

APHIS eFile: BRS Applicant Training

BRS Permit Applications (APHIS 2000) in APHIS eFile

- Welcome to APHIS eFile
- Submitting Permit Applications
- Post-Submission Activities
- Managing Compliance

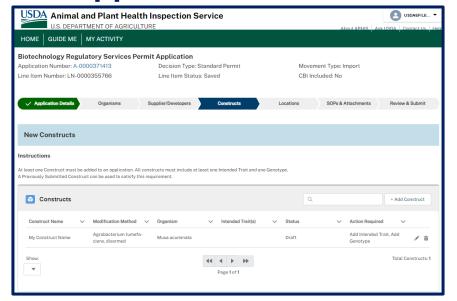
WELCOME!

USDA APHIS Biotechnology Regulatory Services (BRS) applicants must use APHIS eFile to submit permit applications for importation, interstate movement, or environmental release of organisms developed using genetic engineering.

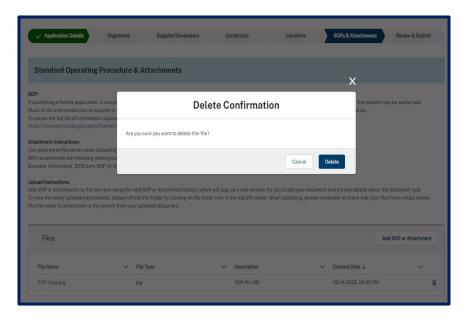
WHAT'S NEW?

On March 28, 2022, BRS' Permit Application was updated in APHIS eFile:

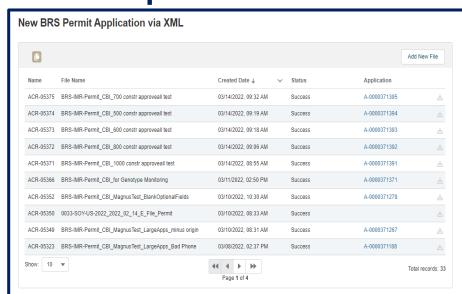
Modernized Web Application Interface



Improved SOP/Attachment Area



Remodeled XML Upload Table



Applications up to 500 Constructs and 250 Locations may be submitted!

PDF generation process updated to output PDFs of all sizes!

TRAINING OBJECTIVES

This training will teach new and existing BRS applicants how to draft and submit BRS applications for review using the updated interface, and perform post-submission activities such as editing applications, reviewing permit conditions, and submitting compliance reports.

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Watch Training Recording Part 1:

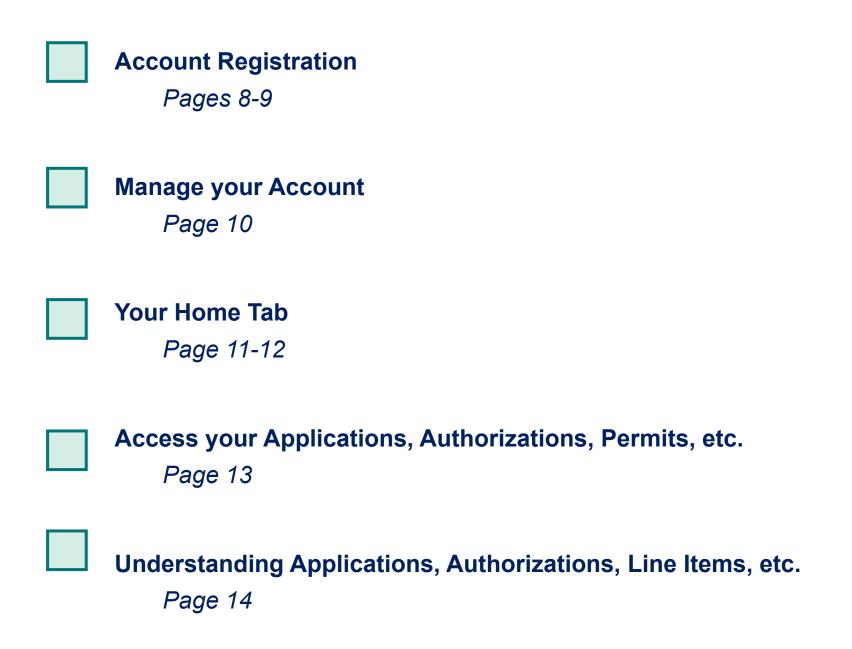
https://usda.adobeconnect.com/pikjvu9ygw8w/

Watch Training Recording Part 2:

https://usda.adobeconnect.com/p5pxmosp10ns/

Welcome to APHIS eFile

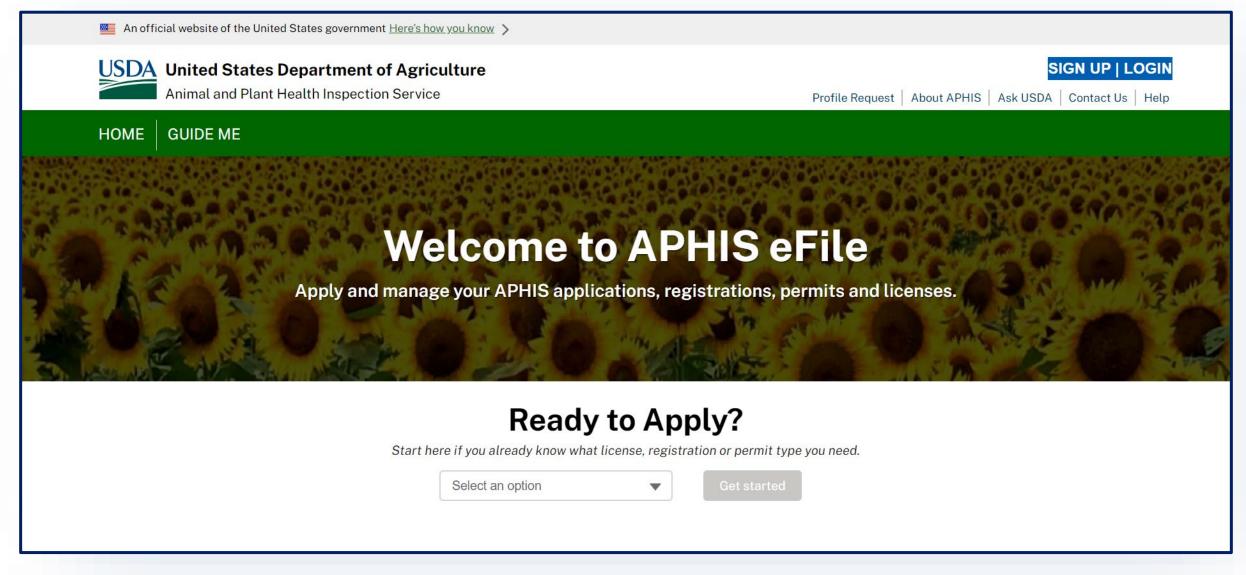
WELCOME TO APHIS EFILE



Account Registration

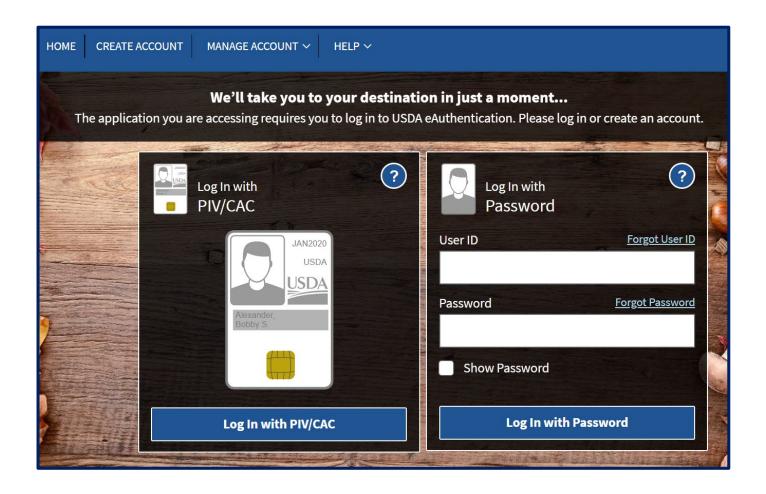
Visit https://efile.aphis.usda.gov/ to create your APHIS eFile account.

To sign up, an identity-verified <u>USDA eAuthentication Account</u> is <u>required</u>.



