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BIOTECHNOLOGY INSPECTION MANUAL FOR NOTIFICATION FIELD RELEASE

A Procedural Guide for PPQ Officers Conducting Notification Field Release Inspections and Background Information For Other Biotechnology Inspections

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INTRODUCTION

Overview

The manual was originated in the spring of 2000 by interested field officers and management seeking uniformity on how biotechnology field inspections should be conducted and reported. A draft version of the main section, Inspection Guide for Notification Field Release was implemented by Regional program managers and staff biotechnologists and tested in the summer of 2000 by field officers and supervisors.

Additionally, there have been requests for an instruction manual to assist officers and supervisors with responsibilities to conduct Notification field inspections. This need has increased significantly since notification inspections began in 1993, because the number of facilities and field sites continues to increase annually. A draft version of the main section, Inspection Guide for Biotechnology Notification Field Sites was implemented by Regional program manager and staff biotechnologists in the Biotechnology Permit and Risk Assessment Unit (BPRAU) in Riverdale.

Authority

APHIS regulation 7 CFR 340 was published in the Federal Register July 16, 1987, and extended the Federal Plant Pest Act to include genetically engineered organisms (GEO's) that are plant pests. From 1987 until 1993, field release, importation, or interstate movement of GEO's were based on applications through the APHIS Permit Unit. On March 31, 1993, APHIS began a Notification process as an alternative to traditional Form 2000 Permits. Notification expedited the regulation of frequently tested, thus familiar, plant material in the permit process without loss of biosafety for six major crops under 7CFR 340.3. The six crops were corn, cotton, potato, soy bean, tobacco, and tomato. Regulation 7 CFR 340 was amended again on June 3, 1997, to include all plant species, in addition to the six crops listed above for Notification. However, to qualify for the Notification alternative, plants must be in accord with the eligibility requirements (7CFR 340.3(b)) and the performance standards (7 CFR 340.3(c)) of the new rule.

In general, a Notification or a Permit must be completed and approved for applicants who seek to import, move interstate, or release into the environment, genetically engineered organisms derived from a plant pest, virus, or organisms of unknown pest status.

Inspection of biotechnology Notification field release sites, permit field release sites, or permit movement facilities, is conducted by PPQ field work units.

Scope

The manual provides background and information on the biotechnology permit program and inspections. It is divided into sections on introduction, purpose, procedure, training, references, and appendices. It assists the officer in planning for inspections, becoming familiar with essential documentation, and encouraging use of the PPQ Biotechnology Web site and other educational resources in this rapidly advancing area of science.

There are currently two types of biotechnology field sites: 1) notification field release sites, and 2) permit field release sites. In addition, permit movement or importation requests may require a facility site inspection. Emphasis in this manual was placed on biotechnology notification field release site inspection because these have comprised most of the total biotechnology inspections nationally for the last 7 years. The approach for permit inspection is similar to notification field site inspections, with the notable exception being the protocol to meet performance standards for a field test can be found by the inspector in the permit application, rather than requested by the inspector as for notification field site inspections (See Procedure section, page 3.2).

The Procedure section contains essential material for notification site inspection and reporting. Information on biotechnology permit field releases is given in the Procedure section under "Background to Notification and Other Permits." The Appendices also include essential permit and reporting documents pursuant to Form 2000 including permit conditions, supplemental conditions, and standard conditions. These materials provide background for the inspecting officer. New or inexperienced officers may not be familiar with these materials because they are not requested as frequently as Notification inspections.

Because of the urgency for this manual and its accompanying Notification Inspection Guide, we have not included a section that we recommend to be added later on transgenic arthropod facilities and field release sites. Only a few transgenic arthropod permits have been issued, but this is anticipated to increase.

Users

The manual is intended for PPQ officers and supervisors responsible for biotechnology on-site field inspections of transgenic plant material. To make best use of the manual, officers should read it and become thoroughly familiar with the reporting documents before contacting a researcher or cooperator to schedule an inspection. Information presented can be comprehended if carefully read by new officers.

Time Sensitivity

Notification inspections may be scheduled at any time during the planting year. However, the Notification Inspection Guide points out that the ideal time to schedule an inspection is prior to flowering time for the crop. This arrangement allows the inspector to see if containment is being followed and would also give a view of surrounding crops. It is important to determine if sexually compatible crops or weeds are growing too close to the permit site. Timing of inspections conducted based on crop material grown under auspices of a permit would normally be ideal near flowering for the reasons explained for notification. However, later in the season near harvest can also be an important time for inspection.

Time of scheduling inspections is important with the permit movement facility inspections because live plant material may be on mailing delay pending inspection. Unnecessary delays expose the Agency to negligence and legal action. The officer should be mindful of the requested deadline for the inspection by the Regional Program Manager. Officers should attempt to expedite these inspections by simultaneously inviting a representative from the State Department of Agriculture to attend the inspection on a specific date mutually acceptable to all parties. From the time the permit application is received (called "starting the clock") by BPRAU, until the permit is issued cannot exceed 60 work days according to regulation 7 CFR 340. Facility inspections are the only permit inspection the Agency conducts that is time sensitive.

Violations

Noncompliance with performance standards or permits results in a Letter of Warning or a penalty written by the Regional Program Manager for the biotechnology program. In order to issue a Notice of Violation letter to the permittee, the Regional Program Manager depends on timely and accurate reporting and documentation by the inspecting officer.

PURPOSE

The manual is for instruction and reference of officers with biotechnology responsibilities as follows:

1. Conducting field inspections pursuant to notification and Form 2000.

2. Completing appropriate reports and associated permit inspection checklists, worksheets, and other relevant documents.

3. Having familiarity with permit conditions (see Appendices for Standard and Supplemental Permit Conditions).

4. Interpreting field site conditions and determining if the site or facility is in compliance.

5. Educating researchers, cooperators, and the public to enhance self-compliance.

6. Increasing awareness of the permit biotechnology process.

7. Introducing officers to APHIS Biotechnology Home Page and associated educational reference material.

8. Having familiarity with how to treat written documents with confidential business information.

9. Learning frequently used terms of notifications and biotechnology permits.

10. Enforcing APHIS biotechnology regulations.

11. Developing self-compliance with permittees and cooperators.

PROCEDURE

Background to Notification and Other Biotechnology Permits

There is no substitute for a good field site inspection to determine if the permittee is in compliance. In addition, our mission is to educate the permittee and cooperator to use self-compliance and to reduce the need for continuous inspection. The guide on the following page for notification field release, presents a rationale for when and where to conduct an inspection. Also, the guide has a format that asks essential questions of the permittee prior to the inspection. Notification inspection reports should be supported by a cover page to document features not apparent or requiring clarification on the worksheet report. For example:

If "no" is circled to any question on the report worksheet.

1. If the permittee/cooperator failed to present site specific performance standards on request.

2. If challenge inoculations were planned or occurred.

3. If an essential action to meet performance standards was neglected, i.e., failure to close or repair a screen cage and safeguard transgenic flowers from pollinators (i.e., bees). Negligence should be reported even if corrective action was taken to bring the site back into compliance.

Inspection requests to PPQ work units originate from the Regional Office. Reports of all biotech inspections are written by the inspecting officer for the Regional Program Manager who conducts the biotechnology program.
In addition to notification inspections, officers occasionally inspect biotechnology permit plant material for APHIS biotechnology permits pursuant to Form 2000, with higher risk that may involve joint effort with State Departments of Agriculture including importation, interstate movement, field releases, comprehensive permits, and transgenic arthropod rearing facilities. In the event of an arthropod facility inspection or field trial, the officer will be furnished with special instructions and reporting format. It is recommended that when scheduling a facility inspection, the officer invite a representative from the State Department of Agriculture to be present at the inspection. Also, it is advisable to invite a representative from the Institutional Biosafety Committee (or IBC) to be present. This cannot be overemphasized at a university, other Agency laboratories, or at private industry facilities. Except for arthropod GEO'S, worksheets and permit forms for all other non-notification field trials are included in the manual Appendices.

An APHIS biotechnology permit does not exempt GEO'S from quarantines required by other Federal regulations (i.e., the pink bollworm quarantine in Arizona, certain regulated counties in California, etc.) or from special conditions required by State Departments of Agriculture.

Additionally, field inspections are conducted by biotechnologists from the BPRAU, but these are mainly for field releases of plants with genes that express pharmaceutical products.

Inspection Guide for Biotechnology Notification Field Sites–Purpose of Site Inspections

The purpose of inspections for field tests under notification is to determine if the applicants have the means to accomplish the performance standards and are following them.

Procedures for Site Inspections

1. When calling the applicant to arrange a site inspection, ask him or her to Fax or e-mail to you a written description detailing the site-specific protocols they will be using or are using to meet the performance standards described in 7 CFR 340.3(c). Applicants are not required to submit a written copy of these protocols when they submit a notification to APHIS, but should be prepared to send them to you upon request. Review these before the inspection .

Additional details on performance standards are provided below and can be found at the APHIS Biotech Web site- http://www.aphis.usda.gov/biotech/usergdn.html

2. Ask the applicant for times of anticipated planting, flowering (if any), harvesting (if any), and terminating of the field test. Arrange the field site inspection after planting has occurred, preferably when the plants normally would be flowering or during harvest.

3. It will not be possible to inspect the application for all of the protocols to meet the performance standards while in progress. Inform the applicant that you will ask for evidence during the inspection that the applicant has the capability/materials to meet or to have met all of their performance protocols as they have been described by the applicant (e.g., shipping container, field tags, devitalization devices, etc.).

4. You may meet with the applicant's cooperator rather than the applicant at the field site. Remind the applicant that it is his or her responsibility to ensure that the cooperator understands and can answer questions about the applicant's site-specific protocols to meet the performance standards during the inspection. This is an opportunity to educate for self-compliance.

5. If you have questions before or during the inspection, make a note and contact the Regional Program Manager for consultation.

6. Some specific questions to be addressed by the inspectors regarding the applicant's protocols are listed in **bold-type** in the following section on performance standards.

