



United States Department of Agriculture

# **USDA APHIS PPQ CONTAINMENT FACILITIES AND PEST PERMITS**

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**Animal and Plant Health Inspection Service**

**Plant Protection and Quarantine**

**Plant Health Programs**

**U.S. Dept. of Agriculture**

**Riverdale, MD 20737**

**62<sup>nd</sup> Annual ABSA Biosafety and Biosecurity Conference**

**Birmingham, AL**

**November 15-20, 2019**



United States Department of Agriculture

## APHIS Headquarters- Riverdale, MD



## Welcome and Introduction

USDA-APHIS protects and promotes American agricultural health. We also protect natural resources and regulate agricultural trade.

APHIS Plant Protection and Quarantine (PPQ) regulates the movement of agricultural and associated products to safeguard American agriculture and natural resources from the risks associated with the entry, establishment, or spread of animal and **plant pests (and biocontrol organisms of plant pests) and noxious weeds.**

**Goal: Learn how APHIS PPQ determines and ensures compliance for containment facility requirements for PPQ 526 plant pest permits.**



## Welcome and Introduction, cont.

Permitting policies, processes, and procedures related to the containment of USDA regulated organisms.



Under the authority of the Plant Protection Act (PPA), the Secretary of Agriculture **may prohibit or restrict** the movement into or through the United States, including Territories and Possessions, or interstate commerce of plant pests, plants and plant parts, and associated articles (such as soil).

**This authority is to prevent the introduction or dissemination of a plant pest or noxious weed within the United States.**

## Permits

Permit applications include: importation, interstate/ intrastate movement, and environmental release of a variety of regulated organisms. These include **plant pests and pathogens and biocontrol organisms of plant pests (such as biopesticides)** as well as soil, Federal noxious weeds, and earthworms.

Biopesticides for commercial use are under jurisdiction of the Environmental Protection Agency (EPA).

Prior to August 9, 2019 (the date our Plant Pest Regulations became final (Docket No. APHIS–2008–0076]), PPQ issued PPQ 526 import permits for EPA registered biopesticides under an MOU with EPA. Now it's EPA's responsibility.





## Biocontrol Side Note

PPQ uses drones as well to disseminate sterile insects for select eradication programs. And research for additional uses such as biocontrol is ongoing (pilot project biocontrol arthropod release- Army Corps of Engineers ex.).



*The sterile pink bollworm rearing facility in Phoenix (left) supplied up to 31 million sterile moths daily to the eradication program. Workers load the moths into release devices (center), which fit into specially modified airplanes for moth dispersion over cotton fields (right).*

# PPQ 526 Permits

## PPQ 526 Permit

The PPQ 526 permit for importation, interstate movement, possession, and/or release into the environment of:

- [Insects and Mites](#) (other than Bees, Butterflies and Moths, and Biocontrol Organisms)
- [Bees](#)
- [Butterflies and Moths](#)
- [Biocontrol Organisms](#)
- [Pet Food, Fish Bait, and Animal Feed](#)
- [Plant Pathogenic Bacteria, Viruses, Fungi, Mycoplasmas, and Nematodes](#)
- [Snails and Slugs](#)
- [Federal Noxious Weeds and Parasitic Plants](#)
- [Earthworms](#)
- [Soil](#) (Use PPQ Form 525-A, Application for Permit to Receive Soil)
- [Western Corn Rootworm, \*Diabrotica virgifera\*](#) 
- [Plant Growth Enhancers](#)