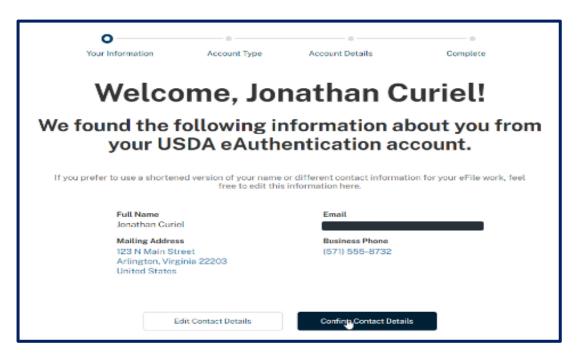
Account Registration

If you do not have a USDA eAuthentication Account, select **Create Account** and follow the on-screen prompts.



When you register, your contact information will import from your USDA eAuthentication account.

Edit your **Contact Details** to match your business address, email, and phone number, and confirm.

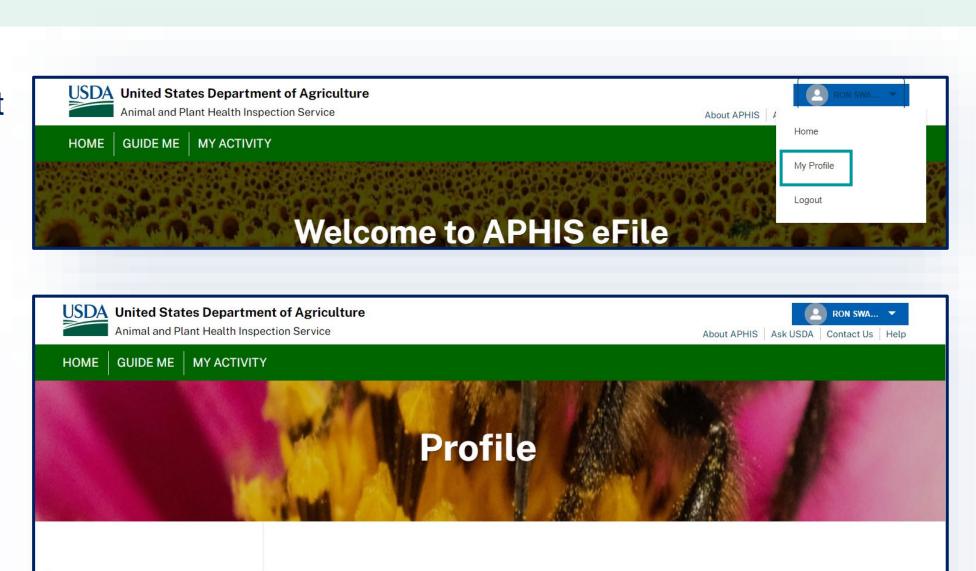


Manage Your Account

Visit **My Profile** to update Contact and Organization information as needed.

Use the **Associated Organizations** tab to:

- Adjust your private account name.
- Set up or join a shared Organization Account.
 - Note that new Organizations take a few minutes to appear after creation.



Edit Contact Details

melissa.cavazos@accenturefederal.c

Email

Contact Details

Full Name

Ron Swanson

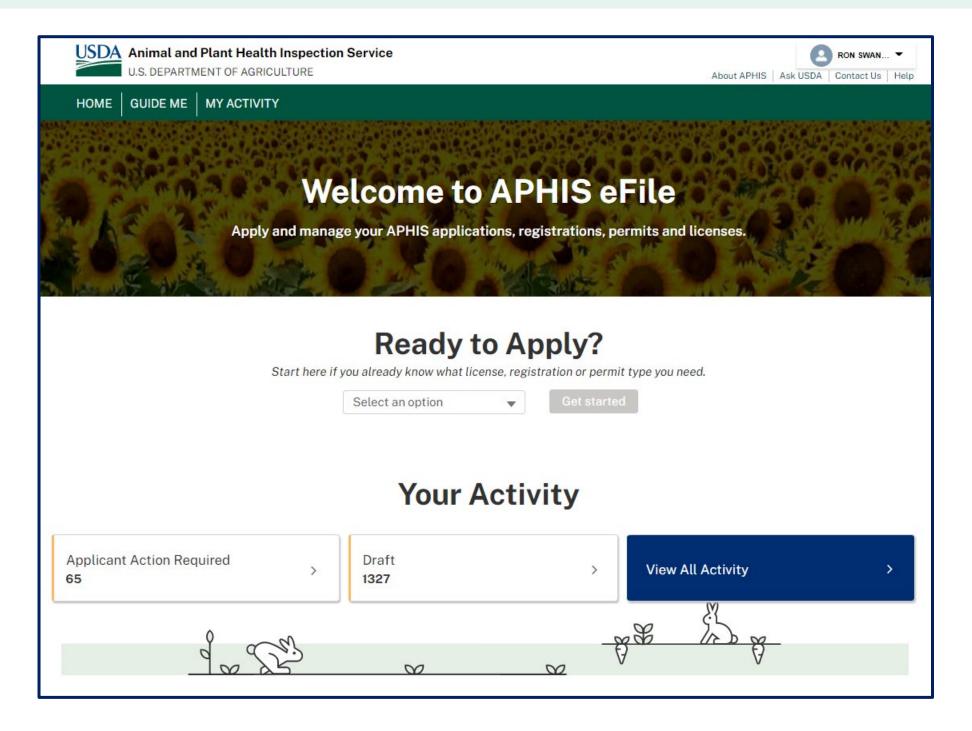
Mailing Address

Contact Details

Application Contacts

Associated Organizations

Your Home Tab



Your **Home** tab in APHIS eFile includes several shortcuts to:

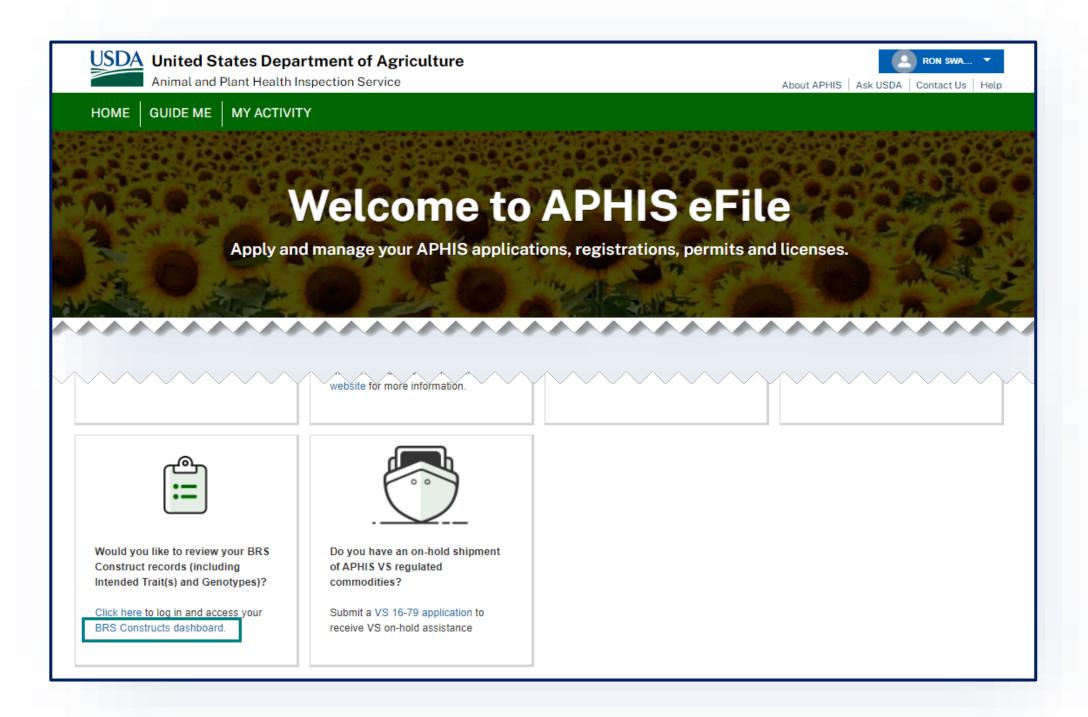
- Start an APHIS application, including an APHIS 2000.
- Pre-filtered views of your activity in APHIS eFile.

 Links and resources for various APHIS programs.

Your Home Tab

Your Home Tab also contains a link to view constructs submitted on BRS applications.

The BRS Construct dashboard is linked in the Construct card.