Performance Standards

The performance standards are a set of six conditions that must be met in order to assure containment of the field test of transgenic plants. The goal of the performance standards is to manage the field testing of the transgenic plant such that its offspring will not persist in the environment. To give applicants flexibility in managing their field tests, the performance standards may be met by various protocols. This variability is why it will be necessary for the inspector to request a copy of each applicant's protocols before the inspection. The six performance standards described in 7 CFR 340.3(c) are:

1. Shipping and maintenance at destination;
2. Inadvertent mixing of materials in environmental releases;
3. Identify and devitalization;
4. Viable vector agents;
5. Persistence in the environment; and
6. Volunteer plants.

Performance Standard 4 (viable vector agents) is primarily a concern for interstate movement and importation of newly transformed plant material, and does not require inspection in the field. The remaining performance standards can be group into three areas for inspection: (1) shipping, maintenance at destination, and inspection, (2) field test site requirements addressing inadvertent mixing, persistence, and volunteer plants, and (3) devitalization.

I. Shipping, Maintenance at Destination, and Identification

For most plant material, any shipping container that consists of an inner container that is a sturdy bag, box, or other such structure would be acceptable in most circumstances. Both inner container and outer container must be capable of preventing seed or material loss. Small

seeds like tobacco could be treated similarly, but the inner container should be a sealed bag; lidded bottle, jar, metal can; or other appropriate container for the small seeds.

Identification extends over all aspects of the field trial. Unidentified seed or other plant material should not be present at any phase.

To prevent accidental mixing of transgenic plants/seeds and nonregulated material, a uniform identification system should be implemented, such as obvious marks, obvious morphological differences, color-coding, or strict segregation.

A. Did all aspects of field trial maintain identity (seed storage, planting-harvest site, borders, field cages, etc.)?

B. Was a site map obtained or drawn by you for reference later (i.e., for harvest, flower removal, volunteers, etc.)?

II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants.

This is the most technical, difficult, and variable standard because it deals with the biology of the plant and field site location. One of the most critical performance elements is to ensure that the transgenic plants do not pollinate sexually compatible plants that are nearby, including other cultivated plantings or free-living plants of the same crop species, and any compatible wild plants of a species related to the crop. Free-living means that the plants grow outside of cultivation or where they have not been planted. Sexually-compatible means that the cultivated plant can cross-pollinate with each other successfully. See Table 2 at our Home Page http://www.aphis.usda.gov/biotech/sec6.html for a list of most of the crops that have free-living populations of the same species or compatible species. The applicant should know whether or not the crop plant has compatible free-living or wild relatives.

A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop?

B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located within the pollination distance for the plants?

To prevent offspring from being formed and persisting, means must be taken to minimize the likelihood of pollination and successful fertilization of receptive plants outside the field trial. These means will vary with the biology of the plant. Five of the most common ways sometimes used in combination, are:

- Removing flowers (detasseling).
- Bagging of flowers/tassels to prevent open pollination.
- Terminating the experiment prior to flowering.
- Physical isolation — Generally, those methods that are used to certify purity of foundation seed may be adapted successfully to minimize development of persistent offspring outside the field trial. The certified foundation seed distances for most crops can be found in Table 1 or at our Web site at: http://www.aphis.usda.gov/biotech/isolate.html for recent updates on any changes in isolation distances.
- Temporal isolation of pollination — This involves planting earlier or later than any sexually compatible plant within foundation seed certification distance. If this option is used, it will be necessary for the cooperator to monitor the test plot by walking the rows and inspecting the tassels to determine the onset of pollination. If it appears that the pollination period of the transgenic plants will overlap with that of nearby non-transgenic plants, then remedial methods must be taken.

These may include de-tasseling or bagging of tassels of transgenic plants or bagging flowers of non-transgenic plants.

Plant varieties have varying maturity times and phytologic development may vary due to environmental factors.

C. Which of the five containment options is the applicant using?

1. If flower removal is used: **Is there any evidence that the plants have flowers or that flowers have been removed?**

2. If bagging of flowers/tassels is used: Does the applicant have material to bag reproductive structures?

3. If the experiment is to be terminated before flowering: **Were plants destroyed or removed from the field before any flowers were allowed to release pollen?**

4. If physical isolation is used: **If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenic plants?**

5. If temporal isolation is used: **Is there evidence that flowering times of the transgenic plant and any non-transgenic plants will not overlap, and is the applicant monitoring the plants to ensure that flowering times do not overlap?** Applicant's protocols should state how often they checked for flowering (e.g., every other day) for 2 weeks.

As an option, applicants may surround the test plot with border rows in addition to the measures above to trap the pollen or to physically prevent it from leaving the test plot.

D. If the applicant's protocols use border rows, are there the stated number of border rows?

For most material, inadvertent mixing of regulated material and nonregulated material may be prevented by planting the regulated article in a defined area with an unplanted alley between it and any other material. The width of this alley will vary depending on the method of harvesting and other operations. For machine harvesting, the alley should be wide enough to allow for machine movement without mechanical mixing.

E. Is there an alley or other marking system to separate any transgenic plants from non-transgenic plants of the same species?

Volunteers shall be minimized by growing transgenic material in defined areas in the field and by performing adequate termination protocols. Applicants should have monitoring protocols of adequate duration to ensure that all volunteers have been eliminated by the methods described in the sections above. Volunteers can be eliminated by treating them with herbicides, plowing them under, or by roguing and collecting them by hand for devitalization.

F. If transgenic plants were grown the previous year, were volunteers removed according to the applicant's protocols?

G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their protocols, to eliminate them?

The field site must be clearly identified because it needs to be separated from nearby non-transgenic plants. The site must be identifiable the following growing season to ensure any volunteer transgenic plants were grown may help in identifying volunteers for later elimination. The use of Global Positioning Satellite (GPS) position locators are an excellent way to identify a site.

H. Was the field site marked as stated in the protocols?

All machinery used for planting or harvesting that may retain reproductive parts must be cleaned after use in transgenic fields. If seeds or reproductive parts could be washed off of the equipment, the applicant should have a way of eliminating plants that might grow from these plant parts.

I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts?

J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive?

III. Devitalization

After the field test is complete, seeds, ears, tubers, or other common reproductive material are saved at the site or shipped to another contained facility. If there is plant material left over, including that sent to landfills, it must be non-reproductive or rendered non-viable. Non-viable plant material is not regulated under biotech regulations. Final disposition and devitalization is often achieved as follows: following harvest of all seeds, ears, tubers, or other common reproductive material for transport to a laboratory and devitalization, the remaining vegetative material (non-reproductive) in the field is incorporated into the soil and left to devitalization by the elements. Depending on local conditions, some materials, such as potato tubers, may be devitalized by surface winter exposure in the field.

A. Does the applicant have the necessary equipment to devitalize the plant material as described in their protocols (e.g., an autoclave, steamer, burial pit, incineration, etc.)?

B. Remind applicants that their transgenic plants cannot be used for food or feed unless consultation with Food and Drug Administration (FDA) regarding the transgenic plant has been successfully completed.

Part B above also applies to three other features: 1) Plant waste being properly disposed of, i.e., not being used for animal feed, off-site mulch, etc., where volunteer plants are out of the applicators control.; 2) Border rows of sexually compatible plants are considered to be transgenic; and 3) Samples sent for processing should not be commingled and must be handled as regulated.

Table 1 on the following pages, does not include isolation distances for all crops under APHIS permit. Examples are: tropical fruit (papaya), sugar beets, trees (coffee, poplar, apple, and pear) and berries (blackberry, raspberry, and strawberry). In permits under Form 2000, specified isolation distance and safeguards is written in the field plot design. As discussed earlier under Part II. B of the Notification Guide and under performance standards (see PPQ Web site under reference given earlier) for notification, there are many protocols that are acceptable in place of minimal isolation distance for a given crop. For example, sunflowers are sometimes a research crop on notification permits. Although sunflowers are listed on Table 1 with wide isolation distances, an acceptable protocol in lieu of isolation distance is to cover sunflowers with cages having fine mesh screen prior to and at flowering or forced cage insect pollination. After pollinators are killed or removed and contained, the cages are removed.

However, if questions arise on crops with unknown isolation distances, the inspecting officer should immediately contact the Regional Program Manager designated for biotechnology for advice and if necessary, a staff Biotechnologist can advise you.

Table 2 begins with subscript number 4 under Footnotes and there are several skips in numbering. However, we present subscripts and numbering as copied from the original document with the exception of pharmaceutical corn.

Table 1. Isolation Distances in Feet From Any Contaminating Source Adapted from Table 5, 7 CFR Part 201.76

CROP KIND FOUNDATION DISTANCE

Crop Kind:	**Foundation Distance:**
Alfalfa	
Nonhybrid	600 [44, 48]
Hybrid	1320 [43]
Barley	
Nonhybrid	0 [23]
Hybrid	660 [21, 32]
Beans	
Field and garden	0 [23]
Mung	0 [23]
Broadbean	0 [23]
Clover (all kinds)	600 [5, 18, 44]
Corn	660 [10, 11, 12]
Cotton	0 [19]
APHIS APPROVED ALTERNATIVE — See footnote 19. A 40 foot-wide perimeter of non-transgenic cotton could surround the transgenic plants to act as pollen sink for insect pollinators. The perimeter cotton would be disposed of by harvesting, disking, and monitoring.	
Cowpea	0 [23]
Crambe	660
Crownvetch	600 [5, 44]
Cucurbits (squash, melons)	No foundation seed distance reported
APHIS APPROVED ALTERNATIVE — A minimum of a 30 foot border row of the same non-transgenic species could surround the transgenic plants. Border row plants are treated as transgenic plants and are disposed or in the same manner as transgenic cucurbits.	
Flatpea	600 [5, 44]
Flax	0 [23]
Grasses	
Cross-pollinated	900 [4, 18, 20]
Lespedeza	10^4