## Permits, cont.

### Import, Interstate, and Intrastate Movement Permits

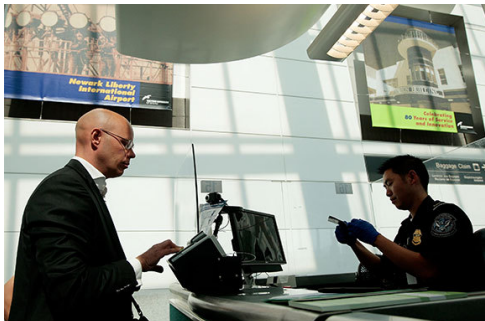
- When importing most non-native organisms for research, containment facilities must be inspected by APHIS and State cooperators and deemed adequate for the regulated organisms and any hosts.
- Intrastate and interstate movement permits are issued for movements **between containment facilities**.
- Even when APHIS does not require an **inspected containment facility** for research, additional interstate movement permits are typically required.
- Some biological control organisms that are native or widely established in the U.S. have few permit restrictions after importation (such as those used commercially for biocontrol in greenhouses).



## Permits, cont.

Generally, permits are issued based on:

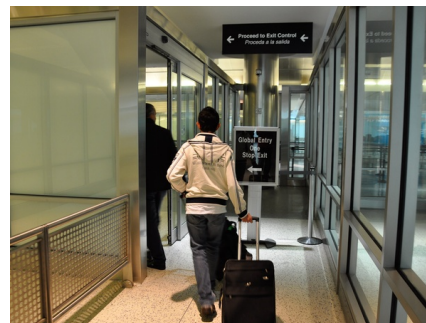
- **Movement Type** (e.g. importation, interstate/ intrastate transport, continued curation);
- **Type of Pest** (e.g. arthropod, microorganism, mollusk, FNW); and
- **Intended Use** (e.g. laboratory, greenhouse, field research/ release)



## Permits, cont.

Separate applications by **Movement Type**:

- Use an importation permit application for all foreign sources of regulated organisms or material to be moved into the U.S., territories, and possessions.
- Use an interstate/ intrastate movement permit application for all regulated organisms or material to be moved within the U.S., territories, or possessions\*.



# PPQ 526 Permits Process and Timeframes

## ✓ Permit Processing Steps and Timelines

Applications for 526 permits are processed in the order received. PPQ receives over six thousand (6,000) 526 permit applications per year. The average application processing time is eighty (80) days. The processing time depends on the complexity of the request. On-line application submission using ePermits can save up to thirty (30) days.

**The PPQ 526 permit review process includes the following steps\***

Step	Time Range
Review application for completeness of required information, such as: applicant contact information, genus and species of regulated material, destination state, origin, and shipment information. Add one month for processing paper applications that are not submitted on-line.	1 week
Evaluate pest risk.	1-4 weeks



# PPQ 526 Permits Process and Timeframes, cont.

Prepare environmental assessment and publish in the Federal Register, if necessary. Environmental assessments are typically required for first time releases of biological control agents.	6 months - 1 year
Inspect containment facility, if necessary.	1-4 months
Determine conditions necessary to mitigate risk.	1-4 weeks
Consult with the State department of agriculture.	1-4 weeks
Evaluate State response.	1-2 weeks
Send draft permit to the applicant for agreement to permit conditions.	1-4 weeks
Issue final permit. For importation only, issue Red and White Labels.	1 week
<b>Total</b>	<b>8 weeks to 18 months</b>

\*These steps and timelines are not all-encompassing; if necessary, additional steps or time may be required

## Permits- Containment

APHIS evaluates the need to require a containment facility based on the environmental risk.

- Organisms that require containment must remain in the facility.
- Additional permits are required to remove the organism from containment, including a transfer to another containment facility within the same State.
- Continued curation (no movements) or renewal permits are required to retain organisms after the original permit expires.



# Containment Facilities

## ✓ Containment Facility Inspections

A facility inspection may be required before a PPQ 526 Permit is issued. A PPQ inspector will document aspects of the facility to determine if the facility and equipment are adequate for containment of the organism(s). A PPQ containment specialist will evaluate the documentation and determine if the facility is adequate. In most cases, if the application is for the receipt of foreign organisms (i.e., foreign strain, biotype, race, isolate) or a Program Pest (i.e., currently under federal quarantine) the facility must be inspected. Diagnostic facilities are also inspected. The applicant will be informed if their facility must be inspected after review of the permit application. Guidelines are available.

