

# eFile and Permits for NPDN labs

Carrie L Harmon

Regulatory Relations Committee

2023

# Which permits do I need?

## **PPQ526 for importation/movement of plants and plant products from outside your state into your lab**

- eFile (replaced ePermits in 2023)  
<https://efile.aphis.usda.gov>
- Have your old permit on hand plus all lab SOPs that concern containment and handling of samples and their associated stuff – packaging, cultures, inoculations, etc.
- Get eAuthentication credentials (keep your eAuthentication active, even if you only log in once a year)

## **Permits for positive control or reference cultures**

- See last slide for FAQs from the Permits experts
- Consider where the culture/organism is from (inside your state/outside your state)
- Consider whether the organism is regulated at the state or federal level

efile.aphis.usda.gov/

USDA Animal and Plant Health Inspection Service  
U.S. DEPARTMENT OF AGRICULTURE

HOME | GUIDE ME | MY ACTIVITY

# Welcome to APHIS eFile

Apply and manage your APHIS applications, registrations, permits and licenses.

## Ready to Apply?

Start here if you already know what license, registration or permit type you need.

PPQ-526

## Your Activity

Applicant Action Required 0

Draft 0

## PPQ 526 Setup Assistant



You must review the [PPQ 526 CBI Guidance](#), which outlines policies regarding Confidential Business Information (CBI).

- I have read the PPQ 526 CBI Guidance document and understand that CBI claims:
  - Require justification
  - Only apply to confidential information related to:
    - Trade secrets
    - Commercial or financial information
  - Require a CBI redacted version for documents containing CBI, excluding justification

Will your application include trade secrets, or commercial or financial information which is confidential and needs to be claimed as CBI?

- Yes
- No

These answers cannot be changed after you start the application.

## Start a PPQ 526

Welcome to the PPQ 526 Application OMB#: 0579-0054, 0579-0088 and 0579-0207

Proceed if planning to engage in the business of importation, interstate movement, possession, or release into the environment of plant pests, biological control organisms of plant pests and weeds, bees, parasitic plants, and Federally listed noxious weeds. To amend, renew, or transfer a permit, start from the permit's card in [My Activity](#).

**Application Process**

- If your articles require a permit, complete the PPQ 526 Setup Assistant. You will not be able to change answers from the PPQ 526 Setup Assistant once you start the application process.
 

You'll need to identify:

  - If you will claim Confidential Business Information (CBI) in your application
  - Intended Use
  - Movement Type
- After completing the PPQ 526 Setup Assistant, continue to fill out and submit a PPQ 526 application.
- Once submitted, PPQ will begin processing your application. Processing typically takes 80 business days or longer.