Crop Kind:	Foundation Distance:
Millet	
Cross-pollinated	1320 [44]
Self-pollinated	0 [23]
Mustard	1320
Oat	0 [23]
Okra	1320
Onion	5280
Pea, field	0 [23]
Peanut	0 [23]
Pepper	200 [25]
Potato (See APHIS comments)	
Male-sterile	0
Male-fertile	30
Rapeseed Cross-pollinated 1320 [24] Self-pollinated 660 [24] APHIS APPROVED ALTERNATIVE — A 30 foot border of non-transgenic canola which flowers concurrently with the transgenic canola can be used as a pollen and bee trap.	
Rice	10
Rye	660 [17]
Safflower	1320
Sainfoin	600 [5, 44]
Sorghum	
Nonhybrid	990
Hybrid Seedstock	990
Soybeans	0 [23]
Sunflowers	
Nonhybrid	2640 [41, 45]
Hybrid	2640 [41, 45]
Tobacco	
Nonhybrid	150 [37]
Hybrid	
Tomato 200 [25] APHIS APPROVED ALTERNATIVE — Based on experimental results, common requirements would be isolation by at least 30 feet from other tomatoes to minimize pollen flow to any non-transgenic tomatoes.	
Trefoil, birdsfoot	600 [5, 44]

Crop Kind:	Foundation Distance:
Triticale	0 [23]
Vetch	10
Vetch, milk	600 [17, 44]
Watermelon	2640 [26]
APHIS APPROVED ALTERNATIVE — A minimum of a 30 foot border row of the same species. Border row plants are treated as transgenic and are disposed of in the same manner as transgenic watermelons.	
Wheat	
Nonhybrid	0 [23]
Hybrid	660

Footnotes:

4 Isolation between classes of the same variety may be reduced to 25 percent of the distance otherwise required.

5 This distance applies when fields are 5 acres or larger in area. For smaller fields, the distances are 900 feet and 450 feet for the Foundation and Registered classes, respectively.

10 No isolation is required for the production of hand-pollinated seed.

11 When the containment is of the same color and texture, the isolation distance may be modified by (1) adequate natural barriers, or (2) differential maturity dates, provided there are receptive silks in the seed parent at the time the containment is shedding pollen. In the case of inbred lines and foundation single crosses, these modifications may apply only for fertile seed production.

12 If transgenic corn is pharmaceutically modified, the physical isolation distance should be at least 1320 feet and there must be at least 6 border rows from trial margin to any non-experimental corn outside the plot.

17 All cross-pollinating varieties must be 400 feet from any contaminating sources. 18 Isolation between diploids and tetrapolids shall be at least 15 feet.

19 Minimum isolation shall be at least 100 feet if the cotton plants in the contaminating source differ by easily observable morphological characteristics from the field to be inspected. Isolation distance differ by easily observable morphological characteristics from the field to be inspected. Isolation distance between upland and Egyptian types shall be at least 1320 and 660 feet for Foundation, Registered, and Certified classes respectively.

20 These distances apply when there is no border removal. Border removal applies only to fields of 5 acres or more. Removal of a 9-foot border (after flowering) decreases the required distance for Foundation, Registered, and Certified seed to 600, 225, and 100 feet respectively, for cross-pollinating species, and to 30, 15, and 5 feet, respectively for apomictic and self-pollinated species. Removal of a 15 foot border (after flowering) allows a further decrease to 450, 150, and 75 feet, respectively for cross-pollinated species.

21 Isolation distances between two fields of the same kind may be reduced to a distance adequate to prevent adequate mechanical mixture if the sum of percentages of plants in bloom in both fields does not exceed 5 percent at a time when more than 1 percent of the plants in either field are in bloom.

23 Distance adequate to prevent mechanical mixture is necessary. For nonhybrid wheat, the new required isolation distance (as of July 7, 2001) is 3 meters or 33 feet.

24 Required isolation between classes if the same variety is 10 feet.

25 The minimum distance may be reduced by 50 percent if different classes of the same variety are involved.

26 The minimum distance may be reduced by 50 percent if the field is adequately protected by natural or artificial barriers.

32 An unplanted strip at least 2 feet wide shall separate male sterile plants and pollinator plants in inter-planted blocks.

37 This distance is applied between varieties of the same type and may be waived if four border rows of each variety are allowed to bloom and set seed between the two varieties but are not harvested for seed. Isolation between varieties of different types shall be 1,320 feet except if protected by bagging or topping all plants in the contaminating sources before bloom.

39 Isolation between varieties shall be 100 feet if aerial seeded and 50 feet if ground broadcast.

40 Isolation between millets of different genera shall be 6 feet.

41 Does not apply to *Helianthus similes, H. ludens,* or *H. Agrestis.*

43 Parent lines (A and B) in a crossing block or seed and pollen lines in a hybrid seed production field shall be separated by at least 6 feet and shall be managed and harvested in a manner to prevent mixing.

44 Distance between field of certified classes of the same variety may be reduced to 10 feet regardless of the class or size of the fields.

45 An isolation distance of 5,280 feet is required between oil and non-oil sunflower types and between either type and other volunteers or wild types.

48 This distance applies for fields over 5 acres. For alfalfa fields of 5 acres or less that produce the Foundation and Registered seed classes, the minimum distance from a different variety of a field of the same variety that does not meet the varietal purity requirements for certification shall be 900 and 450 feet, respectively.

Table 2. Crops that have free living populations of the same species or sexually compatible free living relatives.

Crop Compatible:	**Free living species:**
Alfalfa (*Medicago sativa*)	Same species
Asparagus (*Asparagus officinalis*)	Same species
Beet (*Beta vulgaris*)	Sea beet (not found near most production areas in the Central Valley of CA)
Bermuda grass (*Cynondon dactylon*)	Same species
Blackberry (Rubus spp.)	Same species
Blueberry (*Vaccinium angustifolium*) and *V. corymbosum*	Same species and other *Vaccinium* spp.
Canola (*Brassica napus*)	Same species and *B. campestris, B. juncea*
Chenopodium quinoa (a grain)	*C. berlandieri*
Carrot (*Daucus carota*)	Same species
Celery (*Apium gravelolens*)	Same species
Chickory (*Chicorium intybus*)	Same species
Clover (*Trifolium* spp.)	Same species
Cranberry (*Vaccinium macrocarpon*)	Same species
Grape (*Vitus vinifera*)	Wild grape (*Vitus* spp.)
Lettuce (*Lactuca sativa*)	Wild lettuce (*L. serriola*)
Oat (*Avena sativa*)	Wild oats (*A. fatua*)
Oilseed rape (*Brassica napus*)	Same species and *B. Camprestris, B. juncea*
Populus alba x *P. grandidentata*	Many populus species
Radish (*Raphanus sativus*)	Same species, *R. raphanistrum*
Raspberry (Rubus spp.)	Same species
Rice (*Oryza sativa*)	Same species = *O. sativa* var. *Spontanea*, red rice
Serviceberrry (*Amelanchier laevis*)	Same species
Sorghum	Johnsongrass (*S. halapense*)
Spruce (*Picea glauca*)	Same species
Squash (*Cucurbita pepo*)	Same species = *C. texana*
Strawberry (Fragaria sp.)	*F. viginiana, F. chiloensis, F. vesca, and F. ovalis*

Crop Compatible:	**Free living species:**
Sunflower (*Helianthus annuus*)	Same species
Sweetgum (*Liquidambar stryraciflua*)	Same species
Tobacco (*Nicotiana tabacum*)	Same species
Turnip (*Brassica rapa*)	Same species = *B. campestris*
Walnut (*Juglans regia*)	*J. hindsii*
Wheat (*Triticum aestivum*)	Jointed goatgrass (*Aegilops cylindrica*)

SAMPLE NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed, this is an Internal PPQ Document

APHIS Notification Number(s): _____ Crop: _____

Applicant's Name: _____ Trait/Gene: _____

Name of Cooperator at Inspected Site: _____ Phone: _____

Location of Site: _____ Date of Inspection: _____

Type of Location: Farm ____ Nursery ____ Research ____ Other ____ (Describe) _____

GPS Coordinates (If available): Latitude _____ Longitude _____

Provide answers below. Circle "Y" for Yes and "N" for No. If the answer to any question is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

I. Shipping, Maintenance at Destination, and Identification

A. Did all aspects of field trial maintain identity (seed storage, planting-harvest site, borders, field cages, etc.)? Y N

B. Was a site map obtained or drawn by you for reference later? (For harvest, flower removal, volunteers, etc.)? Y N

II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? Y N

B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located outside the pollination distance for the plants? Y N

C. Which of the five containment options is the applicant using? Check one below. If none, please note it here and state this in your cover letter to the Regional Program Manager.

_____ 1. Removing flowers.
C.1. Is there any evidence that the plants have flowers or that flowers have been removed? Y N

_____ 2. Bagging flowers/tassels
C.2. Does the applicant have material to bag reproductive structures? Y N

_____ 3. Terminating the experiment before flowering.
C. 3. Were plants destroyed or removed from the field before any flowers were allowed to release pollen? Y N

_____ 4. Physical isolation.
C. 4. If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics? Y N

_____ 5. Temporal isolation.
C.5. Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? Y N

D. If the applicant's design standards use border rows, are there the state number of border rows? Y N

E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic plants of the same species? Y N

F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards? Y N

G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards? Y N

H. Was the field site marked as stated in the design standards? Y N

I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts? Y N

J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive? Y N

III. Devitalization.

A. Does the applicant have the necessary equipment to devitalize the plant material as described in the design standards (e.g., an autoclave, steamer, burial pit, incineration)? Y N

B. Remind applicants that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed.

Inspecting Officer: _____ Phone: _____

Location of PPQ Office _____

Names and Affiliation of Any Other Persons at the Inspection:

_____

_____

_____

_____

Return completed Worksheet to the Regional Program Manager for Biotechnology in your Region.

Sample Notification Response from
Biotechnology Evaluation

==========

This one notification required 61 correspondence before it could be acknowledged. That's a lot of time waiting at the FAX machine.

==========

May 8, 1995

Applicant
Company
Address
City, MO 0000000

Dear Applicant:

Your notification request number (0000000) 00-000-00N requesting permission to move interstate the regulated article xxxxxxx, under 7 CFR 340.3(c) is acknowledged. The notification will become effective and may be execute on or after May 8, 1995.

