meet the notification procedure's planting requirements as stated in 7 CFR 340.3. At the time of submission of a notification, certain general information about each planting location is allowed. However, specific information must be provided in one or more subsequent planting reports.

The information in this appendix is intended for all applicants, especially those who do not include specific planting location information in their original notification. The appendix primarily clarifies and describes the planting information APHIS requires 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 required 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.

As stated in the regulation, APHIS requires three types of information related to the environmental release of plants under notification. They are the location, size of planting, and date of the environmental release. This information must be provided when the notification is submitted to APHIS prior to environmental release. However, a notification is typically submitted many months prior to the expected date of release, which has made it difficult for the responsible person to predict, and for USDA to know, the exact field location, size, and release date at the time the notification was submitted. In order to meet this requirement, APHIS allows this information to be provided in two stages.

In the first stage, the State and County of each location, at least one GPS coordinate, a maximum planted area, and the proposed start and end dates of the release are provided with the notification and are sufficient for BRS to review. Notifications submitted without this information are not acknowledged (i.e., not authorized to proceed).

In the second stage, following acknowledgement of the notification, the actual location (which must be situated within the State and County authorized), size of the planting and planting date must be submitted in a planting report within the required time frame. Each of these planting reports must be submitted to APHIS by the 15th of the month following the month in which the planting occurred, and must include the following data:

1. Location. The location must be assigned, by the applicant, a Location Unique ID that exclusively identifies one release site for the location described in the notification. If this Unique ID has been assigned previously as part of the notification submitted via ePermits, 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.

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. If the planting occurred on multiple days, provide the first date.

4. Size of release. The applicant must report the amount of regulated material planted or otherwise released in acres. In most cases, the applicant must provide the area occupied only by the regulated article(s) for the planting 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

To be deemed compliant, all required planting information must be provided in a written report, preferably as an electronic file, no later than the 15th day of the month following the month in which the planting occurred. When multiple plantings are made under a single notification, a planting report must be submitted for each planting, unless they occur within the same calendar month. For example, if two plantings are made during the month of May, the planting information for both may be submitted in one report no later than June 15th.

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 B**). As stated above, all required planting information must be provided in the consolidated report, preferably as an electronic file in tabular format, no later than the 15th day of the month following the month in which the plantings occurred.

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 electronic planting reports be sent via email or on compact disc.

They may be submitted via email to: BRSCompliance@aphis.usda.gov

OR

By mail to:

Permit and Program Services Branch
Biotechnology Regulatory Services
USDA-APHIS, Unit 91
4700 River Road
Riverdale, MD 20737

Compliance Actions

1. Required report "late"

If APHIS does not receive a planting report containing the required information by the due date (i.e., by the 15th of the month following the month in which a planting was made), the requirements specified in 7 CFR parts 340.3(d)(2)(iii) and 340.3(d)(2)(iv) have not been met, and the late report is considered a compliance infraction. Therefore, BRS identifies as "late" any planting report that is submitted within 30 calendar days after the due date. For example, a report due June 15 would be deemed late if it was delivered to APHIS June 16 through July 15.

2. Required report "not provided"

If APHIS does not receive a planting report containing the required information 31 or more days after the due date, the requirements specified in 7 CFR parts 340.3(d)(2)(iii) and 340.3(d)(2)(iv) have not been met, and the absent report will be considered a compliance infraction. APHIS identifies as "not provided" any planting report that is submitted 31 or more calendar days following the due date. For example, a report due June 15 would be deemed "not provided" if it was delivered to APHIS on or after July 16, or not delivered to APHIS. This determination would not eliminate or set aside the requirement for the planting report; the report must still be submitted.

3. Required report 'incomplete"

If APHIS receives a planting report that does not contain required information, then the requirement specified in the requirements specified in 7 CFR parts 340.3(d)(2)(iii) and/or 340.3(d)(2)(iv) have not been met. An incomplete report will be considered a compliance infraction.