> My articles are select agents or toxins

> Paperwork reduction act of 1995 statement

> My Articles are Genetically Engineered

## PPQ 526 Setup Assistant



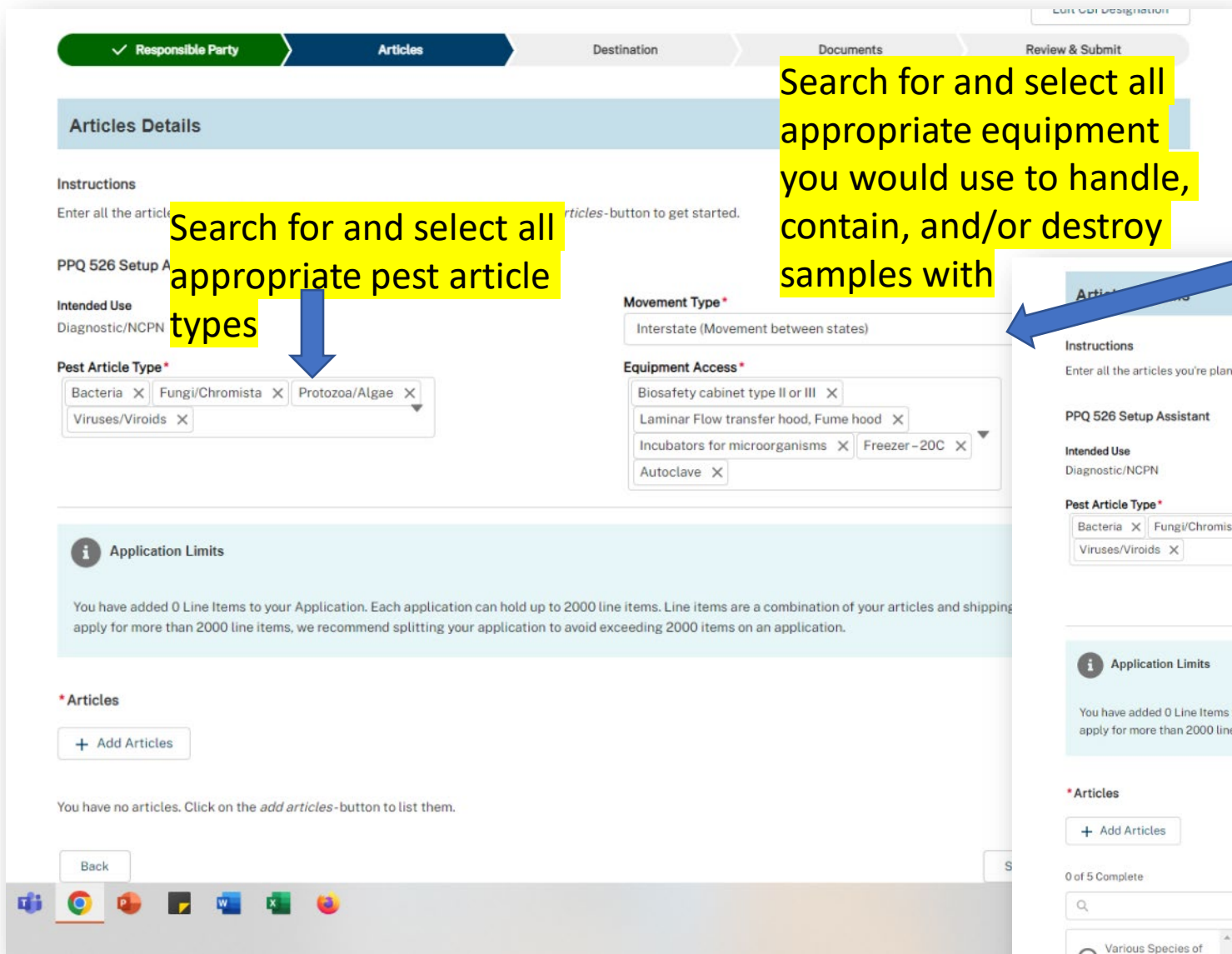
### Intended Use

Diagnostic/NCPN

### Movement Type

Interstate (Movement between states)