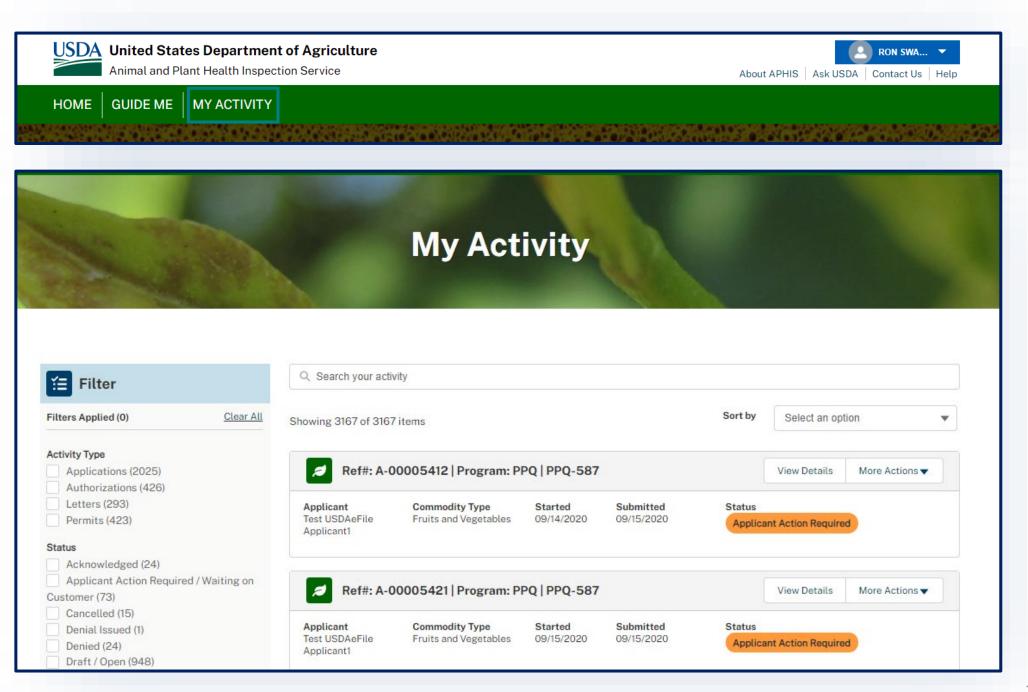


Access your Applications, Authorizations, Permits, etc.

Select My Activity to access your Applications, Authorizations, Permits, etc.

This area will be blank until you create applications in APHIS eFile.

Use the **Filter** to select Activity Type or Status to further refine your results.



APHIS eFile Records: Understanding Applications, Authorizations, Line Items, etc.

Applications

Draft and submit for permit authorizations.

Application Details

Application Number: A-0000184628

Application Type: New

Application Name: Test USDAeFile Applicant-2
Application Email: tara.marostica@usda.gov

Application Phone: 3235551114

Application Fax:

Organization: Leslie Knope Account LLC
Shared With: Leslie Knope Account LLC

Status: Draft

Withdrawn By:

Withdrawn Date/Time:

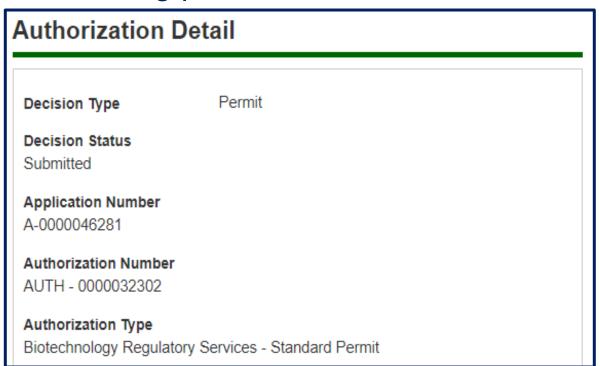
330 Lurgan, SOUTH SAN

Applicant Address: FRANCISCO, California, 94080,

United States

Authorizations

APHIS process for reviewing applications and issuing permits.



Line Items

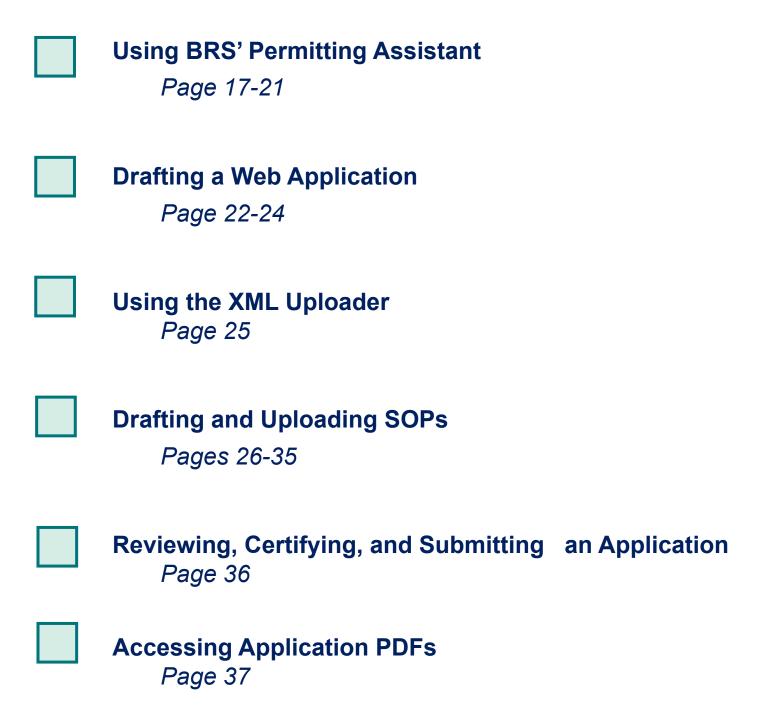
Contains all the details of your application.

Application Details Organisms Supplier/Developers Constructs Locations SOPs & Attachments Review & Submit

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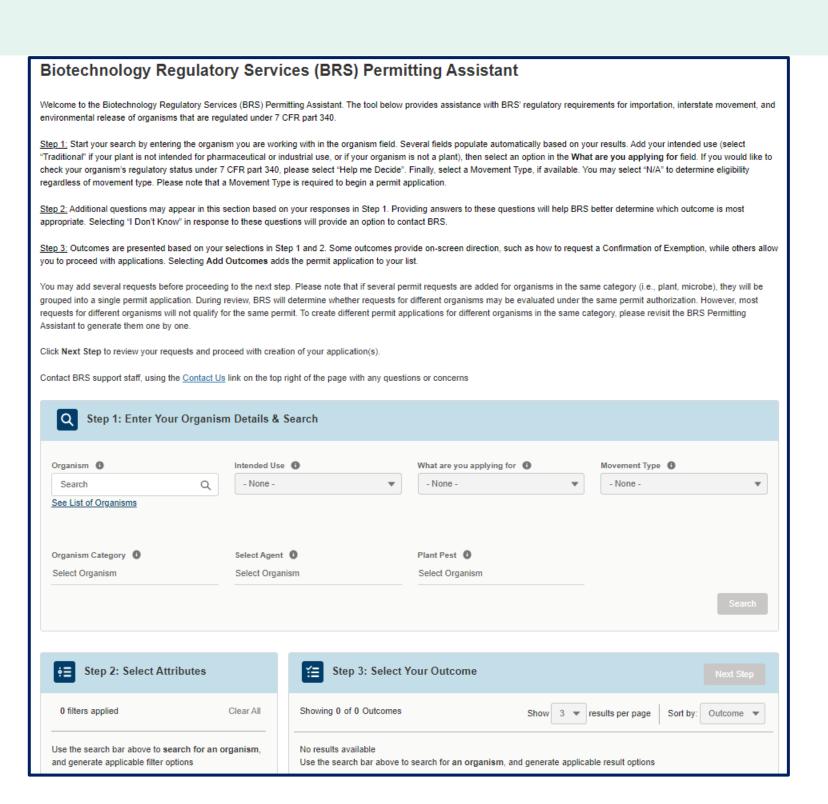
Submitting Permit Applications

SUBMITTING PERMIT APPLICATIONS



The **BRS Permitting Assistant** (BRSPA) is an interactive interface that allows applicants to:

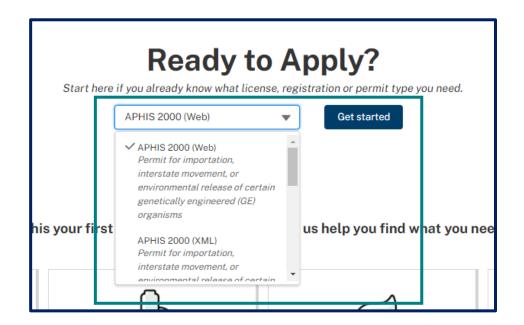
- Enter details about their organism and activity to determine whether a permit is required.
- Quickly initiate a new web-entry application.