- [Containment Facility Inspections](#)





# Containment Facilities, cont.

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## Containment Facility Inspections

Last Modified: Jun 19, 2019






One of the purposes of PPQ permits is to prevent the dissemination of plant pests into or through the United States. As a consequence, PPQ may only issue permits for certain organisms when the receiving facility can adequately contain the organisms so as to prevent dissemination of the organisms.

Containment of regulated organisms may be accomplished by a combination of proper handling of the regulated organisms and by physical and security attributes of the premises where the regulated organisms will be held. PPQ containment specialists can determine the adequacy of a facility either by a computer assisted facility evaluation

## Containment Facilities, cont.

All facilities with PPQ -regulated organisms may be inspected at any time by agency officials during normal business hours.

### Criteria used to Determine the Kind of Evaluation (CAFÉ or Full) Needed Before Permit Issuance:

- [Guidance for Containment Evaluation of Arthropod/Snail Permit Applications When Containment is Required](#) 
- [Guidance for Containment Evaluation of Plant Pathogens and Noxious Weeds Permit Applications When Containment is Required](#) 
- [Guidance for Containment Evaluation of Diagnostic Permit Applications](#) 

### Related Information

If you are applying for a PPQ permit that meets the criteria for an inspection and your facility or laboratory has not been previously inspected, then you should anticipate a one to three month delay in processing your application.



# Guidelines for Containment Levels

*Guidance for containment evaluation of arthropod/snail permit applications when containment is required.*

Type	Movement	Evaluation
1. Unknown and/or unidentified regulated organisms (actual or suspected)	Importation	Full
2. Field-collected regulated organisms	Importation	Full
3. Not established species/subspecies of invertebrate regulated organisms.	Importation	Full
4. Pure cultures of not established species/subspecies of large invertebrates where intended use does not include rearing or propagation, and the organisms must be killed within	Importation	Cafe



# PPQ 526 Permits- No Facility Number Listed

United States Department of Agriculture  
Animal and Plant Health Inspection Service  
Plant Protection & Quarantine  
4700 River Road  
Riverdale, MD 20737

## Permit to Move Live Plant Pests, Noxious Weeds, and Soil Interstate Movement Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

<b>PERMITTEE NAME:</b>	XXXXXX XXXX	<b>PERMIT NUMBER:</b>	P526P-19-XXXXXXX
<b>ORGANIZATION:</b>	XXXXXXXXXXXXXXXX	<b>APPLICATION NUMBER:</b>	XXXXXXXXXXXX
<b>ADDRESS:</b>	XXX XXX XXXX XXX, XX XXXXX	<b>FACILITY NUMBER:</b>	N/A
<b>MAILING ADDRESS:</b>	XXX XXXXXXX XX XXX, XX XXXXX	<b>HAND CARRY:</b>	No
<b>PHONE:</b>	XXX-XXX-XXXX	<b>DATE ISSUED:</b>	06/04/2019
<b>FAX:</b>		<b>EXPIRES:</b>	<b>06/04/2022</b>
<b>DESTINATION:</b>	XXXX XXXXXXX XX XXXX, XX XXXXX		
<b>RELEASE:</b>	No		

Under the conditions specified, this permit authorizes the following:



# PPQ 526 Permits- “Containment”

United States Department of Agriculture  
Animal and Plant Health Inspection Service  
Plant Protection & Quarantine  
4700 River Road  
Riverdale, MD 20737