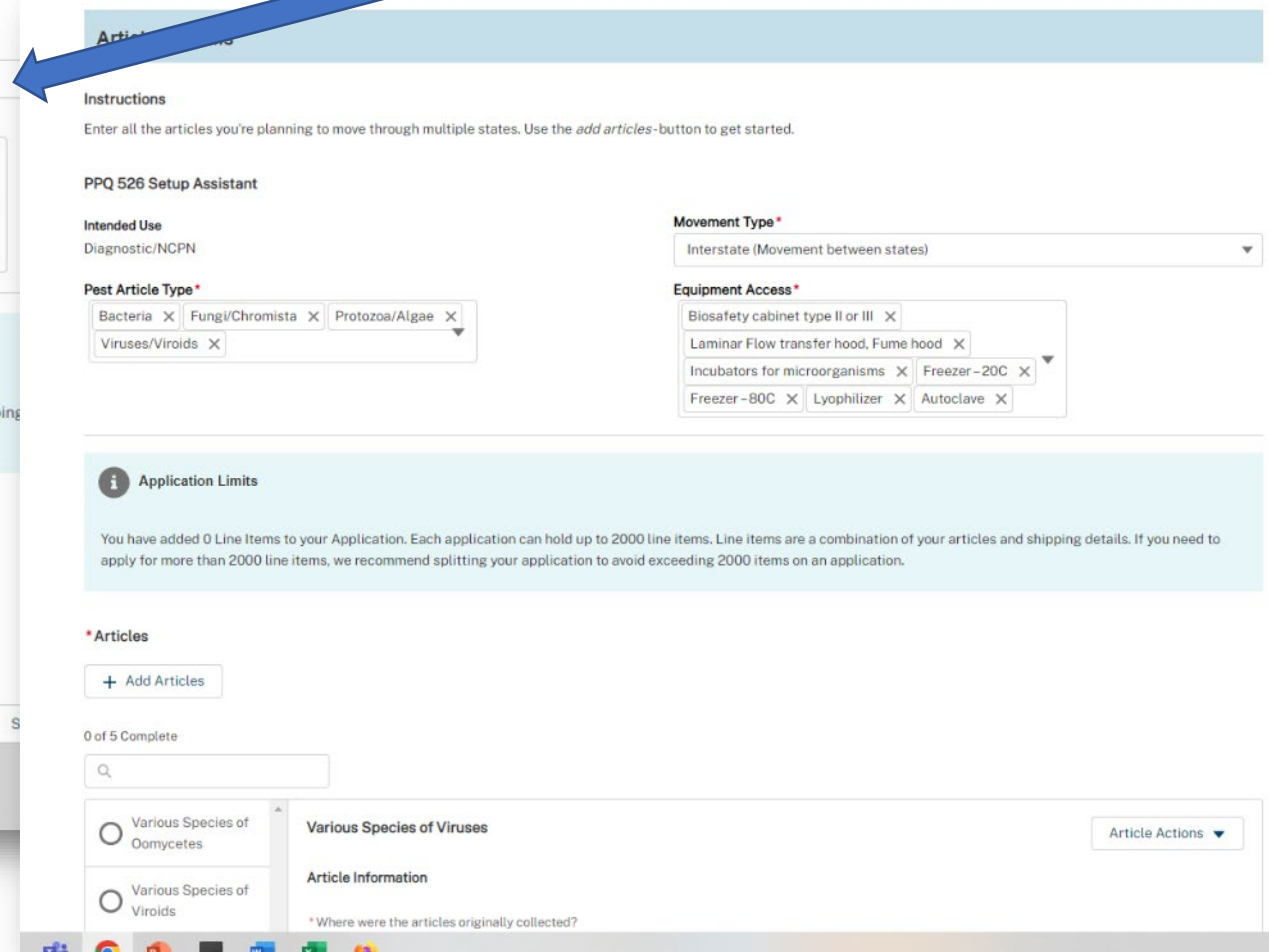
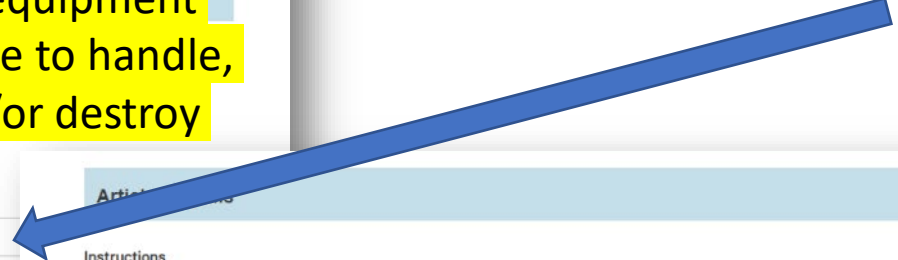
These answers cannot be changed after you start the application.



Search for and select all appropriate equipment you would use to handle, contain, and/or destroy samples with

Search for and select all appropriate pest article types

For interstate (US) samples



If relevant, add additional articles for your lab: various species of arthropoda, invertebrate organisms, various species of federal noxious weeds.

\*Articles

+ Add Articles

5 of 5 Complete

Q

- Various Species of Oomycetes
- Various Species of Viroids
- Various Species of Fungi
- Bacteria Various Species
- Various Species of Viruses

Various Species of Viruses

Article Information

\*Where were the articles originally collected?

U.S. including territories

Subspecies

\*Life Stages

Any X

\*Are the articles established in the US?

- Yes
- No
- I don't know

\*Major Host

plants

\*Additional Accompanying Material

Pure cultures and infested or infected host material

Material Explanation

diagnostic purposes

Isolate or Strain (for your selected organism, if appropriate) ⓘ

Article Actions ▼

Copy shipment deets to all articles,  
then save at the bottom

Shipping and Transport

Add Shipment Details

\* Do you have a specific shipping origin address?