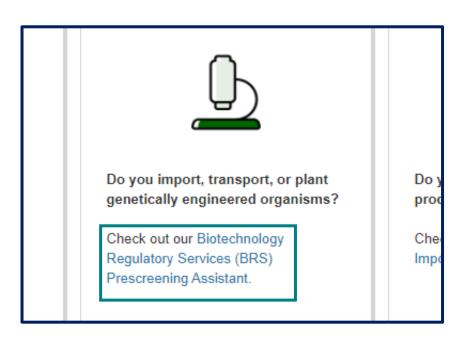
Login to begin the BRSPA



Select APHIS 2000 (Web) Application



OR Select the BRSPA card



Step 1:

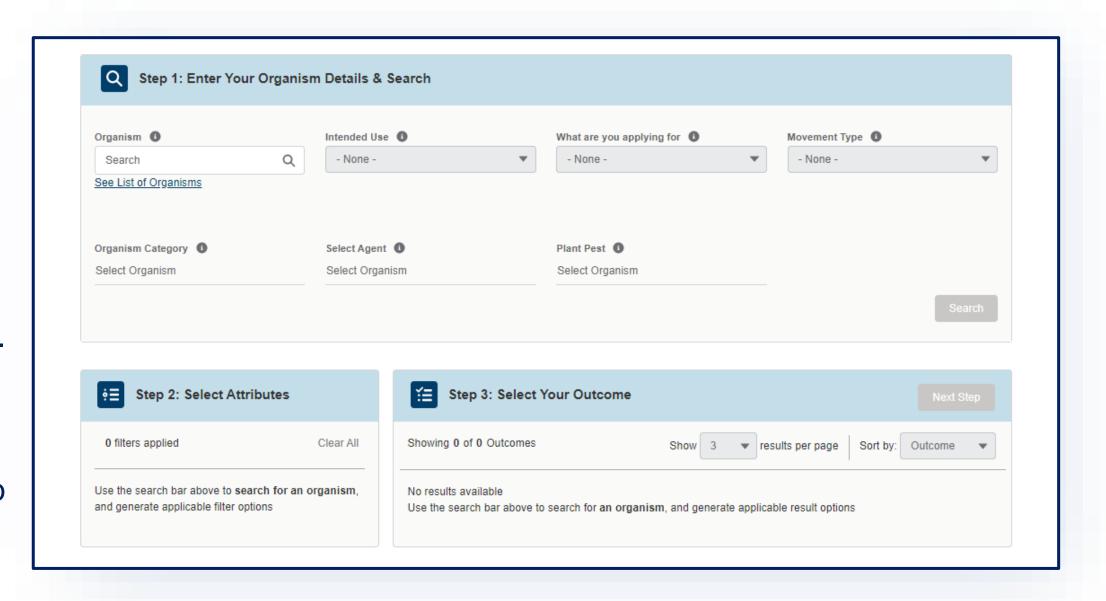
Enter your organism details.

Step 2:

Use the attribute filters to refine your outcomes.

Step 3:

Add the outcome and proceed to the next step to confirm your selections.

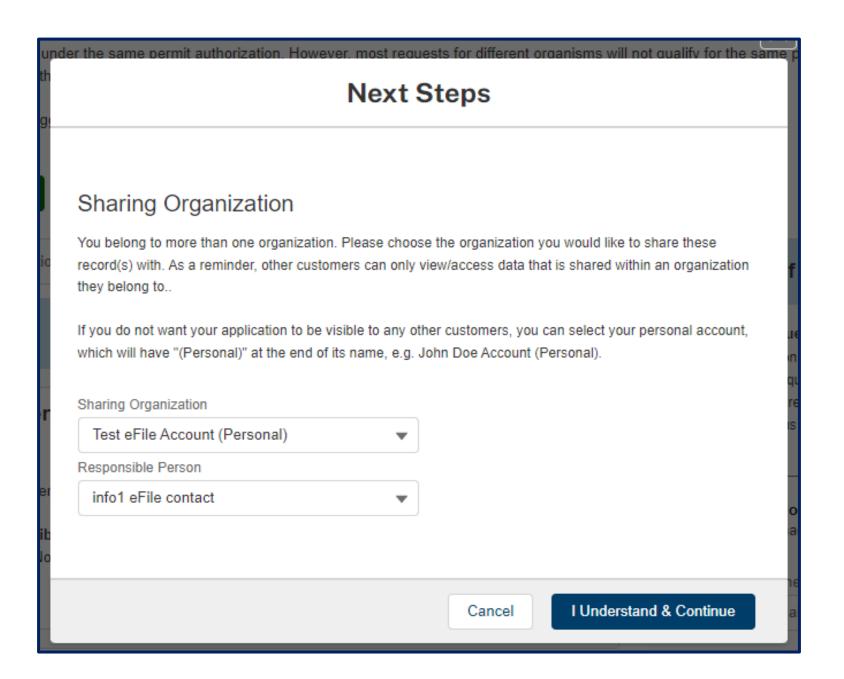


Select a Sharing Organization

This determines who can see the application, as well as the name of the organization on the application.

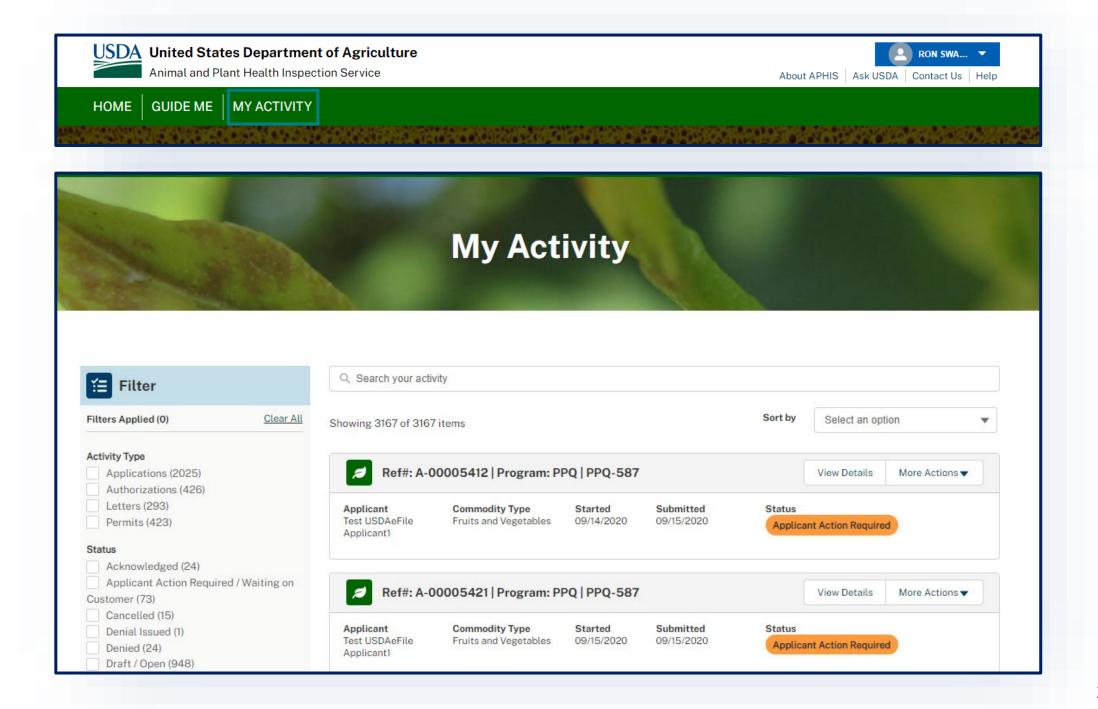
Select a Responsible Person

This is the name of the applicant who is responsible for overseeing compliance with permit conditions.



Locate the **Draft Application** you intend to submit.

Select **View Details** to begin drafting the new application.



Drafting a Web Application

Application Details

Organisms

Supplier/Developers

Constructs

Locations

SOPs & Attachments

Review & Submit

Key Application Fields!

Application Details

- Identify whether your application includes CBI.
- Include details of the dates needed and preliminary organism details.

Organisms

- Review organism details entered in the BRSPA.
- Add/Edit organism details (if needed).

Supplier/Developers

- Information is not required.
- Add CBI claims to contacts after saving for reuse.

Drafting a Web Application

Application Details

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Key Application Fields!

Constructs

- Add a new construct or use a construct from a previously submitted application (in APHIS eFile).
- Provide intended trait and genotype details for each.

Locations

- Select and enter the applicable Location Types for your application.
- Provide Agent contact details for each of the locations.
- Add Materials to locations that include destinations.
- Enter your Location Unique ID and include four pairs of GPS coordinates for release location.

Drafting a Web Application

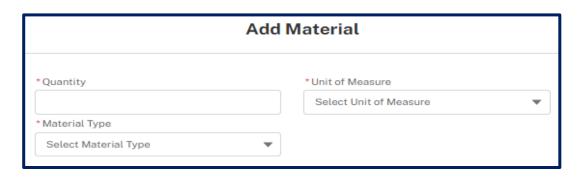


Key Reminders!