## Permit to Move Live Plant Pests, Noxious Weeds, and Soil Interstate Movement Regulated by 7 CFR 330










This permit was generated electronically via the ePermits system


<b>PERMITTEE NAME:</b>	XXXXXX XXXX	<b>PERMIT NUMBER:</b>	P526P-19-XXXXXXX
<b>ORGANIZATION:</b>	XXXXXXXXXXXXXXXX	<b>APPLICATION NUMBER:</b>	XXXXXXXXXXXX
<b>ADDRESS:</b>	XXX XXX XXXX XXX, XX XXXXX	<b>FACILITY NUMBER:</b>	5262
<b>MAILING ADDRESS:</b>	XXX XXXXXXX XX XXX, XX XXXXX	<b>HAND CARRY:</b>	No
<b>PHONE:</b>	XXX-XXX-XXXX	<b>DATE ISSUED:</b>	06/04/2019
<b>FAX:</b>		<b>EXPIRES:</b>	<b>06/04/2022</b>
<b>DESTINATION:</b>	XXXX XXXXXXX XX XXXX, XX XXXXX		
<b>RELEASE:</b>	No		

Under the conditions specified, this permit authorizes the following:

# Containment Guidelines

APHIS has developed guidelines for the containment of organisms. These guidelines vary depending upon the type of organism to be contained and the risk posed by those organisms. **Not all elements in the following guidelines apply to all organisms to be contained and the guidelines are guidelines not regulations.**

- [Containment Guidelines for Educational Displays of Adult, Butterflies and Moths \(Lepidoptera\)](#) 
- [Containment Facility Guidelines for Noxious Weeds and Parasitic Plants](#) 
- [Containment Guidelines for Non-Indigenous, Phytophagous Arthropods and Their Parasitoids and Predators](#) 
- [Containment Guidelines for the Receipt, Rearing and Display of Non-Indigenous Arthropods in Zoos, Museums, and Other Public Displays](#) 
- [Containment Guidelines for Plant Pathogenic Nematodes](#) 
- [Containment Guidelines for Non-Indigenous Snails](#) 
- [Containment Guidelines for Plant Pathogenic Bacteria](#) 
- [Containment Facility Guidelines for Viral Plant Pathogens and Their Vectors](#) 
- [Containment Facility Guidelines for Fungal Plant Pathogens](#) 

Before beginning construction of a containment facility, you should contact [Pest Permit Evaluations](#)  staff and discuss our containment requirements with a Containment Facility Evaluation Specialist.





United States Department of Agriculture

# **Ex.: Containment Guidelines for Non-Indigenous, Phytophagous Mollusks (Snails/ Slugs)**

**UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
PLANT PROTECTION AND QUARANTINE**



**CONTAINMENT GUIDELINES**

**For Nonindigenous, Phytophagous Mollusks**

# Standard Operating Procedures (SOP) Guidance

## Related Information

If you are applying for a PPQ permit that meets the criteria for an inspection and your facility or laboratory has not been previously inspected, then you should anticipate a one to three month delay in processing your application.

When PPQ evaluates the containment capabilities of a facility, physical and operational characteristics are examined relative to the risks of the organisms and their methods of actual or potential dispersal from the facility. The operational characteristics of the facility are developed by the applicant and the attached [Outline for Standard Operating Procedures \(SOP's\)](#)  may be used to prepare this document. For butterflies, use the attached [Outline for Standard Operating Procedures](#) . These documented operational features will be confirmed during the inspection.

# SOP Guidance, cont.

## **OUTLINE FOR STANDARD OPERATING PROCEDURES (SOPs)**

### **I. INTRODUCTION**

1. Background information on the facility
2. Major objectives and activities (arthropods, plant pathogens, noxious weeds, biological control agents, etc.)
3. Location of the facility

### **II. PHYSICAL CONTAINMENT STANDARDS**

**Describe the physical characteristics of the facility in detail using the guidelines.**

1. Description of site (e. g. distance from commercial crop production areas, airports, international borders, highways, etc.)
  2. Fence
  3. Buffer area
  4. Demarcation of the facility
-


# Soil Containment Facilities

## Soil

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Last Modified: Jun 17, 2019



Soil is strictly controlled under APHIS quarantine regulations [7 CFR 330](#)  because it can readily provide a pathway for the introduction of a variety of dangerous organisms into the United States.