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

Appendix B

Consolidated Monthly Planting Report Submission Formats for Applicable Organizations

Information that must be submitted in a planting report is described in Appendix A. 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 guidance 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 needed to satisfy the planting report requirements in a consolidated monthly planting report must be arranged in a tabular, spreadsheet format. The data elements described below are consistent with a future ePermits module that will allow for the electronic uploading of planting information into that system. This module will become available in the fall of 2010. However, until that module is adopted, APHIS is requesting certain data elements from that system 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. 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 applicant 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 identifier even if there will be only one planting at the site. Provide this identifier only if you entered "Y" 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). This quantity must be submitted in acres; use no more than three decimal places. APHIS prefers that border rows not be included in this figure, even though they usually are treated as regulated during the release. For complex field designs that involve plantings 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.

12. Site cooperator contact information. Provide the name and contact information for the person responsible for conducting the trial at this specific location. Provide this contact information only if you entered "Y" for "Planting occurred" (**#6** above).

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 ePermits

A new Permits module will become available in the fall of 2010 and will allow for the electronic uploading of planting information. The module contains additional data elements that applicants may optionally include in consolidated monthly reports. Although their use will not be required, applicants who plan to use these elements in ePermits may want to establish some continuity in their planting report submissions prior to implementation by beginning to use one or more of these elements. They are described below.

1. 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.

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

3. Phenotypic designation. The applicant 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

An applicant may voluntarily provide in a consolidated planting report other information not listed above. However, when the ePermits reporting module becomes available in the fall of 2010, an applicant may continue to submit all such voluntary information to ePermits, but these additional elements will need to be submitted either in the single "Comments" text field that will be available for each planting, or in a separate attachment.

Formatting of Data Elements

APHIS requests this information as an Excel spreadsheet file containing the above information in the columnar format shown on the next page, or in another format that allows for data extraction. Formats such as the portable document file (pdf) do not allow for data extraction and processing. However, a second file in a non-extractable format may be submitted with the extractable 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 monthly planting report table is shown on the final page of this appendix. This example includes only data elements that will be required by the ePermits reporting module when it becomes available in the fall of 2010. It does not include optional data elements. APHIS requests receiving the report in the format shown, but applicants may include optional fields. Columns may be arranged in any order the applicant desires. In either instance, these column headings are requested to facilitate accurate data processing.

If CBI is involved, please submit a CBI-deleted version with the CBI version.

Method of Report Submission

APHIS requests that these consolidated reports be sent via email or on compact disc.

Planting reports may be submitted via email at: BRSCompliance@aphis.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 91
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 July 15, 2010 (i.e., the 15th of the month following the calendar month in which the plantings were made).

Appendix C

Example Importation, Interstate Movement, and Release Notifications

The sample documents included in this section are fictional and for educational purposes. Any similarity to real persons, companies, or technologies is coincidental.

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BIOTECHNOLOGY REGULATORY SERVICES

BRS NOTIFICATION - INTRODUCTION OF GENETICALLY ENGINEERED PLANTS

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

Name: Dr. Joe Scientist
Position:
Organization: A Major University
Organization Unique ID:
Address: 2005 Research Drive
Bluefield, MD 12345
County/Province:
Township/Island:

Day Telephone: 301-555-1212
FAX:
Alternate:

Email 1: Joe@university.edu
Email 2:

2. INTRODUCTION TYPE

- [x] Importation
- [ ] Interstate Movement
- [ ] Interstate Movement and Release
- [ ] Release

3. APPLICANT REFERENCE NUMBER

4. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)

Does this application contain CBI? [ ] Yes [x] No

CBI Justification:

N/A

5. REGULATED ARTICLE

Scientific Name: Tagetes erecta

Common Name: Marigold

Cultivar and/or Breeding Line:

6. PHENOTYPIC DESIGNATION

1) Phenotypic Designation Name:

Identifying Line(s): TE 001

Construct(s): BG 456

Mode of Transformation: Biolistic

Phenotype(s)

PQ - Flower color altered

Genotype(s)

Gene(s) of Interest
Promoter: 35S **from** Cauliflower mosaic caulimovirus - 35S promoter

Gene: Flavonoid hydroxylase **from** Viola sp. (Pansy) - Flavonoid 3' - 5' hydroxylase