- Yes
- No, I'll enter the states instead

\* Search for and select states

Search

States

Search for and select all  
appropriate states; use  
these specific phrases

3 states selected

Clear All

Continental United States X United States Minor Outlying Islands X Puerto Rico X

Contact Details

\* Do you have shipment contact information?

- Yes
- No

Shipping Details

\* Do you have shipping details? ⓘ

- Yes
- No

Cancel

Add

Total records: 5

Save

Save and Next

## Articles Details

### Instructions

Enter all the articles you're planning to import. Use the *add articles*-button to get started.

### PPQ 526 Setup Assistant

#### Intended Use

Diagnostic/NCPN

#### Pest Article Type \*

Bacteria X Fungi/Chromista X Protozoa/Algae X  
Viruses/Viroids X

Search for and select all appropriate pest article types

#### Movement Type \*

Import

#### Equipment Access \*

Biosafety cabinet type II or III X  
Laminar Flow transfer hood, Fume hood X  
Incubators for microorganisms X Freezer -20C X  
Freezer -80C X Lyophilizer X Autoclave X

For international samples

### Add Articles

\* Search for and select articles

Search  Add

I can't find my article

#### Articles

5 articles selected [Clear All](#)

Various Species of Viroids X Various Species of Fungi X Bacteria Various Species X Various Species of Oomycetes X  
Various Species of Viruses X

#### Articles Details

\* Where were the articles originally collected?

Foreign locations

Subspecies

\* Life Stages

Any X

\* Are the articles established in the US?

Yes  
 No  
 I don't know

\* Major Host

Plants

\* Additional Accompanying Material

Pure cultures and infested or infected host material

Material Explanation

for diagnostic purposes

Mode of Transport

Express delivery X

Search for and select all appropriate pests. Use these specific phrases.



Select "foreign locations"

Select "any"

Type "plants"

Type "for diagnostic purposes"

### Add Shipment Details

Yes  
 No, I'll enter the countries or continents instead

\* Search for and select continents or countries of origin

Search

#### Continents or Countries of Origin

6 continents or countries of origin selected [Clear All](#)

Africa X South America X Europe X Asia X  
North America (excluding USA) includes Central America and Caribbean Islands X Australia and Oceania X

#### Contact Details

\* Do you have shipment contact information?

Yes  
 No

#### Shipping Details

\* Do you have shipping details?

Yes  
 No

Cancel Add

Search for and select all appropriate countries/continents. Use these specific phrases.

## Add Destination

Enter the following information about your destination where activities involving the regulated articles will take place. APHIS will contact you if additional information is required to verify your containment facility.

\* Destination Name

UF-IFAS Plant Diagnostic Center

\* Type

Laboratory X

Research Center or Department

Department of Plant Pathology

Building or Room Number

For multiple numbers, enter them in the Description field.

Bldg 1291

Description ⓘ

Salesforce Sans

12

B

I

U

☺

☰

☰

☰

☰

☰

ePermits Containment Facility Number ⓘ

This is used to help verify if the containment facility already exists.

3083

### Destination Address

#### Instructions

Enter the following information about your destination's address. Be as specific as possible. This address must be a physical address, not a P.O. box.

\* Address Line 1

Address Line 2

\* City

\* State

Cancel

Use your old permit to  
find the details



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> Dr. Carrie Harmon	<b>PERMIT NUMBER:</b> P526P-22-05631
<b>ORGANIZATION:</b> University of Florida	<b>APPLICATION NUMBER:</b> P526-220515-002
<b>ADDRESS:</b> 2570 Hull Road Building 1291 Gainesville, FL 32611	<b>DATE ISSUED:</b> 06/15/2022
	<b>EXPIRES:</b> 06/15/2023
<b>MAILING ADDRESS:</b> 2570 Hull Road Building 1291 Gainesville, FL 32611	<b>FACILITY NUMBER:</b> 3083
<b>PHONE:</b> 352-392-1795	<b>HAND CARRY:</b> Yes
<b>ALT. PHONE:</b> 352-871-5156	<b>FACILITY ACCOUNT:</b> University of Florida
<b>EMAIL:</b> clharmon@ufl.edu, pdc@ifas.ufl.edu	<b>RESEARCH CENTER:</b>
	<b>FACILITY NAME:</b>
	<b>FACILITY ADDRESS:</b> Building 1291 2570 Hull Road Gainesville, Florida 32611
<b>FAX:</b>	<b>FACILITY GPS:</b>
	<b>MAIL ADDRESS:</b> Building 1291 2570 Hull Road Gainesville, Florida 32611
	<b>FACILITY CONTACT:</b> Dr. Carrie Harmon
	<b>PHONE:</b> 352-392-1795
	<b>ALT. PHONE:</b> 352-273-4645
	<b>FAX:</b> 352-392-3438
	<b>EMAIL:</b> clharmon@ufl.edu
<b>DESTINATION:</b> Building 1291 2570 Hull Road, Gainesville, FL 32611	
<b>RELEASE:</b> No	