Importation of soil into the United States from foreign sources is prohibited, and movement within the continental U.S. is restricted unless authorized by APHIS under specific conditions, safeguards and controlled circumstances described in a permit and/or compliance agreement.


- [Apply for a Permit](#) - Use PPQ Form 525-A, Application for Permit to Receive Soil or PPQ Form 526, Application for permit to move live plant pests, biological control agents, or noxious weeds

# Butterfly Containment Facilities

## Butterflies and Moths

Last Modified: Jun 6, 2019



USDA requires permits for the importation and interstate movement of live butterflies and moths under the authority of [7 CFR 330](#) .

- [Apply for a Permit](#) - Use PPQ Form 526, Application for permit to move live plant pests or noxious weeds

### [Information about Shipping Requirements and Red and White Labels](#)

### [Frequently Asked Questions](#)

View a list of the commonly asked questions and concerns associated with the application process for butterflies and moths.

### [Butterflies for Release](#)

USDA will only consider permits for specific species for release into the environment depending on where the butterflies are coming from and where they are being sent. For the monarch butterfly, *Danaus plexippus* the USDA does not issue permits for interstate movement across the continental divide for release into the environment.



# Butterfly Containment Facilities



Source: Philadelphia  
Insectarium and  
Butterfly Pavilion  
Philadelphia, PA



# Laboratory, Growth Chamber, (Greenhouse) Facilities

## Insects and Mites

Last Modified: Feb 15, 2017



A PPQ 526 permit is required for the importation, interstate movement and environmental release of **most** insects and mites that feed upon or infest plants or plant products, including agricultural crops, trees, shrubs, native plants, etc.

- [Apply for a Permit](#)

If you plan to import an exotic insect or mite, you will most likely be required to import the organism into an inspected containment facility. The following factors are taken into consideration when evaluating the level of containment required to receive imported insects and mites:

- whether the organism is indigenous to the U.S;
- whether the organism is indigenous to the area where you plan to move it;
- host plant availability;
- size and mobility of organism;
- life stage to be moved;
- number of organisms to be shipped; and

# Laboratory, Growth Chamber, (Greenhouse) Facilities, cont.

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## Bacteria, Fungi, Nematodes, Phytoplasmas and Viruses

Last Modified: Jun 14, 2019



USDA regulates the importation and interstate movement of plant pathogens by requiring permits (codified at 7 CFR 330.200 to 330.212 [↗](#)). Generally, plant pathogens are recognized as bacteria, fungi, nematodes, phytoplasmas, viroids, viruses, and similar/allied organisms. But for the purposes of this regulation, plant pathogens also include non-genetically engineered infectious substances which can directly or indirectly injure, cause disease, or damage in any plants, plant parts, or plant products.

If the organism is imported on/in host material, no separate permit is required if the host material is not intended for propagation. Most permits for domestic movement and importation are issued for 3 years. The application could be processed in as little as 30 days but there are many factors which cause the review process to take longer. These factors include, but are not limited to: the need for a facility inspection, the need to obtain additional equipment or equipment certifications, or the need for additional information by PPQ or your State Department of Agriculture. All PPQ 526 permit applications are submitted to the destination states(s) for review. The PPQ staff process permits in the order they are received and recommend that you apply for your permit four to six months in advance.

- [Apply for a Permit](#) - Use PPQ Form 526, Application for permit to move live plant pests or noxious weeds

# Laboratory, Growth Chamber, (Greenhouse) Facilities, cont.



Source: ARS Ft. Lauderdale Containment Research Facility



# Laboratory, Growth Chamber, (Greenhouse) Facilities, cont.



Source: ARS Ft. Lauderdale Containment Research Facility

# Laboratory, Growth Chamber, (Greenhouse) Facilities, cont.



Source: ARS Ft. Lauderdale Containment Research Facility



# Laboratory, Growth Chamber, (Greenhouse) Facilities, cont.



Source: ARS Ft. Lauderdale Containment Research Facility





# Laboratory, Growth Chamber Facilities

Plant Health / Import into the U.S. / Permits / Regulated Organism and Soil Permits / Noxious Weeds

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## Federal Noxious Weeds

Last Modified: Mar 26, 2019



USDA requires permits for the importation and/or interstate movement of Federal noxious weeds (FNWs) - aquatic and wetland, parasitic and terrestrial- under the authority of [7 CFR 360](#). You will find a list of the regulated taxa in [7 CFR 360.200](#).