You must comply with the performance standards as stated in 7 CFR 340.3(c). All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

The State of California concurs with APHIS determination, provided all requirements of 7 CFR 301.85, Golden Nematode Quarantine are met.

The State of Hawaii concurs with APHIS determination, with the attached recommendations.

The State of Maine has attached supplemental conditions for movement and release of regulated article.

Transgenic plants and organisms will not be shipped from this facility without notification and prior approval from the Michigan Department of Agriculture.

The State of North Carolina concurs based on .0303 (a)(7), of the North Carolina Administrative Code, a general permit provides for this release in North Carolina.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Operations Officer.

Sincerely,

Chief, Biotechnology Program Operations
Biotechnology Permits
Biotechnology, Biologics, and Environmental Protection

Enclosure

cc:
B. Hass, California Dept. Of Food and Agric., Sacramento, CA
L. Zermuehelen, Colorado Dept. of Agri., Lakewood, CO
D. Eggen, Delaware Dept. of Agric., Dover, DE
C. Riherd, Florida Dept. of Agric. & Consumer Services, Gainesville, FL
L. Nakahara, Hawaii Dept. of Agric. Honolulu, HI
R. Vega, Idaho Dept. of Agric., Boise, ID
R. Waltz, Indiana Dept of Natural Resources, Indianapolis, IN
A. Carl, Massachusetts Dept. of Food and Agric., Boston, MA
A. Sindermann, Maryland Dept. Of Agric., Annapolis, MD
T. Bourgoin, Maine Dept of Agric., Augusta, ME
P. Sood, Michigan Dept. Of Agric., Lansing, MI
C. Fox, Minnesota Dept. Of Agric., St. Paul, MN
J. Francka, Missouri Dept. Of Agric., Jefferson City, MO
W. Kissinger, Montana Dept.of Agric., Helena, MT
W. Dickerson, North Carolina Dept. Of Agric., Raleigh, NC
W. Brandvic, North Dakota Dept. Of Agric., Bismarck, ND
S. Johnson, Nebraska, Dept. Of Agric., Lincoln, NE
R. Mungari, New York State Dept. Of Agric., Albany, NY
D. Hammer, Ohio Dept. Of Agric., Reynoldsburg, OH
D. Hilburn, Oregon Dept. Of Agric., Salem, OR
D. Stehr, Pennsyulvania Dept. Of Agric., Harrisburg, PA
J. Lawrence, Rhode Island Dept. Of Agric., Providence, RI
H. Jackson, Dept of Plant Industry, Clemson, SC
W. Eggborn, VA Dept. of Agric. & Consumer Services, Richmond, VA
D. Williams, Washington Dept. Of Agric., Olympia, WA
J. Klein, Wisconsin Dept. Of Agric., Madison, WI
D. DeWeese, PPQ, SCR, Brownsville, TX
J. Burch, PPQ, NER, Moorestown, NJ
D. Fielselmann, PPQ, Gulfport, MS
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-000-00

Sample **Memo Request for Inspection of Notification Site**

Biotechnology Field Release Inspections

July 27, 2000

See DISTRIBUTION

The enclosed list updates biotechnology reporting for your State. This update is based on new permit notification letter information through 2000.

PPQ Officers should ask the customer/researcher if their biotech permit crops have been recently deregulated prior to inspection.

Please use the Draft Summer 2000 Guidelines and Field Worksheet to report notification field release inspections conducted after June 7, 2000. In general, the purpose of site inspections for field tests under notification is to determine if applicants have written protocols to meet performance standards. And if they are following the standards.

We will furnish you the CBI information separately from our update list to protect the customer/researcher. Please advise us of any completed biotech inspection that is not credited to an Officer or if there is a planting permit cancellation in your State.

Ralph Stoaks
Regional Program Manager
Western Region, PPQ

Enclosures

DISTRIBUTION:
Plant Health Directors, PPQWR
H. Montoya, Honolulu, HI
C. Bejarano, Phoenix, AZ
M. Towata, Honolulu, HI
B. Galvan, Tucson, AZ
E. Uyeda, Hilo, HI
B. Hyde, San Luis, AZ
K. Shinozuka, Kahului, HI
J. Solorzano, Calexico, CA
H. Yanos, Kahului, HI
D. Hamon, Sacramento, CA
A. Ferguson, Kauai, HI
C. Pizzo, Sacramento, CA

A. Doth, Kauai, HI
B. Abel, Shafter, CA
R. McChesney, Boise, ID
M. Abbott, Lemon Grove, CA
S. Vesper, Albuquerque, NM
N. Lau, San Jose, CA
G. Brown, Portland, OR
M. Cantrell, Ontario, CA
S. Miller, Spokane, WA
J. Mason, Port Hueneme, CA
T. Ely, Ellensburg, WA
H. Pyle, Stockton, CA
R. Elliston, Ft. Collins, CO

cc:
J. Reynolds, Sacramento, CA
J. Payne, Riverdale, MD
D. Hatmaker, Riverdale, MD
J. White, Riverdale, MD

Sample of Site Specific Protocols (for Notification)

On the following pages, are four examples of site specific protocols. These examples were approved by Biotechnology Permits and Risk Assessment Unit (BPRAU).

Permittees have flexibility in writing their protocols, but they must agree with scientifically acceptable practices for the given crop and must support the intent of the performance standards. Inspectors should carefully read the above guide for familiarity and understanding of the performance standards with special attention to "Procedures for Site Inspection (of Notification Sites)."

Performance standards must be written and submitted to the inspecting officer at the field site or faxed to the officer earlier, if convenient, if a site is to be inspected. This requirement is consistent for all notification field releases. The BPRAU will post this requirement on the internet and/or include it in the Acknowledgment of the permit letters to the permittee beginning in 2001.

If the permittee or cooperator does not have a copy of the site specific protocols at the time of inspection, it is a violation of permit. Also, it must be documented by date and included in the officer's inspection report that is sent to the Regional Program Manager designated for the Biotechnology Program.

The RPM will write a warning letter and place the concern on 2 years probation. A second violation in a 2 year period will result in a penalty.

Sample 1 of Generic Protocols for Notification Field Release

Regulatory Standards for Field Trials of Genetically Engineered Strawberry (*Frageria x ananassa*)

Company X's policy requires compliance with U.S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA/APHIS) regulations in 7 CFR 340 for the importation, movement, and environmental release of all regulated plant materials. The principal investigator is responsible for complying with the following regulatory standards for field trials of genetically modified strawberries.

Shipping and Maintenance at Destination

1.1 Regulated plant materials will be "double packaged" for shipping in containers which are independently capable of preventing loss of the plant materials.

1.2 Shipping containers will be clearly labeled with the contents and the USDA permit or notification number.

1.3 Regulated plant materials will be segregated from nonregulated materials during shipping and storage to prevent accidental mixing.

Inadvertent Mixing of Materials in Environmental Releases

2.1 Regulated plant materials will be planted in a defined area the boundaries of which are identifiable by the principal investigator and other site personnel.

2.2 Machinery used in the field trial will be brushed clean of fruit or seed within the area for transgenic planting before use in another area.

Identity and Devitalization

3.1 Special colored markings will be placed in or on each container of regulated plant materials in a greenhouse.

3.2 The boundaries of each field planting of regulated plant materials will be identifiable by the principal investigator and other site personnel until the end of the post-harvest monitoring period to aid in the detection of volunteers.

3.3 Regulated plant materials from a greenhouse will be devitalized prior to disposal.

A) Pollen, fruit, and seed may be heated using dry heat or steam until nonviable then composted and discarded as trash.

B) Leaves, stems, and roots may be composted or discarded as trash.

3.4 Regulated plant materials from a field trial may be disced into the soil for natural decay. The trial site will be monitored for the presence of volunteers as prescribed below.

Viable Vector Agents

4.1 Regulated plant material will not be released into the environment until adequately treated to remove viable vector agents capable of transferring DNA.

4.2 Regulated plant materials will be observed in the field for evidence of galls on roots, stems, and leaves that may indicate the presence of viable Agrobacterium tumefaciens. Observations will be recorded.

4.3 Evidence of viable A. tumefaciens will require immediate removal of affected plants from the field.

Persistence in the Environment

5.1 Regulated strawberry plants will be physically isolated from nonregulated commercial strawberry production by at least 100 feet.

5.2 Regulated strawberry plants will be physically isolated from other strawberries being grown for seed or known stands of sexually compatible wild relatives by at least 3 miles.

5.3 Regulated strawberry plant field sites will not contain commercial bee hives and will not be located immediately adjacent to fields containing commercial bee hives.

5.4 No fruit or seed will be harvested from any nonregulated strawberry plant grown within 100 feet of a regulated strawberry plant.

5.5 Transgenic fruit will be hand harvested at regular intervals to reduce dissemination of fruit and seed by foraging animals.

5.6 Any strawberry plants grown within 100 feet of regulated strawberry plants will be treated as regulated plant material and will be disposed of as a regulated article, including destruction of all fruit and seed.

5.7 Transgenic fruit shall not be tasted, consumed, sold, or placed in commercial distribution unless authorized in writing.

Volunteer Plants

6.1 The field test plot will be monitored for volunteers through weather conditions that favor seed germination or plant establishment.

6.2 Volunteers detected within the field site will be eliminated before flowering by herbicide treatment, hand weeding, or mechanical cultivation.

Observation and Monitoring Forms

7.1 Field trial Observation and Post-harvesting Monitoring forms will be completed for each field trial of regulated plant materials and returned to Mr. X of the company to ensure compliance with USDA/APHIS regulations and facilitate future commercial approvals.

Sample 2 of Generic Protocols for Notification Field Release

REGULATORY STANDARDS FOR FIELD TRIALS OF GENETICALLY ENGINEERED PEA *(Pisum satire*)

Company X's policy requires compliance with the US Department of Agriculture, Animal and Plant Health Inspection Service (USDA/APHIS) regulations in 7 CFR Part 340 for the importation, interstate movement, and environmental release of all regulated plant materials. The principal investigator is responsible for complying with the following regulatory standards for conducting a field trial of genetically engineered pea.