Select the destination where you're sending your articles. OR create a new destination to use instead. If it's determined that your articles need containment, APHIS will contact you to discuss next steps regarding your destination.

\* Destinations

 **UF-IFAS Plant Diagnostic Center** Edit  
Carrie Harmon Account

<b>Address</b> Department of Plant Pathology Bldg 1291 2570 Hull Road Building 1291 Gainesville, FL 32611 Alachua, US	<b>Type</b> Laboratory
<b>Is the mailing address the same as the destination address?</b> Yes	<b>ePermits Containment Facility Number</b> 3083
	<b>Contact</b> Carrie Harmon 3523921795 clharmon@ufl.edu

Remove Destination

**Release Details**

\* Is this a Release?

- Yes
- No

Back

Save

Save and Next





## Document Details

### Instructions

Add files you feel would support this application. Don't add an attachment with list of links.

I don't have any files to upload

### Supporting Documentation

Add New File

File Name	File Type	Description	Created Date
UFPDC-WI-G002 ver 1.9 Out-...	9 Out-...	Standard Operating Procedure (SOP)	04/24/2023, 04:14 PM
1PERMIT_US_NonFL_samples_...	pdf	Previous permit	04/24/2023, 04:12 PM

Show: 10 Total records: 2

Upload any SOPs or protocols that describe safe handling and containment of samples

## Additional Information

### Instructions

Enter the following information about your

Detail any additional information you feel wou

Enter text

Back

File Explorer window showing the following files:

Name	Date modified	Type
QIAquick-Gel-Extraction-Kit-EN_2015	3/24/2016 12:12 PM	Adobe Acrobat Document
UFPDC-WI G015 RTDS Triage SOP	10/24/2019 10:08 AM	Adobe Acrobat Document
UFPDC-WI-001-001 ver 2.2 Document Format 141201	4/23/2015 12:48 PM	Adobe Acrobat Document
UFPDC-WI-001-002 ver 1.1 Record Control and Retention 141201	4/23/2015 12:48 PM	Adobe Acrobat Document
UFPDC-WI-005-001 ver 1.2 Nonconformance and Deviations 141201	4/23/2015 12:49 PM	Adobe Acrobat Document
UFPDC-WI-G00X Logging out samples in RTDS Pclinic 170622.doc	6/23/2017 3:56 PM	Adobe Acrobat Document
UFPDC-WI-G001 General Sample Handling 150317	3/17/2015 2:28 PM	Adobe Acrobat Document
<input checked="" type="checkbox"/> UFPDC-WI-G002 ver 1.9 Out-of-state sample handling and Sample Chain ...	6/7/2019 11:12 AM	Adobe Acrobat Document
UFPDC-WI-G003 Sample Destruction 141201	4/23/2015 12:52 PM	Adobe Acrobat Document
UFPDC-WI-G003a_sample destruction and waste disposal temporary duri...	3/23/2018 2:10 PM	Adobe Acrobat Document
UFPDC-WI-G004 Sample Processing Triage 141201	5/19/2016 2:28 PM	Adobe Acrobat Document
UFPDC-WI-G005 deposit into Peoplesoft 160601	6/1/2016 9:14 AM	Adobe Acrobat Document

UFPDC-WI-G002 ver 1.9 Out-...  
Adobe Acrobat Document



Date modified: 6/7/2019 11:12 AM  
Size: 57.1 KB  
Date created: 6/7/2019 11:11 AM

## Congratulations, your application has been submitted and it is being reviewed!

A confirmation email has been sent to the primary email address in your profile.

Once your application has been processed, you will receive a confirmation email. You can also log back in to review your application status at a later time.