Section 403 of the Plant Protection Act (PPA) defines Noxious Weed as:

*“ any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.”*

- [Apply for a permit](#)

If the species is a Federal noxious weed, and/or a parasitic plant, then fill out PPQ Form 526, Application for permit to move live plant pests or noxious weeds. If sending application by mail or fax, please include your phone number, fax number, and your email address. For faster services, [apply on-line using ePermits](#). ePermits is a



# Laboratory Facilities

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## Snails and Slugs

Last Modified: Apr 16, 2019

 Print

A PPQ 526 plant pest permit is required for the importation or interstate movement of mollusks that feed upon or infest plants or plant products. USDA permits are issued under the authority of [7 CFR 330](#). USDA may permit the interstate movement of snails or slugs for research purposes, educational use in classrooms, display in zoos as well as the importation for research and aquatic hobby trade. Authorization depends upon factors such as the risk the species poses if released to the environment, the level of containment at the research facility and the risk of contaminants during importation.

- [Apply for a Permit](#) - Use PPQ Form 526, Application for permit to move live plant pests or noxious weeds.

### Related Information

Live snails or slugs moved under the authority of PPQ Plant Pest Permits must not be released into the environment.

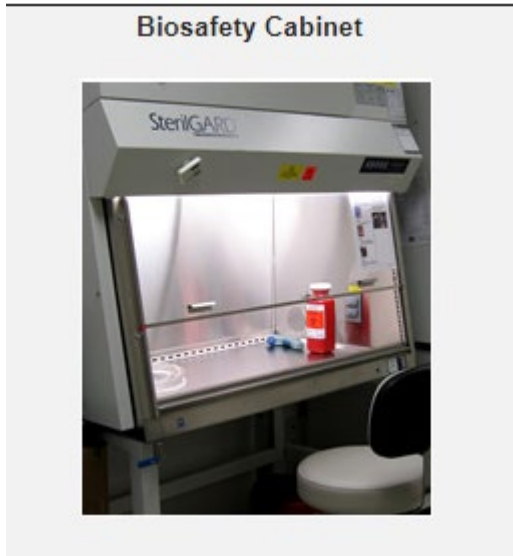
## Equipment

- **Biosafety Cabinets:** Class I (low risk only); ***Class II/ Type A2 (formerly A/B3)(standard)***; Class III (high risk/ closed system)(atypical).
- **Autoclaves:** Required maintenance.
- **Hydroclaves:** Typically not often used in standard research settings.
- **Freezers:** -80 Celsius; ***-29 Celsius (-20 Fahrenheit): colder than most refrigerator/ freezer combinations.***
- **Growth Chambers/ Rooms:** Many different types; usually research specific (plant vs. insect focus).
- **Culturing Apparatuses:** Tanks for large scale operations.