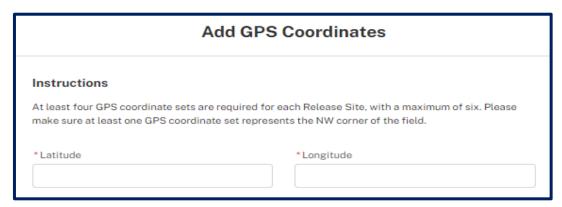
Identify if your application has CBI.



Add **Materials** to **Destination Location** or **Origin and Destination Location** type.



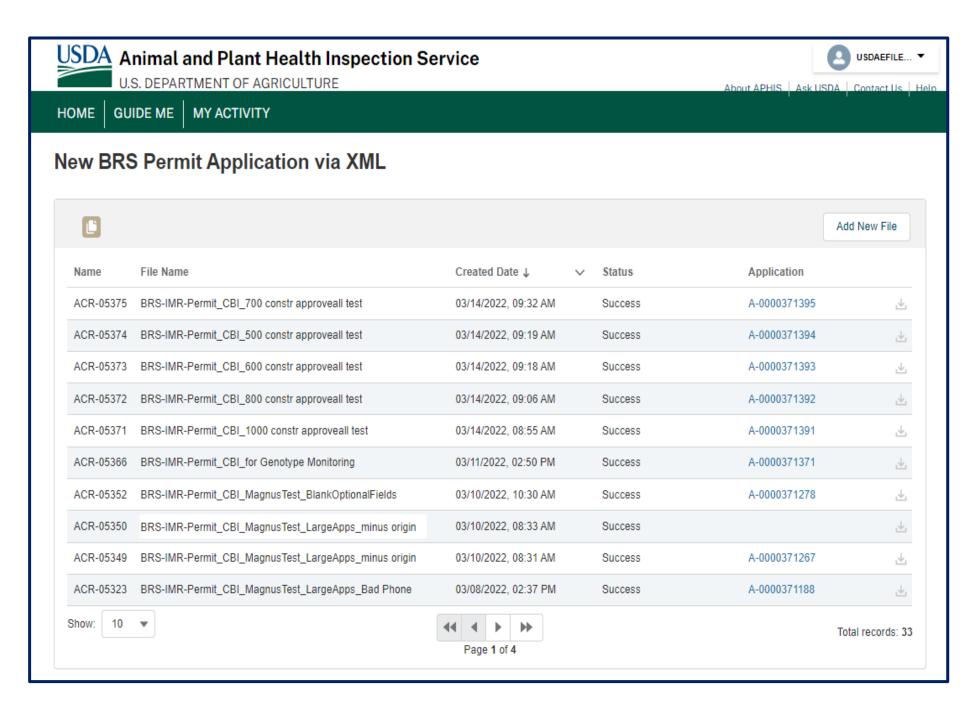
Enter a minimum of four GPS Coordinates.



Click **Save and Next** button to validate data entry.



Using the XML Uploader



Some applicants prefer to **upload XML files** to populate the data.

The remodeled XML upload table:

- Shows the latest upload on top.
- Refreshes every 30 seconds to show upload statuses.
- Allows up to 25 MB of data to be uploaded.

Use **Add New File** button to choose a file for upload.

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What is an SOP?

A collection of procedures that describe how an organism developed using genetic engineering (modified organism) will be:

- Secured during shipment between contained facilities and movement to/from release locations.
- Contained within facilities at origin and destination locations.
- Confined during release into the environment.
- Maintained and disposed of at all locations in a manner that prevents its unauthorized release, spread, dispersal and/or persistence in the environment.

Application Details Organisms Supplier/Developers Constructs Locations SOPs & Attachments Review & Submit

SOP Review Pathways

Submit SOP with permit application



Submit permit application at least:

- 45 days before importation or interstate movement is to begin; or
- 120 days before environmental release is to begin.

Application Details Organisms Supplier/Developers Constructs Locations SOPs & Attachments Review & Submit

SOP Review Pathways

Submit SOP before permit application (pre-review, this task is not a mandatory requirement).



Submit SOP for Pre-review:

- To <u>BRS.Permits.SOP@usda.gov.</u>
- At least 60 days before intended permit application submission.

Application Details

Organisms

Supplier/Developers

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SOPs & Attachments

Review & Submit

Formatting Suggestions for an SOP

- File type and naming convention
 - <Organization Name>_<Organism Common Name SOP>_<Movement Type>_<Date>.<docx or pdf>.
- High level document description
 - Organization name.
 - Applicable Movement type(s).
 - Applicable modified organism(s) (scientific and common names).
- Confidential Business Information
 - If SOP contains CBI, then CBI guidelines must be followed: (https://www.aphis.usda.gov/brs/pdf/CBI Submission Guidance.pdf)

Application Details

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Review & Submit

Data Needs for an SOP

<u>Importation or Interstate Movement</u>

- Secure Shipments of Modified Organisms between Contained Facilities
 - Description of material(s) used to support modified organism during shipping.
 - Description of packaging material(s).
- Containment of Modified Organisms within Facilities
 - Description of how modified organism will be stored and identified.
- Maintenance, Devitalization, and Disposition of Modified Organisms in Containment
 - Description of how supporting and packaging materials will be cleaned and disposed.
 - Description of maintenance and disposal procedures to prevent release, spread, dispersal and/or persistence in the environment.
 - Description of records to demonstrate compliance with SOP and regulations.

Application Details

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Review & Submit

Data Needs for an SOP

<u>Importation or Interstate Movement</u>

 Country and locality where organism was collected, developed, manufactured, reared, cultivated, and cultured (as applicable).

Application Details

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Review & Submit

Data Needs for an SOP

Environmental Release

- Secure Transport of Modified Organisms to and from Release Locations.
- Confinement of Modified Organisms to prevent Unauthorized Release
 - Description of confinement procedures to prevent release, spread, dispersal and/or persistence in the environment.
- Maintenance, Devitalization, and Disposition of Modified Organisms in Confinement
 - Identification of the Release Site and of the modified organisms.

Application Details

Organisms

Supplier/Developers

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Review & Submit

Data Needs for an SOP

Environmental Release

- Termination, Volunteer Monitoring, and Replanting of Environmental Release Sites
 - Termination of release.
 - Monitoring to prevent unauthorized release, spread, dispersal, and/or persistence after trial.
 - Replanting after Field Trial Termination and during Volunteer Monitoring.
- Country and locality where organism was collected, developed, manufactured, reared, cultivated, and cultured (as applicable).

Application Details

Organisms

Supplier/Developers

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SOPs & Attachments

Review & Submit

Resources

Documents

- Suggestions for SOPs Submitted for APHIS BRS Permits.
- SOP Templates (before end of FY2022).

Biotechnology Quality Management System (BQMS)

- BRS BQMS page.
- Program components will be updated before end of FY2022.

Application Details

Organisms

Supplier/Developers

Constructs

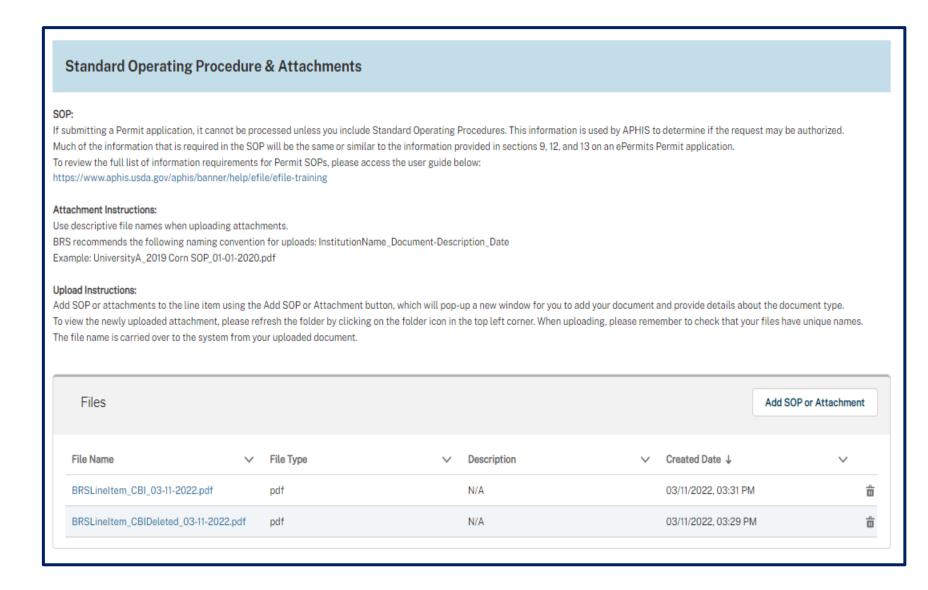
Locations

SOPs & Attachments

Review & Submit

Uploading SOPs

- Use the Add SOP or Attachment button to select a file.
- Select Attachment type and CBI Version attributes.
- Include equal number of CBI-Included and CBI-Deleted attachments.
- Use **Delete** button to remove incorrect attachments.