Shipping and Maintenance at Destination

1.1 Regulated plant materials shall be double packaged for shipping: they shall be packed in a sturdy inner bag or box surrounded by a sturdy outer bag or box. Both containers must be independently capable of preventing loss of the plant materials.

1.2 Regulated seed shall be packed in marked containers labeled "TRANSGENIC."

1.3 Shipping container of regulated plant materials shall be labeled with the contents (Containers Pea Seed) and the USDA Permit or Notification Number (USDA No. xx-xxx-xn)

1.4 Regulated plant materials shall be segregated from nonregulated materials at all times to prevent accidental mixing.

Inadvertent Mixing of Material in Environmental Releases

2.1 Regulated plant materials shall be planted in defined areas. The boundaries of the field trial shall be marked.

2.2 All machinery used in the field trial that may retain reproductive plant parts shall be brushed clean of pod and plant material within the defined area for transgenic planting before use in another area.

Identify and Devitalization

3.1 Markers shall be placed in each container (pot, seed tray) or regulated plant materials in a greenhouse.

3.2 Flags shall mark the boundaries of each planting of regulated plant materials in field trials and shall remain in place until the end of post-harvest monitoring to aid the detection of volunteers.

3.3 Regulated plant materials from a contained facility shall be devitalized prior to disposal.

A) Reproductive plant parts (pollen, pod, seed) shall be collected and devitalized using dry heat or steam heat until non-viable, then composted or discarded as trash.

B) Nonreproductive plant parts (leaves, stems, roots) may be composted or discarded as trash.

3.4 Regulated plant materials from a field trial may be disked into the soil for natural decay. The trial site shall be monitored for the presence of volunteers as prescribed below.

Persistence in the Environment

4.1 Regulated pea plants shall be physically isolated from other sexually compatible species by at least 25 feet. This based on the "Minimum Land, Isolation, Field and Seed Standards" adapted from Table 5, 7 CFR subpart 201.76. This is a distance adequate to prevent mechanical mixture in pea field.

4.2 Any pods or seed harvested from any nonregulated pea plant grown within 25 feet of a regulated pea plant shall be treat as a regulated article.

4.3 Any pea plants grown within 25 feet of regulated pea plants shall be treated as regulated plant material and shall be disposed of as a regulated article, including destruction of all pods and seed.

Volunteer Plants

5.1 The field test plot shall be monitored for volunteers until the end of the next planting season.

5.2 Features used to define the test plot shall remain in place until the end of the next planting season to aid in detection of volunteers.

5.3 Volunteers detected within the field test shall be eliminated before flowering by herbicide treatment, hand weeding, or mechanical cultivation.

Observation and Monitoring

6.1 Field Trial Observation and Post-harvest Monitoring forms will be completed for each field trial of regulated plant material and returned to Mr. X to ensure compliance with USDA/APHIS regulations and facilitate future commercial approvals.

Sample 3 for Genetic Protocols for Notification Field Release

Performance Standards for Sunflowers

Shipping/Receiving/Storage

- Check appropriate sources to ensure material and locations are listed in the permit.
- Do not ship if the state location is not listed in the permit.
- Two days prior to shipments in the State of Michigan, complete and send the Intent to Ship Genetically Modified Material.
- No shipping notice is needed if the county and State are listed on the permit.
- For most plant material, any shipping container consisting of an inner container that is a study bag, box, or other such structure, surrounded by an outer container that is also a sturdy bag, box, or other container would be each independently capable of preventing loss of shipped plant material.
- Each inner container (e.g., seed packet, box, bag of seed, or container of tissue samples) will be specifically labeled to identify it as containing transgenic material. This practice should avoid inadvertent mixing of transgenic with non-transgenic material.
- Place a copy of the USDA, APHIS approval letter in each shipment.
- Complete Transgenic Material Shipping Record; place a copy in the shipment, and send a copy to Regulatory Affairs Department.
- Complete and place a white shipping label on the outside container toward the right side of the address label.
- Store genetically modified seed in a secure facility with a sign stating that regulated, genetically modified material is stored inside.

Planting

- Two days prior to planting, complete and fax the Planting Notice. Seed may be planted by hand or machine. Ensure planters are cleaned thoroughly (completely free of transgenic seed) before using for non-transgenic seed.
- Do not re-use seed packets.

Plot Management

Inspect trial at least every 4 weeks. Send completed Field Monitoring for Disease/Insect/Weediness Characteristic Form and send to Regulatory Affairs Department.

Pollinations

- Bag flower heads or cage transgenic plants and
- Isolate distance of at lest 2,640 feet (USDA minimum).

Harvest

Two days prior to harvest, complete the Harvest/Destruct/Termination of Field Trial Notice and return to Regulatory Affairs Department.

- Hand or machine harvest.
- Store harvested seed in a clearly labeled and secure facility.
- Return unwanted grain to field to be cultivated into the soil or burned.
- Allow plants to dry down in the field and then cultivate.

Final Disposition of Regulated, Transgenic Material

Acceptable methods are:

- Cultivation into soil at the trial site;
- Incineration;
- Burial;
- Disposal at approval landfill **after devitalization**;
- Fermentation;
- Composting;
- Autoclaving; and
- Storage in a secure facility.

Post Trial Monitoring

- During the fallow period, the field should be watered to allow the germination of volunteer sunflowers. The site should be inspected for volunteers every 2 weeks until you have completed two monitoring where no volunteers have been found.
- Volunteers can be destroyed by herbicide treatment, hand weeding, or cultivation.
- Complete Monitoring for Volunteer Plants Form and fax /send to Regulatory Affairs Department.
- The field should be planted to a crop other than sunflower.

Unintentional Release

- Notify Regulatory Affairs Department as soon as possible of your knowledge of any unintentional release of transgenic material. Unplanned releases also include vandalism or destruction of property.

Sample 4 for Genetic Protocols for Corn Notification Field Release Under Comprehensive Permit

Performance Standards for Corn

Shipping/Receiving/Storage

- Check appropriate sources to ensure material and location are listed in the permit.
- Do not ship if the State location is not listed in the permit.
- Complete and send the Ten Day Shipping/Planting Notice when the county shipping destination is not listed in the permit.
- Two days prior to shipment in the state of Michigan, complete and send the Intent to Ship Genetically Modified Material.
- No shipping notice is needed if the county and State are listed in the permit.
- For most plant material, any shipping container consisting of an inner container that is a sturdy bag, box, or other such structure, surrounded by an outer container that is also a sturdy bag, box, or other such structure would be acceptable under most circumstances. Bother inner container and outer container would be each independently capable of preventing loss of shipped plant material.
- Each inner container (e.g., seed packet, box, bag of seed, or container of tissue samples) will be specifically labeled to identify it as containing transgenic material. This practice should avoid inadvertent mixing of transgenic with non-transgenic material.
- Place a copy of the USDA, APHIS acknowledgment letter in each shipment.
- Complete Transgenic Material Shipping Record; place a copy in the shipment, and send a copy to Regulatory Sciences and Resources Department.
- Complete and place a white shipping label on the outer container toward the right side of the address label.
- Store genetically modified seed in a secure facility with a sign stating that regulated, genetically modified material is stored inside.

NOTE: These conditions are in addition to normal phytosanitary and shipping conditions.

Planting

- DO NOT plant if the State planting location is not listed on the permit. Use the Seven Day Planting Notice when county and state planting location is listed in the permit. Use Ten Day Planting Notice when planting in a county not listed on the permit.
- Seed may be planted by hand or machine.
- Ensure planters are cleaned thoroughly (completely free of transgenic seed) before using for non-transgenic seed.
- Do not reuse seed packets.

Plot Management

- Inspect trial at least every 4 weeks. Send completed field Monitoring for Disease/Insect/Weediness Characteristics Form.

Containment

- Cover all tassels at pollen shed and hand pollinate, or
- Isolate by a distance of 660 feet and allow to open pollinate.
- Male sterility: Must be confirmed. Contact Regulatory Sciences and Resources with questions.

Harvest

- Seven days prior to harvest, complete and send the Harvest/Destruct Notice.
- Hand or machine harvest.
- Ensure all machinery (e.g., harvest machinery, dryers, etc.) are cleaned thoroughly (completely free of transgenic seed) before using for non-transgenic seed.
- Store harvested seed in a clearly labeled and secure facility.
- Allow plants to dry down in the field and then cultivate.

Final Disposition of Regulated, Transgenic Material

Acceptable methods are:

- Cultivation into soil at the trial site;
- Incineration;
- Burial;
- Disposal at approved land fill **after devitalization**;
- Fermentation
- Composting
- Autoclaving; and
- Storage in a secure facility.

Post Trial Monitoring

Mainland USA: The following growing season, monitor the trial site every 4 weeks for volunteers.

Hawaii and Puerto Rico: Monitor the trial site weekly, as soon as weather conditions are favorable or germination.

All sites: Continue to monitor until you have completed two inspections where no volunteers have been found.

- Volunteers can be destroyed by herbicide treatment, hand weeding, or mechanical cultivation.
- Complete and send Post-Trial Monitoring for Volunteer Plants.
- The following season, the field should be planted to a crop other than corn.

Unplanned Release

- Notify Regulatory Sciences and Resources Department as soon as possible of your knowledge of any unplanned shipment or planting regulated, transgenic material.
- Unplanned releases also include vandalism or destruction of property.

SAMPLE USERS GUIDE TO COMPREHENSIVE PERMITS
DRAFT 5-5-99 (slightly amended for this manual)

1. What is a comprehensive permit?

Comprehensive permits are submissions in which multiple phenotypes, genes, and donors and all anticipated test release sites and movements for a single crop are included in a single package. All genes to be tested in that crop (including uncharacterized gnomic project genes not eligible under notification) can be included.

