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Standard Operating Procedure (SOP) Template for APHIS BRS Permit Containing Microorganisms Developed using Genetic Engineering (Modified Microbes) for Importation and Interstate Movement

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 an optional tool to assist applicants in developing Standard Operating Procedures (SOPs) for Animal and Plant Health Inspection Service (APHIS) Biotechnology Regulatory Services (BRS) permit applications for modified microbes under 7 CFR part 340.

Although you may add extra information to your SOP, please note that BRS will focus its review on the topic areas mentioned in this SOP template, which are relevant to reviewing your BRS permit application.

The purpose of this SOP is to describe how you will prevent the unauthorized release, spread, dispersal, and/or persistence of modified organisms during activities outlined below:

- **Secure shipment** between contained facilities,
- **Contained use within facilities** at origin and destination, and
- **Devitalization and disposition** at all applicable locations when no longer needed.

Please note that the standard permit conditions (§ 340.5(i)) and supplemental permit conditions contained in your issued permit take precedence over any conflicting information that may exist in your SOP.

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SOP TEMPLATE

1.0 SOP TITLE AND INTRODUCTION TABLE

Standard Operating Procedures for APHIS BRS Permits for the Importation or Interstate Movement of Modified <Scientific name of microorganism> by <Organization name (abbreviated or full legal name)>

Organization Name	
Modified Microorganism(s)	
Movement Type	Importation ☐
	Interstate Movement ☐
Origin of Modified Organism	The country and locality where the organism was originally collected, developed, manufactured, reared, cultivated, and cultured (as applicable)

Note: APHIS reviews a microorganism's origin to understand where it was originally collected (country of origin or possibly the State where it was collected).

For example, if a virus was collected in a foreign country and then imported into the United States, the origin would be the country where it was collected/ isolated. If this same virus is then moved interstate, APHIS needs to understand that the origin was the country where it was collected since the virus may be novel to the United States and/or cause a plant pest risk.

2.0 PROCEDURES FOR IMPORTATION OR INTERSTATE MOVEMENT OF THE MODIFIED MICROORGANISM

2.1 SECURE SHIPMENT OF THE MODIFIED ORGANISM BETWEEN CONTAINED FACILITIES

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

Packing and Shipping Material:
You must inspect packaging material prior to disposal. If any packaging material is exposed to the regulated organism, you must ensure the regulated organism is devitalized prior to disposing the packaging.
Note: Reference Section 4.1 for Devitalization

2.2 DESTINATION FACILITY(IES): INDICATE ALL FACILITIES (INCLUDING INTERMEDIATE DESTINATIONS) WHERE THE MODIFIED MICROORGANISM WILL BE SHIPPED

Locations: List the address(es) for all facilities (including intermediate destinations), which includes building and/or room/greenhouse numbers you will use. Describe how and where you will store the modified organism, so it is contained and segregated from other organisms. If APHIS has previously inspected a facility, provide inspection information in the SOP, such as the APHIS Plant Protection and Quarantine (PPQ) facility number and/or the BRS permit number for each location in the application.

List activities that will occur at each location. See examples below.
Note: Do not describe activities in detail in this section; you will do that in next section, "Use of the Modified Microorganism."

- If the movement is to a single contained facility, describe the activities that will occur at the location.
- If the movement is to several locations, group locations by activities, as indicated below.

Group Locations by Activity (if applicable):

- **Example 1 Multiple Locations**
  XYZ Microbe Company; ABC Microbe Company; and EFG Microbe Company (**XYZ** - No APHIS Inspection; ABC – APHIS Facility No. 0000; EFG - No APHIS Inspection):
  Activity: Storage Only: All material being moved is for storage only. No laboratory or growth chamber work will be performed, and no plants will be inoculated.

- **Example 2 - The University of Microbes** (Inspection by APHIS PPQ: Facility No. 1234):
  Activity: Laboratory only - microbial strain cultivation and no plant inoculation.

- **Example 3 - The Better Microbial Company** (Inspection by APHIS PPQ: Facility No. 2345):
  Activity: Lab, growth chamber studies, including studies with inoculated plants - microbial strain cultivation and corn inoculation. No greenhouse work will be performed.

- **Example 4 - The Best Microbial Company, 4700 Greatest-Lab Way, Riverdale MD 20737** (Inspection by APHIS BRS (Auth-0000123456)
  Activity: Lab, growth chamber studies, and greenhouse (inspected by APHIS BRS for containment), including work with inoculated plants -microbial strain cultivation, insect transmission studies with corn in growth chambers, and plant inoculation in greenhouse.

2.3 USE OF THE MODIFIED MICROORGANISM WITHIN CONTAINED FACILITIES

A contained facility may be approved for laboratory, growth chamber, and/or greenhouse use but only after APHIS has determined that each location is appropriately able to contain all life cycles and trait(s) of the regulated organism for each type of activity.