Terminator: NOS **from** Agrobacterium tumefaciens - Nopaline Synthase 3'

Selectable Marker
Promoter: NOS **from** Agrobacterium tumefaciens - Nopaline synthase

Gene: NPTII **from** Escherichia coli - Neomycin phosphotransferase

Terminator: NOS **from** Agrobacterium tumefaciens - Nopaline synthase 3'

7. INTRODUCTION

Point of Origin

Location Name & Description	Location Address	Contact(s)
1) BlueGenes Corporation LTD	123 Blue Mountain Road Leura, Australia **County:** State = New South Wales	

Destination

Location Name & Description	Location Address	Contact(s)
1) University Research	2005 Research Drive Bluefield, Maryland 12345 **County:** Azure **Proposed Start Date:** 6/1/2010 **Proposed End Date:** 6/1/2011 **Quantity:** 20 Individual Tissue culture containers	**1)** Dr. Lapis Lazuli 2100 Cobalt Dr. Azure Bluefiled, Maryland **Day Telephone:** 301-555-1212

8. ADDITIONAL INFORMATION

Importation example

I, *Joe Scientist*, certify 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 above information is true to the best of our knowledge. I acknowledge this is not an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents, as described in 9 CFR 121. If there are any changes to the information disclosed in this application, I will contact APHIS.

9. SIGNATURE OF RESPONSIBLE PERSON	**10. DATE**

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BIOTECHNOLOGY REGULATORY SERVICES

BRS NOTIFICATION - INTRODUCTION OF GENETICALLY ENGINEERED PLANTS

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

Name: Dr. Pam Pinders
Position:
Organization: Earthnut LLC
Organization Unique ID:
Address: Route 7
Nuttall Hills, GA 12345
County/Province:
Township/Island:

Day Telephone: 404-555-1212
FAX:
Alternate:

Email 1: Pam@earthnut.com
Email 2:

2. INTRODUCTION TYPE

- [ ] Importation
- [x] Interstate Movement
- [ ] Interstate Movement and Release
- [ ] Release

3. APPLICANT REFERENCE NUMBER

4. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)

Does this application contain CBI? [ ] **Yes** [x] **No**

CBI Justification:

N/A

5. REGULATED ARTICLE

Scientific Name: Arachis hypogaea
Common Name: Peanut
Cultivar and/or Breeding Line: Sweet Georgia Brown

6. PHENOTYPIC DESIGNATION

1) **Phenotypic Designation Name:** BR 549

Identifying Line(s): AHT001, AHT002, AHT003

Construct(s): pNC123
Mode of Transformation: Biolistic

Phenotype(s)

MG - Visual marker

Genotype(s)

Gene(s) of Interest
Promoter: 35S **from** Cauliflower mosaic caulimovirus - Enhanced 35S

Gene: Green fluorescent protein **from** Aequorea victoria - GFP from Aequorea victoria (Jellyfish)

Terminator: NOS **from** Agrobacterium tumefaciens - Nopaline synthase 3'

7. INTRODUCTION

Point of Origin

Location Name & Description	Location Address	Contact(s)

1) Peanut Breeding Inc.	123 Groundnut Lane Chinkapin Hickory, North Carolina 54321 **County:** Chinkapin	**1)** Mr. Goober Peabody Peanut Breeding Inc. 123 Groundnut Lane Hickory, North Carolina 54321 **Day Telephone:** 919-555-1212 **Email 1:** Gpeabody@peanutsinc.com

Destination

Location Name & Description	Location Address	Contact(s)
1) Earthnut LLC	Route 7 Huttall Hills, Georgia 12345 **County:** Kubakim **Proposed Start Date:** 6/1/2010 **Proposed End Date:** 6/1/2011 **Quantity:** 20 Lbs Seeds	**1)** Dr. Pam Pinders Route 7 Nuttall Hills, Georgia 12345 **Day Telephone:** 404-555-1212 **Email 1:** Pam@earthnut.com

8. ADDITIONAL INFORMATION

Example of Interstate Movement Notification

I, *Pam Pinders*, certify 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 above information is true to the best of our knowledge.