2. What are the advantages in comprehensive permits?

Some of the advantages of comprehensive permits are as follows:

- Reduces the number of notifications for applicants, APHIS, and States.
- Genes can be listed in a new alternative style that allows any combination of genes of interest, regulatory genes, and marker genes listed to be tested.
- Sites and movements can be quickly and easily added for States and genes in the issued permits.
- Notifications can still be used for entries not anticipated at the time of submission

3. How long are comprehensive permits valid?

Comprehensive permits are good for 13 months from the date of issuance and are NON-RENEWABLE.

4. When should comprehensive permits be submitted and how long does approval take?

Comprehensive permits should be received by APHIS by January 20. Corrections and amendments will be accepted until February 14. Permits will be issued after approximately 60 days (as opposed to 120 days for traditional permits).

5. Can pharmaceuticals be included in the comprehensive permit?

No, pharmaceuticals must be submitted under a separate (traditional) permit.

6. How are new sites and movements added once a permit is issued?

The applicant must send copies of the site specific information (as described in the notification Users Guide), the phenotype, and the permits number to Chief, at APHIS-Riverdale, the APHIS Regional Biotechnologist, and the States(s). Such materials should be sent by an over night carrier. Action may be taken 10 days after sending the information under the conditions set forth by the over night carrier. Action may be taken 10 days after sending the information under the conditions set forth by the States.

7. Item 13, sections b and c of Form 2000 requires key information on the molecular biology of the transformed plants. In what form should information on these and other sections of item 13 be supplied?

- **General information on Sections b and c**
  —At the beginning of these sections list ALL the phenotypes
  —DO NOT USE abbreviations for genes and donors except for Cry designations for Bt genes, CP for plant coat protein and npII.
  —Notification listing of genes is preferred (See the Notification Users Guide). You may also list the genes in the alternative style describe below. **However, if the alternative genes in the notification style including unique identifier and transformation system.**
  —A single comprehensive permit can contain both notification style and alternative style gene listings.
- **Alternative Style Gene Listing**
  The following is an example that comprises item 13b and c under the alternative method.
  —Transformation Method: Disarmed Agrobacterium tumefaciens or particle bombardment.
  —Regulatory Sequences
  PROMOTERS: 35S from CAMV, 34S from FMV, zein from corn
  ENHANCER: leader sequence from TMV, leader sequence from BMV, intron from alcohol dehydrogenease
  TERMINATORS: nopaline synthase gene or octopine synthase gene from A. tumefaciens.

—Any combination of these regulatory sequences with the genes listed below.

Category	Phenotype	Gene
HT IR VR	Glufosinate Resistant Coleopteran Resistant PVA Resistant	Phosphinothricin acetyltansferase S Cry IA (b) B Coat protein P
Markers		NpII E. Coli Phosphinothricin acetyltransferase S

See APHIS Biotech web site at: http://www.aphis.usda.gov/biotech/compguid.html for more detailed information.

TRAINING

Officers have mainly been trained to conduct notification and other permit inspections through two means:

1. When on Developmental Assignment with the Western Regional Office and through special efforts of the Eastern Region;

2. Supplemental lectures at the Professional Developmental Center, PPQ by BPRAU Biotechnologists. Officers have been furnished with information to urgent questions and follow up actions by contact with the designated Regional Program Manager for biotechnology and in special cases, through the Regional Program Manager to a Biotechnologist at the BPRAU.

Training at permit sites in the field has been implemented by the Regional Program Manager to help new officers charged with biotechnology inspection responsibilities. Experienced officers have helped train new Officers on-site. State Department of Agricultural biotechnology representatives are *routinely* invited to attend Notification field site inspections and sites under Permit Form 2000 that require inspection and may subsequently become aware of PPQ permit procedures and inspection methods.

The Western Region (WR) has experimented with a pilot video conference on special Notification training in biotechnology for officers and supervisors and included the Riverdale BPRAU staff Biotechnologists. The WR and ER recently collaborated in a video conference to discuss field site questions on all biotechnology field site inspections. Because of the success with these pilots, additional video links are planned in the future for continuing education. On-site training of field officers is a major job responsibility of the Regional Program Manager in charge of the biotechnology program.

REFERENCES

A wealth of up-to-date information is available from the internet at the addresses below. If you do not have direct internet access through Lotus Netscape Communicator, we provide a working list below that is mainly from the APHIS Biotech Permit Branch.

1. APHIS Biotech Home Page, Permits Branch & Contents): How do I apply to import, move or field a genetically engineered organism? http://www.aphis.usda.gov/biotech.html.

2. A User's Guide to Notifications (overview) http://www.aphis.usda.gov/biotech/usergdn.html

3. Biology of Crop Plants (7 major species) http://www.aphis.usda.gov/biotech/biology.html

4. View Current Status of Application http://www.aphis.gov/biotech/status.html

5. Virginia Tech, Information Systems for Biotech (administered by USDA's Cooperative State Research Service) with references, news, meetings, etc. http://www.nbiap.vt.edu/index.html

6. The regulation of transgenic arthropods http://www.aphis.gov/biotech/arthropod

7. Other biotech web sites of US Government with links to USDA branches http://www.usda.gov/agencies/biotech/links.html#US

The inspecting officer should consult any up-to-date college reference on Introduction to Plant Sciences or Botany to obtain basic background on general morphology, taxonomy, cell biology, microorganisms, and genetics.

Additional general and advanced scientific information may be accessed by internet and at annual meetings of professional societies that involve biotechnology. Examples of Abstracts of articles in scientific journals below is online and free:

1. Entomological Society of America (on line information including ESA branches, sections, position on transgenic insects, etc.) http://www.entsoc.org/about_esa

2. American Phytopathology Society (on line resources, i.e., position papers on plant pest management research, sustainable environment, etc.) http://www.apsnet.org/

3. Ecological Society of America (has an all-electronic publication, Conservation Ecology, an education section, etc.) http://esa.sdsc.edu/

OTHER BIOTECH PERMIT INSPECTION INFORMATION

The following pages present background information on permit-related documents and supporting information. In the Procedure Section, we briefly discussed Biotechnology permits in addition to notification.

These pages present only information specifically for permits issued under Form 2000. Questions concerning these documents or support pages should first be directed to the Regional Program Manager (RPM) responsible for the Biotechnology Program and secondly to the Biotechnology Permits Unit in Riverdale, MD at (301) 734-5787.

In order of importance, the officer should consider Form 2000 to be first. In the sample Form 2000 presented on the next page, note at the top of the page, it is designated the CBI-deleted copy which is to protect the applicant. The non-CBI copy is retained at the Biotech Permits office. The CBI information is furnished to the inspecting officer by the Region. The Form 2000 is always supported by Supplemental Permit Conditions, Standard Permit Conditions, and a Permit Approval Letter regardless of the kind of permit. Samples of each of these follows. The sample *Memo Inspection Request for a Release Site* is prepared by the Region to further assist the inspecting officer. Similarly, the worksheets for release and harvest are routinely furnished by the Region. The *Facility Inspection Checklist* is furnished to the officer from the Region by the RPM. As with notification, all permit reports are returned to the RPM before they are forwarded to the Riverdale, MD office.

After the Form 2000 and the related supplemental and standard permit conditions, the Facility Inspection Checklist is the most frequently used document by officers conducting permit inspections. Supervisors and officers should be familiar with both of these documents if they are designated to conduct inspections on transgenic plant or arthropod material pursuant to APHIS permits.

SAMPLE

Appendix 1.0

CBI-deleted Copy

This application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq. and the Plant Quarantine Act (7 U.S.C. 151 et seq.)). The information will be used to determine eligibility to receive all types of permits. No permit shall be issued until this application has been approved.

See reverse side for additional information

FORM APPROV OMB NO. -579-

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION
APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340
(Genetically Engineered Organisms or Products)

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructic

1. NAME AND ADDRESS OF APPLICANT

XYZ Corporation
1 Blank Street
Sacramento, CA

2. PERMIT REQUESTED ("X" one)
- [ ] Limited - Interstate Movement
- [ ] Limited - Importation
- [X] Release into the Environment
- [ ] Courtesy Permit

3. THIS REQUEST IS ("X" one)
- [X] New
- [ ] Renewal
- [ ] Supplemental

4. TELEPHONE NUMBER

Area Code (000) 000-0000

5. MEANS OF MOVEMENT
- [ ] Mail
- [X] Common Carrier
- [ ] Baggage or Handcarried

By whom _____

6. GIVE THE FOLLOWING (IF APPLICABLE) (IF MORE SPACE IS NEEDED, ATTACH ADDITIONAL SHEET)

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism:	Various - see application			
b. Recipient Organism:				
c. Vector or Vector Agent:				
d. Regulated Organism or Product:				
e. If product, list names of constituents:				

7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHECULE AND NUMBER OF INTRODUCTIONS

See Application

8. DATE (or inclusive dates of period) OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE

March, 2000 - October, 2000

9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

See Application

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

See Application

11. ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT

See Application

12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

13. SEE REVERSE SIDE

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

False Statement: Falsification of any item on this application may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON

15. PRINTED NAME AND TITLE

Joe XYZ, President

16. DATE

2/17/00

FOR APHIS USE ONLY

State Notification Letter Sent	State Review Received	Permit Issued
March 28, 2000	April 5, 2000	[X] Yes [ ] No

Date of Determination	PERMIT	No. of Permit Labels Issued	Supplemental Conditions Enclosed
April 18, 2000	00-000-00R	NA	[X] Yes [ ] No

Signature of BBEP Official	Date	Expiration Date
D. Hatmaker, EPO, PRA, PPQ	April 18, 2000	April 18, 2001

APHIS FORM 2000 (JUL 89) Replaces PPQ Form 1001 which may be used.

SAMPLE

	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a.	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article.		
b.	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the nonmodified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics).		
c.	A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article.		
d.	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced.		
e.	A detailed description of the purpose of the introduction of the regulated article including a detailed description of the proposed experimental and/or production design.		
f.	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: donor organism; recipient organism; vector or vector agent; constituent of each reglated article which is a product; and regulated article.		
g.	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location; production, propagation, and manufacture location; proposed sale and distribution location).		
h.	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.		
i.	A detailed description of the proposed method of final disposition of the regulated article.		