Application Details

Reviewing, Certifying, and Submitting an Application

Organisms

1 Complete Missing Data and Review Submission

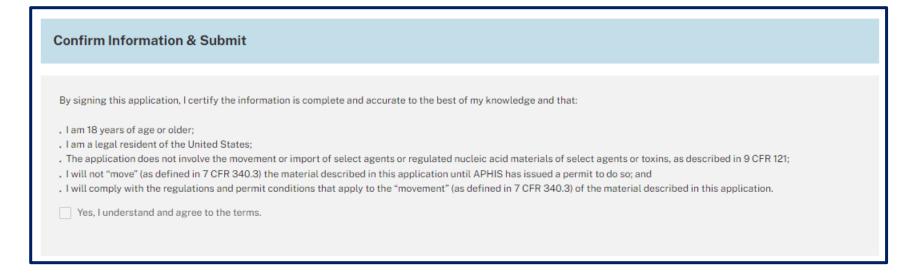


Supplier/Developers

Constructs

Locations

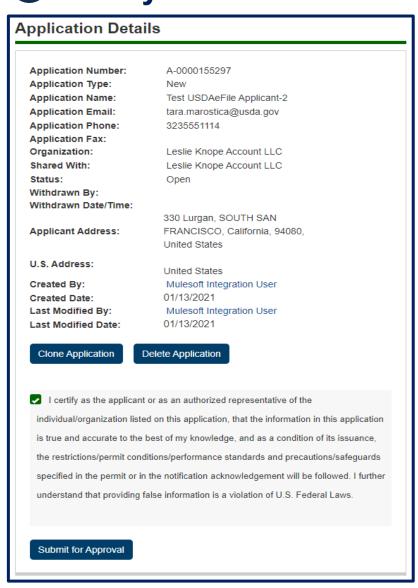
2 Agree to the **Terms**



3 Certify and Submit

SOPs & Attachments

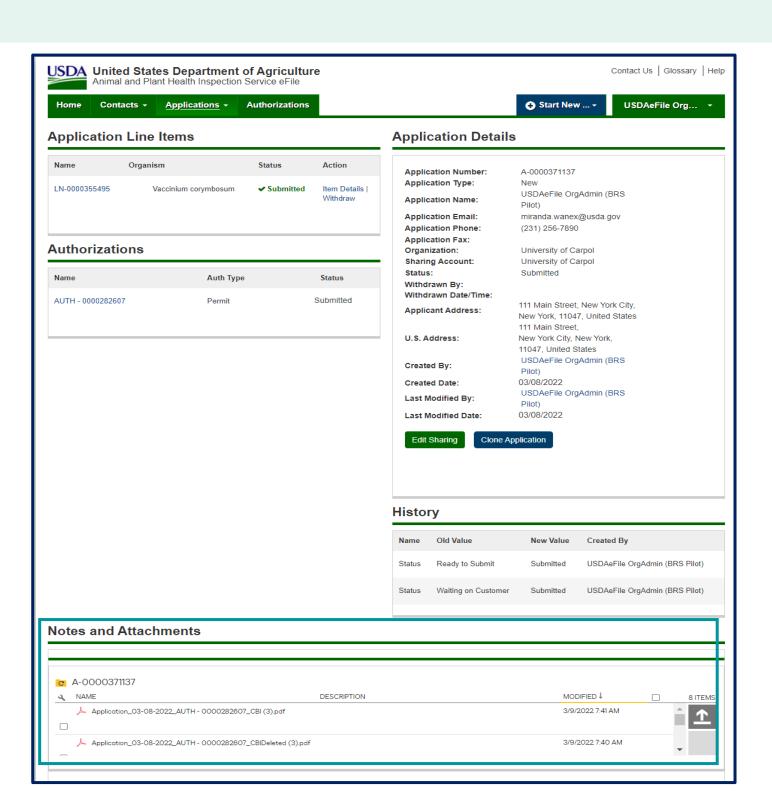
Review & Submit



Accessing Application PDFs

Application PDF Copies may be accessed via the **Notes and Attachments** section.

- Located at the bottom of the Application Details Page.
- Depending on the application's size, these may take time to appear.
- Refresh the folder using the Yellow Refresh button.



Post-Submission Activities

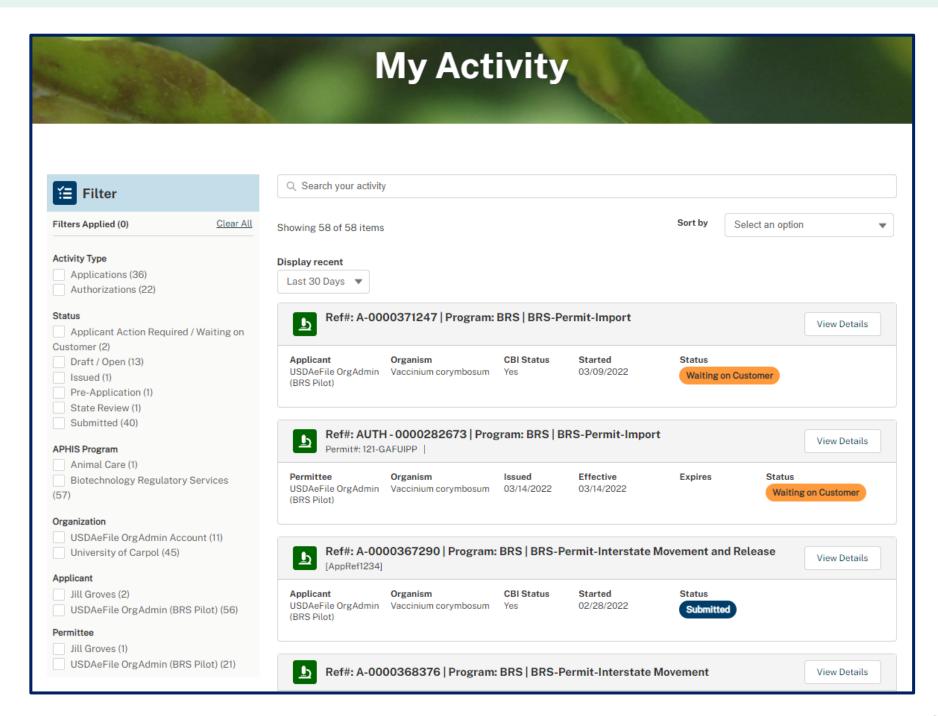
POST-SUBMISSION ACTIVITIES



Using the My Activity Page

APHIS eFile's **My Activity** page may be used to resume applications and access Submitted Authorizations.

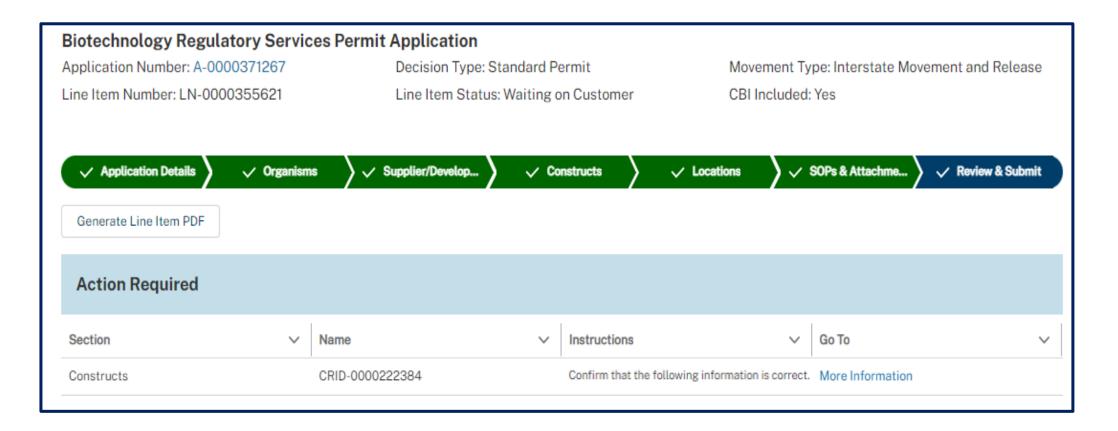
- Use Filters, Search bar, Sort and Display options to locate Applications and Authorizations.
- Home Tab buttons auto-filter this view.



Editing a Permit Application

Login to APHIS eFile and select the **hyperlink** from your APHIS email notification.

Review Action Required table on the Review and Submit section:



Update the Sections in Waiting on Customer status, Save, then Submit your revised responses.