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

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

9. SIGNATURE OF RESPONSIBLE PERSON	**10. DATE**

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BIOTECHNOLOGY REGULATORY SERVICES

BRS NOTIFICATION - INTRODUCTION OF GENETICALLY ENGINEERED PLANTS

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

Name: Mr. Russ Solanum
Position:
Organization: Pa's Potatoes, Inc.
Organization Unique ID:
Address: 2004 Chippewa Rd.
Baker Hill, ME 12345
County/Province: Hancock
Township/Island:

Day Telephone: 301-555-1212
FAX:
Alternate:

Email 1: Russ@taters.com
Email 2:

2. INTRODUCTION TYPE

- [ ] Importation
- [ ] Interstate Movement
- [ ] Interstate Movement and Release
- [x] Release

3. APPLICANT REFERENCE NUMBER

4. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)

Does this application contain CBI? [ ] Yes [x] No

CBI Justification:

N/A

5. REGULATED ARTICLE

Scientific Name: Solanum tuberosum
Common Name: Potato
Cultivar and/or Breeding Line: Gem Russet

6. PHENOTYPIC DESIGNATION

1) **Phenotypic Designation Name:** VR67

Identifying Line(s): ST001, ST002, ST003

Construct(s): pCP123

Mode of Transformation: Agrobacterium tumefaciens, disarmed

Phenotype(s)

VR - Potato Y potyvirus resistant

Genotype(s)

Gene(s) of Interest
Promoter: 35S **from** Cauliflower mosaic caulimovirus - Enhanced 35S

Gene: Coat protein **from** Potato Y potyvirus, Strain 0 - Coat protein from potato virus Y in sense orientation.

Terminator: NOS **from** Agrobacterium tumefaciens - Nopaline Synthase 3'

Screenable Marker
Promoter: 35S **from** Cauliflower mosaic caulimovirus - Enhanced 35S 5'

Gene: Beta-glucuronidase **from** Escherichia coli - GUS gene from E. coli

Terminator: NOS **from** Agrobacterium tumefaciens - Nopaline synthase 3'

2) Phenotypic Designation Name: Potato Y potyvirus resistant

Identifying Line(s): ST004, ST005, ST006

Construct(s): pCP456

Mode of Transformation: Agrobacterium tumefaciens, disarmed

Phenotype(s)

VR - Potato Y potyvirus resistant

Genotype(s)

Gene(s) of Interest
Promoter: 35S **from** Cauliflower mosaic caulimovirus - Enhanced 35S

Enhancer: Alcohol dehydrogenase intron 1 **from** Zea mays - An intron from maize adh

Gene: Coat protein **from** Potato Y potyvirus, Strain 0 - Coat protein from Potato virus Y in antisense orientation

Terminator: NOS **from** Agrobacterium tumefaciens - Nopaline synthase 3'

Selectable Marker
Promoter: 35S **from** Cauliflower mosaic caulimovirus - 35S 5' from CaMV

Gene: Phosphinothricin acetyltransferase **from** Streptomyces hygroscopicus - Bar gene

Terminator: NOS **from** Agrobacterium tumefaciens - Nopaline synthase 3'

7. INTRODUCTION

Release Site

Location Name & Description	Location Address	Contact(s)
1) Russ Burbank's Farm	1776 Yukon Lane Tuber, Idaho 12345 **County:** Bingham **Proposed Field Test Start Date:** 6/1/2010 **Proposed Field Test End Date:** 6/1/2011 **Number of Proposed Plantings:** 1 **Quantity:** 50 acres	**1)** Mr. Gene Green 1776 Yukon Lane Bingham Tuber, Idaho **Day Telephone:** 208-555-1212

Location Unique ID: Farm001

Location GPS Coordinates: 42.892500, -112.471900

Release Site History: A research farm that has been under agricultural production for more than 50 years
primarily used for field testing of field crops such as potato, corn and soybean.

Critical Habitat Involved?: ___ Yes _X_ No

8. ADDITIONAL INFORMATION

Example of a release Notification

I, *Russ Solanum*, certify 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 above information is true to the best of our knowledge.

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

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

9. SIGNATURE OF RESPONSIBLE PERSON	**10. DATE**