APHIS FORM 2000 (Reverse)

SAMPLE

Appendix 1.1

Supplemental Permit Conditions
(Revised 10/18/99)

1. Permits and Risk Assessments or a Regional Program Manager (Biotechnology) will conduct an inspection of the test site at the beginning of the test. The permittee is required to notify the State regulatory official, and the appropriate Program Manager (Biotechnology)(see attached map) at least 1-week before the test begins.

2. Additional inspections may be conducted by a Plant Protection and Quarantine Officer. The permittee is required to notify the Regional Program Manager (Biotechnology) and the State Official at least 1-week before termination of the experiment.

3. **A field test data report must be submitted within 6 months after the termination of the field test.** Field test reports shall include: methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment. We encourage the inclusion of other types of data if the applicant anticipates submission of a petition for determination of non-regulated status for their regulated article. APHIS views these data reports as critical to our assessment of plant pest risk and development of regulatory policies based on the best scientific evidence. Failure by an applicant to provide data reports in a timely manner for a field trial may result in the withholding of permission by APHIS for future field trials.

Confidential Business Information (CBI) will be handled according to the APHIS policy statement at 50 FR 38561-63.

4. The test site shall be monitored for any volunteer seedlings for (1) one year after the completion of the harvest of the test plants; if any volunteer seedlings are found, they should be destroyed before flowering.

5. Permits and Risk Assessments should be notified of any proposed changes to the protocol referenced in the permit application.

6. This approved Biotechnology Permit (APHIS form #2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (1) for the use of any non-genetically engineered plant pest or pathogens as challenge inoculum; (2) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (3) experimental use of unregistered chemical; and (4) food or feed use of genetically engineered crops harvested from the field experiment.

SAMPLE

Appendix 1.2

**Standard Permit Conditions
For the Introduction of a
Regulated Article
(7 CFR 340.3(f))**

Permit Conditions: A person who is issued a permit and his/her employees or agents shall comply with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Deputy Administrator to be necessary to prevent the dissemination and establishment of plant pests:

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

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

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

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

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

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

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

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

(9) A person who has been issued a permit shall submit to Biotechnology, Biologics, and Environmental Protection monitoring reports on the performance characteristics of the regulated article, in accordance with any monitoring reporting requirements that may be specified in a permit.

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

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

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

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

(i) Import or offer the regulated article for entry only at a port of entry which is designated by an asterisk in 7 CFR 319.37-14(b);

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

(iii) Mark and identify the regulated article in accordance with 7 CFR 340.5.

SAMPLE

Appendix 1.3

PERMIT APPROVAL LETTER

APR 19 2000

Mr. XYZ
123 Value Street
Sacramento, CA

Subject: Biotechnology Permit Number 00-000-00R to Conduct a Planned Release of Genetically Engineered CORN

The above permit has been approved and you must adhere to the standard and supplemental conditions enclosed. This permit should not be taken as any type of efficacy determination of the genetically engineered organism.

A copy of this permit is being forwarded to Dr. Rogelio Vega, Idaho Department of Agriculture, and Dr. Ralph Stoaks, Regional Program Manager, Western Region, Sacramento, California, Plant Protection and Quarantine.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure:
Permit No. 00-000-00R
Standard Conditions
Supplemental Conditions
Map - Regional Biotechnologists

cc:
R. Vega, Idaho Department of Agriculture, Boise, ID 83701
R. Stoaks, PPQ Western Region, Sacramento, CA 95827
File 00-000-00R

APHIS:PPQ:PRA:SK:hll:x8231:4/18/2000

SAMPLE

Appendix 1.4

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection and Quarantine

USDA APHIS PPQ
9580 Micron Avenue
Suite I
Sacramento, CA 95827

Subject: Inspection Request for
Field Release: 00-000-00R

Date: May 12, 2000

To: David McNeal
Plant Health Director, Idaho
Western Region, PPQ

XYZ CORPORATION will be conducting a field test of genetically engineered wheat plants with planting proposed near VERY, EMPTY County. These plants have been modified for plant quality and also contain a marker gene. Supplemental condition number 4 gives plot protocols. The local company contact is MR. XYZ , telephone Area Code (000) 000-0000.

A copy of the permit is enclosed. I was notified by the company of the planting and advised that the plot would be less than .5 acre. Protocols would be similar to those in 00-000-00R that we sent to you. I do not have a copy of the application yet. Inspections should be completed near planting and harvest or termination. Contact your state cooperator and request that a state official participate in the inspections.

The inspecting officer should verify that field testing is being performed according to the permit protocols and conditions. Items to be inspected include, but are not limited to, field plot design, location of the plot, accuracy of records, disposal of plant material, use of proper shipping containers, types of treatments, and special practices; i.e., test plot cages and inoculations, etc. The Regional Program Manager should be contacted immediately if the cooperator or permittee is not complying with conditions of permit or if there is evidence of potential gene escape.

The inspection worksheet will be used as a tracking document for important features of your reports. Separate written reports are requested for planting and harvest or termination for any aspect of the trial not covered by the inspection worksheet. These are internal documents to be FAX'd or e-mailed directly to me at the Western Regional Office.

-Ralph Stoaks

Ralph Stoaks
Regional Program Manager
Western Region, PPQ

Enclosure

cc:
James R. Reynolds

APHIS - Protecting American Agriculture

SAMPLE

Appendix 1.5

WESTERN REGION
BIOTECHNOLOGY PERMIT
FIELD RELEASE REPORT WORKSHEET

PERMIT NUMBER_____ CROP_____
ORGANIZATION/COMPANY_____
RESPONSIBLE APPLICANT_____
COOPERATOR CONTACT PERSON_____ PHONE(___)_____
LOCATION_____
TYPE OF LOCATION: _____Farm, _____Nursery, _____Research, _____General, _____Other
DATE OF PPQ NOTIFIED OF FIELD RELEASE_____ ACTUAL DATE OF FIELD RELEASE_____
DATE OF FIELD RELEASE INSPECTION_____
SITE INFORMATION:

1. COOPERATOR HAD COPY OF PERMIT AND CONDITIONS? YES___ NO___
2. WERE VOLUNTEER PLANTS FOUND FROM A PREVIOUS FIELD RELEASE? YES___ NO___
3. NUMBER OF VOLUNTEERS_____ CROP_____ PERMIT NUMBER_____
4. WAS PLOT SPECIFIC LOCATION ACCORDING TO PERMIT? YES___ NO___
5. WAS SECURITY ACCORDING TO PERMIT PROTOCOL? YES___ NO___
6. WAS PLOT DIMENSIONS ACCORDING TO PERMIT? YES___ NO___
7. WHAT WAS ON EACH SIDE OF TEST PLOT?

NORTH_____
EAST_____
SOUTH_____
WEST_____

8. BORDER BUFFER AREA REQUIRED? YES___ NO___
   HOW MUCH? _____
9. WERE SPECIAL PERMIT CONDITIONS MET? YES___ NO___
10. WAS SEED STORAGE AREA INSPECTED? YES___ NO___
11. WERE SHIPPING CONTAINERS INSPECTED? YES___ NO___
    LABELLED? YES___ NO___
12. NUMBER OF REGULATED ARTICLES RELEASED____, NUMBER OF TRANSGENIC LINES IN TEST_____
13. DESCRIBE DISPOSAL OF ANY EXTRA SEEDS OR PLANTS_____
14. HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL?_____
    _____

INSPECTING PPQ OFFICER_____ PHONE(___)_____
LOCATION OF PPQ OFFICE_____

OTHER PERSONS AT INSPECTION_____

(REPORT DUE 10 DAYS AFTER FIELD RELEASE)

RETURN TO: RALPH STOAKS, Regional Program Manager
USDA, APHIS, PPQ
9580 Micron Avenue, Suite I
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

REVISED 01/24/97

SAMPLE

Appendix 1.6

WESTERN REGION
BIOTECHNOLOGY PERMIT
HARVEST REPORT WORKSHEET

PERMIT NUMBER_____ CROP_____

ORGANIZATION /COMPANY_____

LOCATION_____

DATE OF PPQ NOTIFIED OF HARVEST_____ ACTUAL HARVEST DATE_____

DATE OF HARVEST INSPECTION_____

HOW WAS CROP TERMINATED?_____

DESCRIBE METHOD OF DISPOSAL OF REGULATED; (Plant debris, seeds, fruits, tubers, plant parts, etc.)

_____

_____

_____

HOW WAS EQUIPMENT CLEANED OF SEED AND PLANT MATERIAL?_____

_____

WERE REGULATED ARTICLES SHIPPED OUT OF STATE?____ WHERE?_____

PPQ PERMIT/CERTIFICATE TO SHIP FROM STATE_____

DOES PERMIT REQUIRE MORE MONITORING BY APPLICANT?_____

DID THE APPLICANT COMPLY WITH ALL PERMIT CONDITIONS?_____

_____

_____

INSPECTING PPQ OFFICER_____ PHONE (____)_____
LOCATION OF PPQ OFFICE_____

(REPORT DUE 10 DAYS AFTER HARVEST OR TERMINATION OF CROP)

RETURN TO: RALPH STOAKS, Regional Program Manager
USDA, APHIS, PPQ
9580 Micron Avenue, Suite I
Sacramento, CA 95827
Phone: (916) 857-6105
FAX: (916) 857-6100

REVISED 01/24/97

Appendix 1.7

SAMPLE

1

Permit Number_____ Date of Inspection_____

FACILITY INSPECTION CHECKLIST FOR CONTAINMENT OF GENETICALLY ENGINEERED ORGANISMS.