Reviewing Permit Conditions

Login to APHIS eFile and select the hyperlink from your APHIS email notification

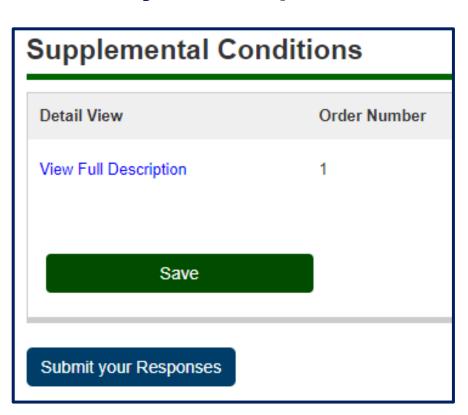
View Conditions to review each Condition Description.



Agree or Disagree and provide Comments (if necessary).



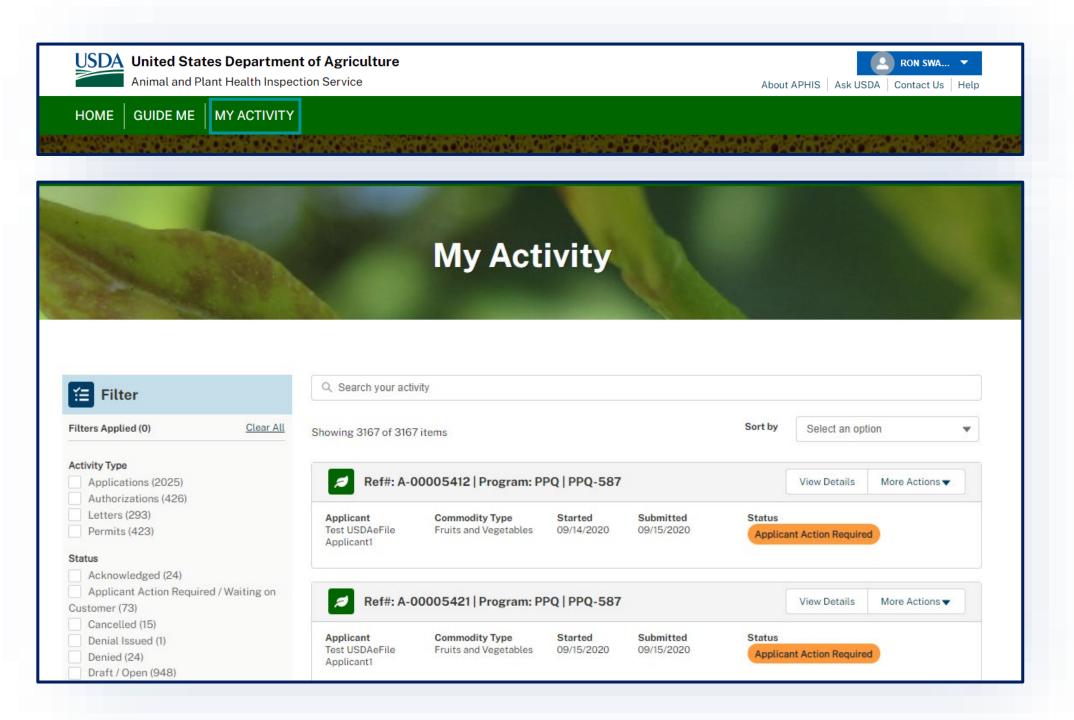
Save each section, then Submit your Responses.



Login to APHIS eFile and select My Activity tab.

Select **Authorizations** from the Activity Type.

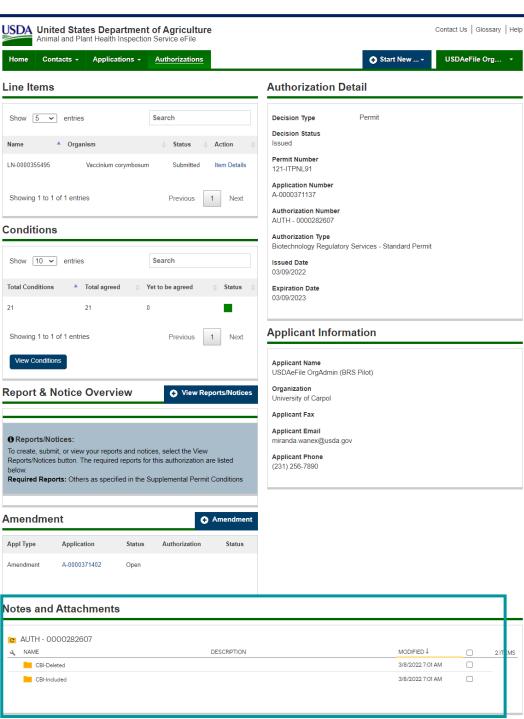
Select **Issued** from the Status filter.



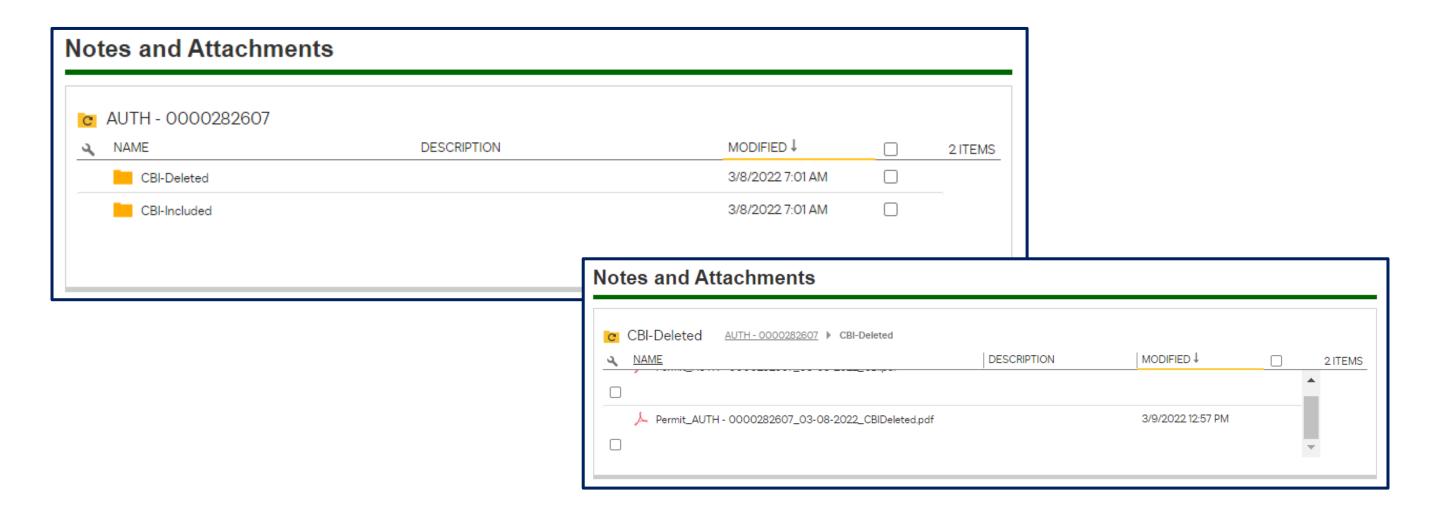
Select **View Details** on the Issued Authorization Activity card.



Scroll to the **Notes and Attachments** section at the bottom of the Authorization Detail Page.



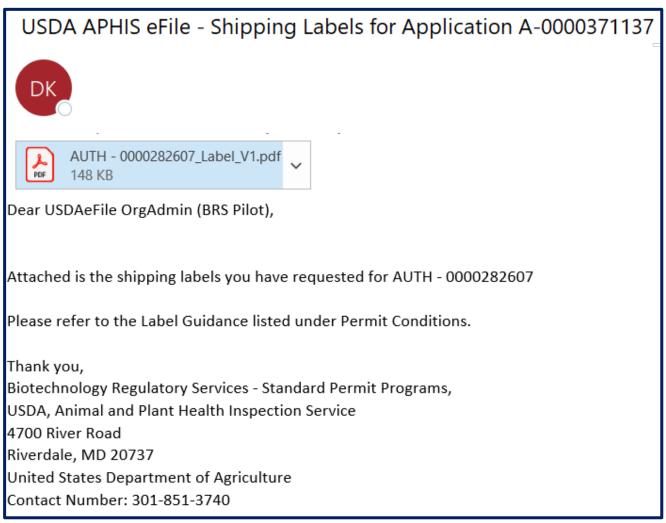
- If your permit contained CBI, there will be a CBI-Included and CBI-Deleted version in the respective folders.
- If your permit did not contain CBI, your permit may be accessed in the No-CBI folder.



Import labels may also be accessed via the Notes and Attachments Section of an issued authorization.



You may also access import labels from the attachment in your email from APHIS noting your labels are ready.



