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Standard Operating Procedure (SOP) Template for APHIS BRS Plant Permits

The information contained in this document is intended solely as optional assistance. Following the assistance contained in this document should not be construed as a guarantee of compliance with applicable statutes and regulations.

PURPOSE

This document serves as tool to assist applicants in the development of Standard Operating Procedures (SOP) for Animal and Plant Health Inspection Service (APHIS) Biotechnology Regulatory Services (BRS) Plant Permits. This tool provides an optional template format applicants may elect to use when preparing SOPs to accompany permit applications under 7 CFR part 340. The SOP template outlines topics and suggested information to include in your SOPs.

Although you are free to include additional information and topics in your SOP, please know that BRS will focus its review on the topic areas described in this SOP template that relate to the evaluation of your BRS permit application.

The purpose of your SOP is to describe how you will maintain the organism developed using genetic engineering (modified organism) in conjunction with the activities noted below to prevent its unauthorized release, spread, dispersal and/or persistence in the environment:

- **Secured during shipment** between contained facilities and during transport to/from release sites.
- **Contained within facilities** at origin, destination, release, and during post-harvest storage.
- **Confined and monitored** during its release into the environment.
- **Devitalized and disposed of** at all applicable locations when no longer needed.
- **Monitored for volunteers/persistence** after termination of the environmental release trials.

Please know that the standard permit conditions (7 CFR § 340.5(i)) and supplemental permit conditions contained in your issued permit supersede any conflicting information that may exist in your SOP.

| [DOWNLOAD A WORD VERSION OF THE TEMPLATE FOR USE](#) |

SOP TEMPLATE

1.0 SOP TITLE AND INTRODUCTION TABLE

Standard Operating Procedures for APHIS BRS Permits for the Movement of Modified <common name of organism> by <Organization name (abbreviated or full legal name)>

Organization Name	
Modified Organism	
Movement Type	Importation <input type="checkbox"/> Interstate Movement <input type="checkbox"/> Environmental Release <input type="checkbox"/>
Origin of Modified Organism	The country and locality where the organism was collected, developed, manufactured, reared, cultivated, and cultured (as applicable)

2.0 PROCEDURES FOR IMPORTATION OR INTERSTATE MOVEMENT OF THE MODIFIED ORGANISM

2.1 SECURE SHIPMENT OF THE MODIFIED ORGANISM BETWEEN CONTAINED FACILITIES

Documentation: Include a document with the names and contact information for the sender and recipient with the secure shipment.

2.2 USE OF THE MODIFIED ORGANISM WITHIN CONTAINED FACILITIES

Intended Activities: Describe how the modified organism will be used in the facility and/or stored for later use.

Locations: List the address(es) for intermediate destinations including building and/or room/greenhouse numbers that will be used. Describe how and where the modified organism will be stored so that they are contained and segregated from other organisms. If APHIS previously inspected a facility, list the facility number for each location in the application and if known, the date of the inspection.

2.3 DEVITALIZATION AND FINAL DISPOSITION OF THE MODIFIED ORGANISM

Devitalization: Describe how the modified organism or viable parts thereof, and any biological material will be treated so that it is rendered non-viable.

- Acceptable methods include desiccation, heating, burning, incineration, autoclaving, chemical treatment, pulverization, fine chopping, and deep burial (if the location is listed as an approved site on a release permit and monitored).
- Consider any implements, tools or surfaces that may have come into contact with the modified organism and include how those will be treated so that any residual materials are also devitalized.

Final Disposition: Describe how you will dispose of and/or store the modified organism when it is no longer in use.

- If the modified organism and any parts will be stored for later use, describe the storage methods and containment facility. Include how you will label and segregate it from other materials and restrict access to authorized personnel only.
- Please note that only non-viable materials may be disposed of in a landfill.

3.0 PROCEDURES FOR ENVIRONMENTAL RELEASE OF THE MODIFIED ORGANISM

3.1 IDENTIFICATION OF RELEASE SITE AND MODIFIED ORGANISM DURING ENVIRONMENTAL RELEASE

Describe methods to identify the environmental release site and modified plants including how the trial will be marked on the field. When formulating your plan, please know that all plants, including any border rows, within the environmental release site (regulated field trial area) must be treated as regulated.

3.2 CONFINEMENT OF THE MODIFIED ORGANISM DURING ENVIRONMENTAL RELEASE

- Describe proposed procedures for containment during transportation to and from the release site(s).
- Describe confinement during the environmental release from planting through harvest or termination.

Perimeter Zone: Describe the perimeter zone you will maintain around each release site.

- Perimeter zone must occur within the authorized area.
- Generally, BRS requires a minimum of a **10-foot perimeter zone** on all sides of a release site; however, the perimeter zone must provide adequate space for turnaround and clearance of any equipment used with regulated material.
- Perimeter zone can be fallow or planted with a non-sexually compatible, morphologically distinct species that allows for the detection of regulated material.
- Perimeter zones are part of the environmental release and must be treated as regulated with respect to confinement and destruction.