## **Equipment, cont.**

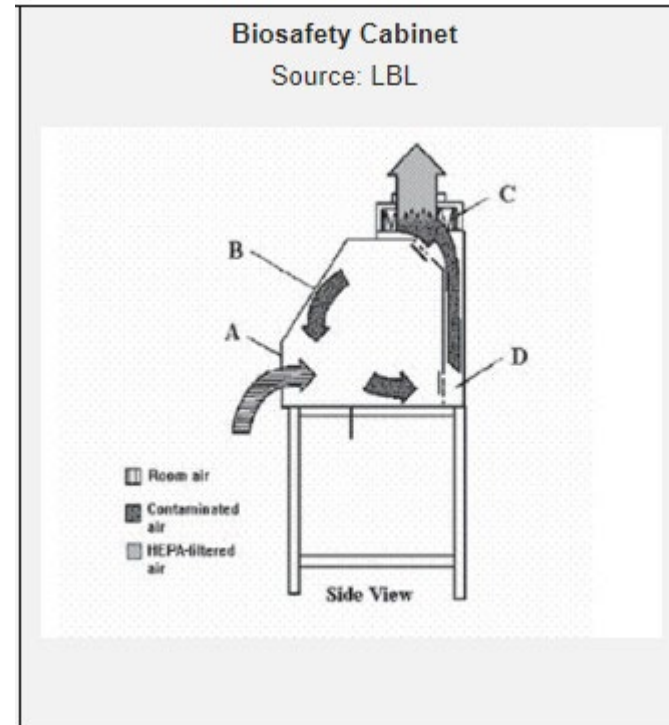
- **Ovens; Incinerators**
- **Insect caging; Bug domes**
- **Fume, laminar flow hoods**
- **Soil trap systems**
- **Lighting systems**
- **Water decontamination systems**
- **Automated greenhouse systems**

# Biosafety Cabinets

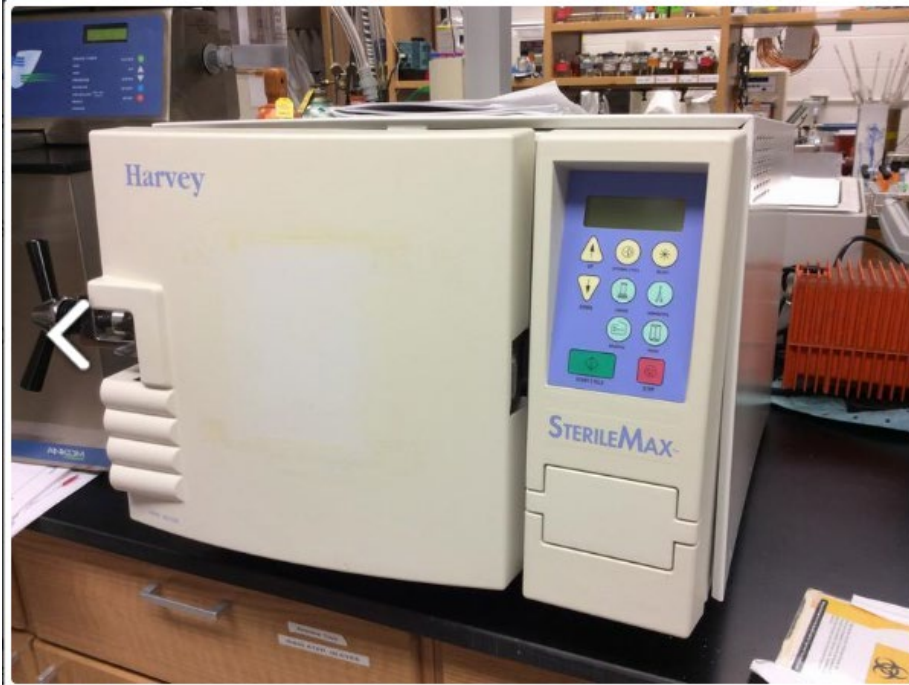


- Annual certification required for Class II and III

Source: U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (<https://www.phe.gov/s3/BioriskManagement/biocontainment/Pages/BSC-vs-Fume-Hoods.aspx> )



# Autoclaves





## Autoclaves- Maintenance- Option 1

- a. Waste must be autoclaved at 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at \*15 psi.
- b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
- c. The autoclave must be calibrated according to the manufacturer's instructions **annually** and a commercially available biological indicator kit that uses bacterial spores of *Geobacillus stearothermophilus* that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used **every three months**.