Request to Amend a Permit

1 Enter the Authorization Number in the Search Bar.



3 Add an Amendment.



Amendment: AUTH - 0000129375 (Issued)

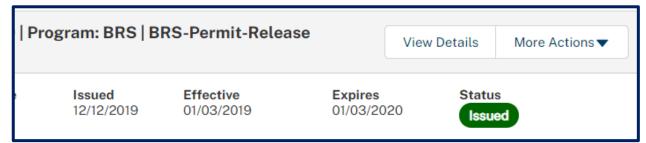
What do you want to do to this Authorization:

Amendment

Proceed With Application

Return to Authorization

2 Select View Details.



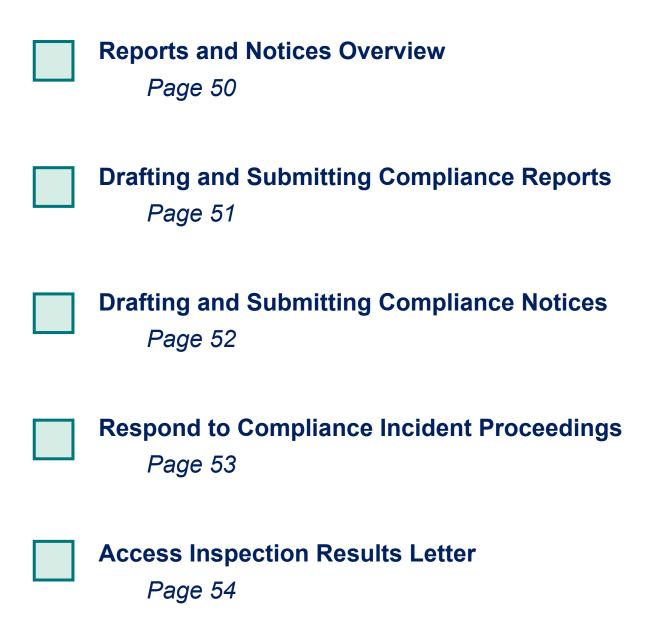
4 Add the **Amendment** Details.

Proposed Effective Date* May 5, 2019	Proposed End Date* May 3, 2020
Purpose of Permit* Phytoremediation	Applicant Reference Number
Additional Information	Amendment Description*

NOTE: You will need to **Certify** and **Submit** the application again for the **Amendment** process.

Managing Compliance

MANAGING COMPLIANCE



Reports and Notices Overview

REPORT/NOTICE	WHEN IS IT NEEDED
Pre-Planting/Release Notice	Create a Pre-Planting Notice prior to planting your APHIS approved organism.
Planting/Environmental Release Report*	Create a Planting Report to notify APHIS that you have planted your approved organism.
Pre-Flowering Notice	Create a Pre-Flowering Notice before your organism flowers.
Pre-Harvest/Pre-Destruct Notice	Create a Pre-Harvest/Pre-Destruct notice before you harvest your organism.
Field Test Report*	Create a Field Test Report to notify APHIS of the location details for your Field Test.
Volunteer Monitoring Report*	Create a Volunteer Monitoring Report to notify APHIS of the location you are monitoring.
Cleaning (Return to General Use) Notice	Create a Cleaning (Return to General Use) Notice to notify APHIS of the location, equipment and date of the cleaning.

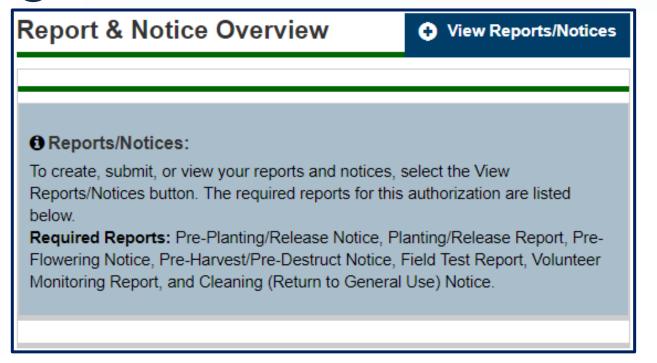
*Indicates a report that is typically required for issued permits that include release locations.

Drafting and Submitting Compliance Reports

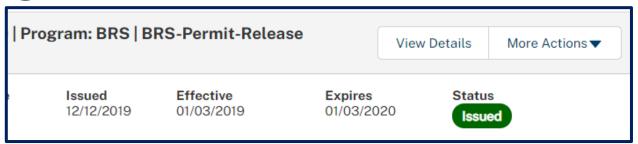
1 Enter the Authorization Number in the Search Bar.



3 Select View/Report/Notices.



2 Select View Details.



4 Select Add to create the applicable Report.



NOTE: Provide Location Details including GPS coordinates, Constructs, and Supporting Documents to certify and submit the report.

Drafting and Submitting Compliance Notices

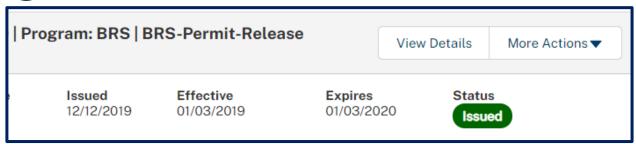
1 Enter the Authorization Number in the Search Bar.



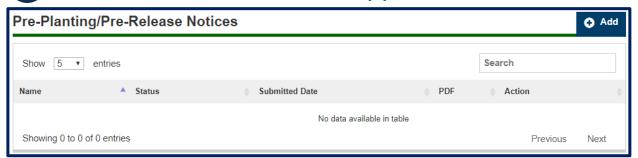
3 Select View/Report/Notices.



2 Select View Details.



4 Select Add to create the applicable Notice.



NOTE: Provide the Location Details, including Site information, and Supporting Documents to certify and submit your notice.

Respond to Compliance Incident Proceedings

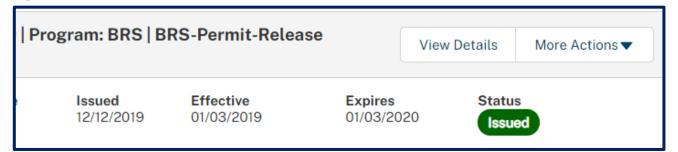
1 Enter the Authorization Number in the Search Bar.



3 Select the CI-00XXXX folder.



2 Select View Details.



4 Select the Responsible Party Documents folder.



5 Select the **Upload Arrow** to add files to the Authorization.



NOTE: You will receive a message notifying you that your files have been successfully uploaded.

Access Inspection Results Letter

1 Enter the Authorization Number in the Search Bar.

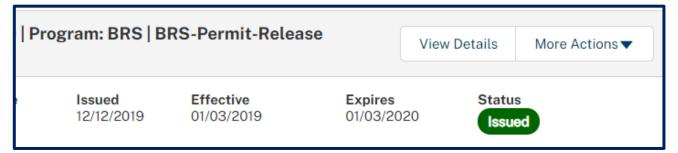


3 Select the IN-00000XXXXX folder.

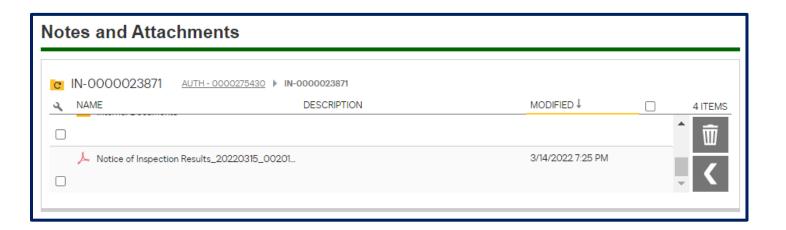


4 Select the Notice of Inspection Results document hyperlink and preview/download as needed.

2 Select View Details.



NOTE: You will receive a message notifying you an Inspection results letter is available.





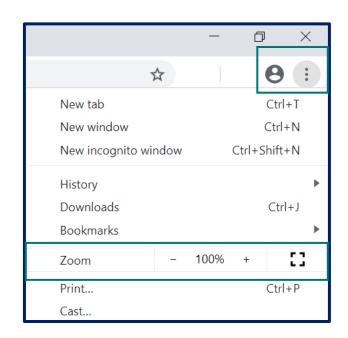
Thank you!

Questions?

APPENDIX

System Setup

- Compatible browser For the best user experience, please use
 Google Chrome. Other available browsers include Firefox, Safari, and
 Edge. APHIS eFile is NOT supported by Internet Explorer.
- Emails Add the APHIS eFile email at aphis.efile@usda.gov and support@salesforce.com to your address book so that any automatic emails are not sent to junk.
- **Zoom** –100%



Contact

If you require technical assistance, please contact:

Help Desk

help@usda.gov

If you require assistance with your applications, please contact:

BRS

BRS.eFile@usda.gov