To ensure our emails reach your inbox, we recommend you add [aphis.efile@usda.gov](mailto:aphis.efile@usda.gov) and [support@salesforce.com](mailto:support@salesforce.com) to your address book.

[Download Application PDF](#)

### Double check that your articles meet all legal requirements!

It's your responsibility to regularly check Agricultural Commodity Import Requirements (ACIR) to make sure all conditions met. Rules and regulations can change at anytime.

[Check ACIR](#)



#### PPQ-526 Application Summary

**Application Number**  
A-00247005

**Status**  
Submitted

**Submission Date**  
4/24/2023

#### Need Help?



If you have any further questions, please call 1-866-524-5421 or 301-851-2357 or email [pest.permits@usda.gov](mailto:pest.permits@usda.gov).

If you have any questions regarding admissibility, please visit <https://acir.aphis.usda.gov/s/> or email [acirdatabase.comments@usda.gov](mailto:acirdatabase.comments@usda.gov).

If you struggle, need eAuthentication, or have questions, reach out to your SPRO – they can help behind the scenes, and are the final stop on the approval list. A good excuse to reach out to them, anyway!

# Questions from Regulatory Relations Committee members, Answers from Deric Picton, USDA-APHIS-Permits

1. If an ***in-state*** diagnostic sample is submitted and found to have a certain organism, do we need a research permit to keep the sample? I thought we only needed a permit if the sample originated from out-of-state or if it is a "regulated" organism. We all know that we need permits to keep out-of-state originating samples. The confusion is about in-state origin samples.
  1. If a sample originated in-state then PPQ does not require a permit. One exception to this is if the situation where the sample originated in the state but was moved out of state (to ATCC for example) and then moved back into the state.
2. We have rose rosette virus throughout Oklahoma and we keep a few frozen leaves to serve as a positive control in the freezer in case we receive a diagnostic sample that needs RRV testing. I do not think I need a permit for the RRV infected rose leaves that came from Oklahoma (my state). Is this correct?
  1. You are correct, PPQ does not require a permit for samples/controls that originated in the same state where they are used.
3. We detected Phytophthora ramorum (Pram) in 2019 in a nursery in Oklahoma. The pathogen was traced back to plants that originated in Washington State and British Columbia. The disease spread to Oklahoma grown plants at the Oklahoma nursery, and we cultured Pram out of Oklahoma grown plants. In this case, I believe I needed to obtain a permit to maintain the isolate since this organism is regulated and we were working to eradicate it from Oklahoma.
  1. Yes, a research permit is required since it is a PPQ program pest and not established in Oklahoma.
4. We want to get set-up to test for a new organism. For example, the Guava root knot nematode, Meloidogyne enterlobii. To date, this nematode has not been found in Oklahoma, so I would request an isolate from another state (ie. LA). For this, I need a research permit, even though the goal will be to run a diagnostic test.
  1. Yes, a research permit is required since it is not established in Oklahoma and you are requesting it from another state.
5. If I only request extracted DNA, I would not need a permit.
  1. If the DNA extract originated from a pure "culture" of the organism then generally no permit is required. It is possible for infectious DNA viruses to be present but the risk of plant infection is generally considered to be very low.
6. If this were an RNA organism, is the answer the same?
  1. If the RNA extract originated from a pure "culture" of the organism then generally no permit is required. It is possible for infectious RNA viruses and viroids to be present but the risk of plant infection is generally considered to be very low.
7. Every year, we screen wheat samples for about 6 viruses found in Oklahoma. It's really expensive to purchase lyophilized positive controls for the ELISA tests, so we freeze Oklahoma wheat samples that tested positive in 2022, so we can use them as positive controls in 2023. I don't think I need a permit for this.
  1. You are correct, PPQ does not require a permit for samples/controls that originated in the same state where they are used.
8. We now have a wheat researcher that is working on a qPCR multiplex for these wheat viruses. Again, they all originated in Oklahoma. Does she need a research permit if she wants to take some of our frozen leaves from last season? Her goal would be to eventually transfer the new diagnostic testing method to our diagnostic lab.
  1. As long as they are working with exclusively Oklahoma strains then no permit is required. If they want to expand the testing to non-Oklahoma strains then a permit will be required.