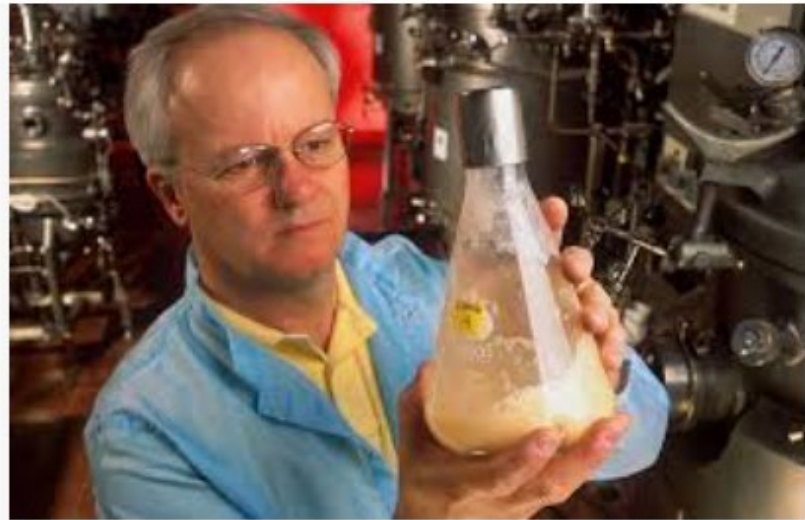
## Autoclaves- Maintenance- Option 2

c. The autoclave must be calibrated according to the manufacturer's instructions **every two years** and a commercially available biological indicator kit that uses bacterial spores of *Geobacillus stearothermophilus* that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used **every two weeks**.

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**Also required for both options:** d. A **written record of the calibration and the biological indicator tests** must be maintained. You must follow the manufacturer's instructions for the *G. sterothermophilus* and if any growth is observed, you must have the autoclave serviced and retested before it is used again for the regulated articles/organisms listed on this permit.

# Culturing Vessels



Formulating Fungal Biopesticides  
[agresearchmag.ars.usda.gov](http://agresearchmag.ars.usda.gov)



Formulating Fungal Biopesticides  
[agresearchmag.ars.usda.gov](http://agresearchmag.ars.usda.gov)

# Plant Pest Regulations Final Rule Effective August 9, 2019.

Glossary

## R Plant Pest Regulations

This Rule document was issued by the **Animal and Plant Health Inspection Service (APHIS)**

For related information, [Open Docket Folder](#) 

Comment Period Closed

### Action

Final rule.

### Summary

We are revising our regulations regarding the movement of plant pests. We are also adding criteria to the regulations for the importation, interstate movement, and release of biological control organisms. This final rule also establishes regulations to allow the interstate movement of certain plant pests and biological control organisms without restriction by granting exceptions from permit requirements for those pests and organisms. Finally, we are revising our regulations regarding the importation and interstate movement of soil. This rule clarifies the points that we will consider when assessing the risks associated with the movement and release of certain organisms and facilitates the movement of regulated organisms and articles in a manner that protects U.S. agriculture.

ID: APHIS-2008-0076-0093

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### Document Information

**Date Posted:**

Jun 25, 2019

**CFR:**

7 CFR Parts 318, 319, 330, and 352

**Federal Register Number:**

2019-13246

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Dates

## Summary

- **Goal: Learn how APHIS PPQ determines and ensures compliance for containment facility requirements for PPQ 526 plant pest permits.**
- Authority- U.S. Plant Protection Act
- PPQ 526 plant pest (and soil) permits
- Containment facilities, SOPs, inspections, and equipment
- A PPQ 526 permit is required to import or move regulated organisms. Inspection of a containment facility may be required depending on the plant pest risk as well as for organisms not established in the destination State

Our main webpage: [Regulated Organism and Soil Permits](#)

**Thanks! Questions?**

**Acknowledgements**

USDA-APHIS-PPQ Permits and Compliance Coordination!