Address of Facility_____ Responsible Person (Applicant)___

_____ Name _____

_____ Address _____

_____ _____

( )_____ ( )_____

Telephone Number Telephone Number

Location of all Facilities Covered by this Inspection

Building Name_____

Room/Laboratory Number_____

Growth Chamber Identification_____

Greenhouse or other Identification_____

RESEARCH QUALIFICATIONS AND GENERAL BACKGROUND

1. Does this facility operate under the National Institutes of Health (NIH) Recombinant Advisory Committee (RAC) recombinant-DNA (r-DNA) guidelines?
   Yes_____ No_____

2. Is there a written policy regarding handling of r-DNA at this establishment?
   Yes_____ No_____

3. Who is the chairperson of the local Institutional Bio-safety Committee (IBC)?

   _____
   Name and Title

4. Who is the scientist who will conduct the research?

   _____
   Name and Title

5. Is the scientist who is conducting the research the applicant?
   Yes_____ No_____

6. What other scientists and technicians will be working on the research? Describe in a general way, their experience and qualifications.

   _____

7. Do researchers and laboratory technicians practice and adhere to the NIH guidelines?
   Yes_____ No_____

SAMPLE

Permit Number_____ Date of Inspection_____

FACILITY PHYSICAL DESIGN AND SECURITY

8. Provide short description of how regulated article is physically marked and identified in the laboratory, growth chamber and green house. Provide floor plan and /or map of facilities if possible.

_____

9. Is the general area secure from public access?
Yes_____ No_____. If not, please elaborate.

_____

10. A. Is the general area secured from unauthorized personnel?
Yes_____ No_____. If no, please elaborate.

_____

B. Can individual laboratories be locked?
Yes_____ No_____.

C. Is there at lease one sign posted on the facility door stating that a regulated genetically engineered organism is present?
Yes_____ No_____.

D. If no, when will a sign be installed? DATE_____

11. Who is allowed in the research area?
Cleaning Personnel Yes_____ No_____
Trades Persons Yes_____ No_____
Others Yes_____ No_____

12. How distant from each other are the germination laboratories, growth chamber and greenhouses? Be specific.

_____

13. What kind of records, logs or inventory are maintained regarding receipt, increase and destruction of regulated articles?

_____

_____

HANDLING OF MATERIAL- GENERATION

14. A. Is there a cabinet(s) or locker(s) to store seeds, plant material, tissue culture, etc.?
Yes_____ No_____

B. If yes, does it have a lock?
Yes_____ No_____

SAMPLE

Permit Number_____ Date of Inspection_____

C. Is the storage container identified with placards as containing a genetically engineered organism?
Yes_____ No_____

D. If no, when will a sign be installed? DATE_____

15. Where will seeds, tissue cultures, plant material, etc., be grown or germinated?

_____

16. What medium will be used for seed germination? (eg. germination paper, pertile, or sand).

_____

17. Is there any danger of seeds, tissue cultures, plant material, etc., being lost during this germination process, or of ungerminated seed being transferred into subsequent research stages?

_____

18. Are there water cracks of irregular surfaces in the germination laboratory that could trap seeds?
Yes_____ No_____. If yes, describe the size and location of cracks.

19. Are there water drains in the laboratory?
Yes_____ No_____

20. Are the drains screened?
Yes_____ No_____. If so, what is the size of the screen? _____

21. Does the drain system enter into a special waste trap?
Yes_____ No_____

22. How will the germinated seed be moved to the growth chamber?

_____

23. How will petri dishes, tissue cultures, spores, plant material, etc., be moved from the laminar flow hood, to the incubator, to the growth chamber?

_____

24. How will the regulated articles be kept separated from other organisms?

_____

25. Does the growth chamber have access by authorized personnel only?
Yes_____ No_____

26. Describe the growth chamber. Lab top____, walk in____, built on site____other_____

SAMPLE

Permit Number_____ Date of Inspection_____

27. Will the material be grown with any other plant materials in the same chamber?
Yes_____ No_____. If yes, name the types of plants.

28. How will genetically engineered plants and/or containers be physically marked?
_____

29. Does the growth chamber have water drains?
Yes_____ No_____
If so, can they be screened?
Yes_____ No_____

30. Does the drain system enter into a special waste trap?
Yes_____ No_____

31. Where is the autoclave or incinerator in relation to the growth chamber?
_____

32. Can the growth chamber be locked and separated from other growth chamber(s)?
Yes_____ No_____

33. How will the material be transferred to the greenhouse?
_____

34. How will the regulated articles be kept separated from other organisms?
_____

HANDLING OF MATERIAL- GREENHOUSE

35. What is the name of the greenhouse manager?_____

36. Is the greenhouse accessed by authorized personnel only?
Yes_____ No_____

37. A. Does the greenhouse have a double door entry system?
Yes_____ No_____
B. Is the greenhouse entry through a "Head- House"?
Yes_____ No_____

38. A. Do the greenhouse doors have locks?
Yes_____ No_____
B. Is there a rear exit door?
Yes_____ No_____

SAMPLE

Permit Number_____ Date of Inspection_____

39. What type of greenhouse? Glass_____ Lexan_____ Plastic_____ Poly_____ Screen_____ Other_____.
If screen, what size mesh used? If poly, what thickness?
_____

40. What are the approximate outside dimensions of the greenhouse(s)?
_____

41. A. Do the roof vents open?
Yes_____ No_____
B. If the roof vent opens, is it screened?
Yes_____ No_____.
What size is the screen mesh?_____

42. What kind of floor does the greenhouse have?
Concrete_____ Gravel_____ Packed Dirt_____ Other(Explain)_____

43. Does the greenhouse have water drains? Describe.
_____
Do they enter into a special waste trap?
Yes_____ No_____

44. A. Does the greenhouse have black light traps for vectors?
Yes_____ No_____
B. Does the greenhouse have "Sticky Board" traps for vectors?
Yes_____ No_____
C. Does the greenhouse have other kinds of vector traps? Describe.
_____

45. How will the plants be grown in the greenhouse? On Benches_____, In Flats_____, In Pots_____, Other(describe)_____

46. Will there be physical markers on each plant indicating that the plants are genetically engineered?
Yes_____ No_____

47. Where is the autoclave or incinerator in relation to where the plants will be grown?
_____

48. Are there any openings in the greenhouse through which animals and pollinating insects could enter?
_____

SAMPLE

Permit Number_____ Date of Inspection_____

49. How will the regulated articles be kept separate from other organisms?

_____

GENERAL CONSIDERATION

What kind of "Spill" responses action plan/equipment is available for items spilled in transit between labs, chambers and greenhouses? Items are carried in contained vessels, so 'spills' should not be a problem.

_____

Are any other similar plants growing in the area, either on the facility grounds or outside of the facility grounds?

_____

You should look for any other factor which may influence the handling of seed plants and may have an effect on containment or risk.

_____

Inspect for other specific conditions as stipulated on the permit.

_____ _____

Name of State Plant Pest Regulatory Official Performing the Inspection

Printed Name or PPQ Officer Performing the Inspection

_____

Signature

ADDITIONAL INFORMATION

Instructions to the inspector: 1. Inform permittee that on termination of this experiment all transgenic plant material should be devitalized.

2. After completing checklist, return to:

Ralph Stoaks
USDA, APHIS, PPQ
9580 Micron Avenue, Suite I
Sacramento, CA 95827
Commercial: (916) 857-6105
FAX: (916) 857-6100

Prepared 8-8-96 by R. Stoaks

SAMPLE

Appendix 1.8

INSTRUCTIONS

This application form may be used to apply for a limited permit for interstate movement or importation; a permit for release into the environment; or a courtesy permit.

Two copies of this application must be submitted to the Biotechnology Permit Unit, Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782. *

Each copy of the application must be signed by the "responsible person". The responsible person is the person who has control and will maintain control over the introduction of the regulated article and assure that all conditions contained in the permit and regulations in 7 CFR Part 340 are complied with. A responsible person must be a resident of the United States or designate an agent who is a resident of the United States.

Confidential Business Informaiton

If there are portions of the application deemed to contain trade secret or confidential business information (CBI), each page of the application containing such information should be marked "CBI Copy". In addition, those portions of the application which are deemed "CBI" shall be so designated. The second copy shall have all such CBI deleted and shall be marked on each page of the application where CBI was deleted, "CBI Deleted". If an application does not contain CBI, the first page of both copies shall be marked "No CBI".

Limited Permit for Interstate Movement or Importation

The responsible person seeking a limited permit for interstate movement or importation must complete all items on the application EXCEPT 12, 13(a), (b), (e), and (f).

a. Interstate Movement - The responsible person may apply for a single limited permit for the interstate movement of multiple regulated articles in lieu of submitting an application for each individual interstate movement. Each limited permit issued shall be valid for 1 year from the date of issuance. If a permit is sought for multiple interstate movements between contained facilities, the responsible person shall specify in the permit application all the regulated articles to be moved interstate; the origins and destinations of all proposed shipments; a detailed description of all the destinations (contained facilities) where regulated articles will be utilized; and a description of the containers that will be used to transport the regulated articles. A limited permit for interstate movement of a regulated article shall only be valid for the movement of those regulated articles moving between those locations specified in the application. If a person seeks to move regulated articles other than those specified in the application, or to locations other than those listed in the application, a supplemental application shall be submitted to Biotechnology, Biologics, and Environmental Protection. No person shall move a regulated article interstate unless the number of the limited permit appears on the outside of the shipping container. The responsible person who ships a regulated article interstate shall keep records for 1 year to demonstrate that the regulated article arrived at its intended destination.

b. Importation - The responsible person seeking a limited permit for the importation of a regulated article shall submit an application for a permit prior to the importation of EACH shipment of regulated articles. The responsible person importing a regulated article shall keep records for 1 year demonstrating that the regulated article arrived at its intended destination.

Permit for Release into the Environment

The responsible person seeking a permit for release into the environment of a regulated article should complete this form in its entirety by submitting data called for by items (1) - (16).

Courtesy Permit

The responsible person seeking a courtesy permit for the introduction (importation, interstate movement, or release into the environment) of genetically engineered organisms not subject to regulation under Part 340 must complete items (1) through (4), (6), (12), (13 (b)), and (14) through (16).

*NOTE NEW ADDRESS: Permits and Risk Assessments, USDA, APHIS, PPQ, 4700 River Road, Unit 147, Riverdale, MD 20737.