Describe Spatial and Reproductive Isolation Methods that will be used to ensure confinement and prevent gene flow from the modified organism to sexually compatible relatives (SCRs) that are not part of the environmental release but are within pollen-mediated gene flow distance. These methods may include one or more of the following:

- **Reproductive isolation distance:**
 - List any SCRs of the modified organism within pollen-mediated gene flow distance.
 - Consult the [Separation Distance Table](#) on the BRS website or with BRS if your crop is not listed, then state the separation distance you will use for reproductive isolation.
 - List the frequency of monitoring for and methods of destroying SCRs (e.g., herbicide, hand pulling, etc.).
- **Border rows:**
 - Describe any border rows planted around the release site.
 - Border rows must be managed to prevent co-mingling with nonregulated plants.

- **Physical isolation of flowers (during the entire flowering period):**
Describe methods used to prevent gene flow to nonregulated organisms of the same or sexually compatible species (e.g., bagging, caging, use of tunnels).
- **Removal of flower buds prior to flowering/anthesis:**
 - Describe methods used to prevent flowering/anthesis (e.g., detasseling, emasculation, and mowing the plants to prevent flowering/anthesis).
 - To ensure reproductive isolation, BRS generally requires spatial isolation. However, if you wish to remove floral buds/detassel as the means of isolation, this distance is optional, but caution must still be exercised. Wind dispersal may occur if removal/detasseling is not completed before the pollen shed. Therefore, we recommend a minimum of 30-50 ft. isolation to prevent unintended pollen dispersal.
- **Termination of the field trial prior to flowering/anthesis:**
Describe the in-season monitoring regime to ensure termination occurs prior to flowering/anthesis.
- **Male sterility:**
 - BRS expects 100% sterility.
 - If there is any breach in the sterility system, the species-specific separation distance applies.
- **Temporal isolation:**
 - Describe how the plants will be reproductively separated by temporal isolation. Temporal isolation is when the timing of planting is such that flowering of the modified plants is asynchronous with flowering of any sexually compatible relatives within the isolation zone. This is typically based on planting dates, growing degree days, or heat units and needs to be documented.
 - When temporal isolation is used, describe how monitoring will be conducted to ensure that there is no outcrossing from the modified plants to sexually compatible relatives.

3.3 DEVITALIZATION AND DISPOSITION OF THE MODIFIED ORGANISM AFTER ENVIRONMENTAL RELEASE

Secure Transport: If viable regulated material will be harvested, describe how the material will be securely transported to and stored in a contained facility and devitalized when no longer in use.

Field Trial Termination: Describe how the field trial will be terminated, including how you will devitalize and dispose the modified organisms that are not harvested. Note: APHIS does not allow viable regulated material to remain in the field to grow, persist, or reproduce in subsequent growing seasons.

- Effective devitalization methods include autoclaving, chemical treatment, incineration, composting in an authorized location, permanent/constant deep burial (crop dependent, and usually at least two feet deep), and disposal in a landfill listed as a destination location on the application.
- If disposing of viable regulated material in a landfill, the material must be covered the same day at depth sufficient to prevent exposure of viable material due to weather, erosion, or animal incursion, and to prevent volunteers from emerging.
- Deep burial on a site other than the original planted area (regulated field trial area) is considered a release, and the site must be listed on the permit and monitored for volunteers.

3.4 TERMINATION, VOLUNTEER MONITORING, AND REPLANTING OF ENVIRONMENTAL RELEASE SITES

In-Season Monitoring of the Field Trial

- Describe the methods to monitor for volunteers during the environmental release.
- Provide the frequency and duration of monitoring for volunteers and SCRs.
- Describe methods to destroy volunteers and SCRs prior to flowering/anthesis.
- Describe record-keeping procedures for in-season monitoring.

Post-Termination Volunteer Monitoring of the Field Trial

- Describe the methods of volunteer monitoring following the termination of each environmental release.
- Provide the frequency (e.g., monthly) and duration (e.g., one year) of volunteer monitoring after trial termination.
- Describe method(s) to devitalize volunteers prior to flowering/anthesis.

Replanting Options after Field Trial Termination and during Volunteer Monitoring

Describe the field management or replanting options during the volunteer monitoring period.

Options include:

- Leaving the site fallow.
- Planting to another morphologically distinct, non-sexually compatible crop that allows you to detect and destroy volunteers.
- Planting to another morphologically distinct, non-sexually compatible cover crop for erosion control that will be plowed under.
- Replanting the same regulated crop in a regulated trial where the volunteers are subject to the confinement methods applicable to the regulated crop and the latter trial is monitored for volunteers.
- Replanting to the same nonregulated crop for justified reasons (e.g., maintaining field pest pressure) and where the volunteers are subject to the confinement methods applicable to the regulated crop and the latter trial is monitored for volunteers.