Movement at Facility: Describe how you will contain the modified microorganism (and inoculated material) when moving it throughout the facility, including structures such as unattached greenhouses or autoclave buildings. Describe how you will contain the material to prevent unauthorized release.

Intended Activities: Describe how you will use the modified microorganism in the facility. Describe activities you will perform (e.g., DNA extraction for genetic analysis, pathogenicity testing, insect vector transmission studies, etc.).

Usage: Describe how you will contain the modified microorganism in the areas you will use them, considering all applicable life stages (spores, dormant structures, vegetative/ sexual).

Describe how you will prevent dispersal and transmission of the modified microorganism in the facility(ies).

- If air-dispersed, describe measures you will take to prevent dissemination in the facility.
- If spore-producing, describe how you will contain the spores in the facility.
  - If water or splash dispersed, describe how you will prevent splash dispersal and/or the measures you will take to treat collected water.

Plant Inoculation (If Applicable): If you plan to inoculate plants, specify the plant(s) you will use and describe the method of inoculation. If you do not plan to inoculate plants, indicate that you will not perform plant inoculation studies.

- State where plant(s) inoculation will be performed within the facility (e.g., laboratory, growth chamber, and/or greenhouse).
- Describe where the modified microorganism is expected to be present in inoculated plant(s): (soil, roots, pollen, fruit, seeds, or other aerial tissues of the inoculated plant).
- Describe how you will contain the modified microorganism and inoculated plant(s) (to include soil, water run-off, pots, benches, tools, etc.) during use and how you will devitalize the regulated organism once your research is complete.
- Describe how you will collect and treat water to ensure the regulated organism is devitalized.
- Describe how you will identify the inoculated plant(s) (markings/tags, etc.).

Insect Vector and Insect Transmission Studies (If Applicable): If you plan to use insect vectors for transmission studies, describe the insects you will use and describe how you will control/contain to prevent unintended transmission.

Other Vectors (If Applicable): If nematodes or other microbial organisms can serve as a vector the modified microorganism, describe mitigation measures.

2.3.1 GROWTH CHAMBER

If APHIS has inspected and approved a facility and determined the growth chamber is adequate for contained use with the modified organism and proposed activities, provide the APHIS Facility number and/or applicable BRS permit numbers in the permit or SOP. If the facility has not yet been inspected, provide a description of containment.

Structure: If you plan to use the modified microorganisms in a growth chamber, describe the containment measures or features of the chamber designed to contain the modified microorganism(s), plants, insect vectors, etc.

Segregation: Describe how you will keep the modified microorganism separated from unmodified organisms. If non-regulated plants are in the same growth chamber, describe how you will isolate these plants from contact/ infection/ hosting the modified microorganism.

2.3.2 GREENHOUSE

If a Greenhouse is not Intended to be Used – State No Greenhouse Work Will be Performed:

If APHIS has inspected and approved the greenhouse for use of the modified organism and proposed activities, provide the APHIS facility number and/or applicable BRS permit numbers in the permit or SOP. If the greenhouse has not yet been inspected, provide a description of containment. BRS may determine that the greenhouse still needs to be inspected for the organism under permit.

Applicants can read the microbial guidance document (draft-brs-microbe-permit-guide.pdf (usda.gov) and view Appendix III "Inspection Checklist" to learn more about the factors BRS considers when assessing containment for research activities in a greenhouse.

Structure: Describe how the structure will contain the modified microorganism in all life stages (e.g., if the modified microorganism is airborne). Describe whether greenhouse structures are non-porous and able to be treated to ensure no persistence of modified microorganisms.

Equipment Used: Describe how you will treat materials in contact with the regulated organism to ensure the regulated organism is nonviable prior to disposal or re-use.

Segregation: Describe how you will keep the regulated organism separated from unmodified organisms. If non-regulated plants are in the same greenhouse, describe how you will isolate these plants from contact/ infection/ hosting the regulated organism.

2.4 DEVITALIZATION AND FINAL DISPOSITION OF THE MODIFIED MICROORGANISM

Devitalization: Describe how you will treat the regulated organism, reproducible parts thereof, and any associated biological material to render non-viable.

- Acceptable methods may include incineration, autoclaving, or alternative treatment (as appropriate). Consider the biology of the microorganism, such as cell wall structure, and types of plants and media. The choice of disinfectant, concentration, and exposure time will be based on each microorganism.
  Note: if using an alternative (such as chemical) method, include a scientifically justified reference, documentation, or testing information that indicates the method is appropriate to devitalize all life stages of the modified microorganism.
- Describe how you will treat any implements, tools, or surfaces that may have come into contact with the regulated organism to ensure the regulated organism is devitalized. This includes all plants, growth media, soil, storage containers, equipment, laboratory surfaces, PPE, etc.

Mitigation Measures: Describe how you will treat spills of the regulated organism.

Final Disposition: Describe how you will dispose of the devitalized regulated organism when it is no longer in use.