



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

APHIS Biotechnology Regulatory Services (BRS) User Guide for the BRS Permitting Assistant

For Developers of Organisms That May Be Regulated Under 7 CFR Part 340

**Version 1.0
August 2021**

WELCOME!

USDA APHIS Biotechnology Regulatory Services has a new tool that helps developers navigate BRS regulatory requirements for importation, interstate movement, and environmental release of organisms that are developed using genetic engineering.

This user guide will take you through the process of using the Biotechnology Regulatory Services Permitting Assistant (BRSPA).

BRS PERMITTING ASSISTANT USER GUIDE



Step 1: Access the BRS Permitting Assistant
Page 4



Step 2: Complete the BRS Permitting Assistant
Page 5-7



Step 3: Review and Confirm Outcomes
Page 8

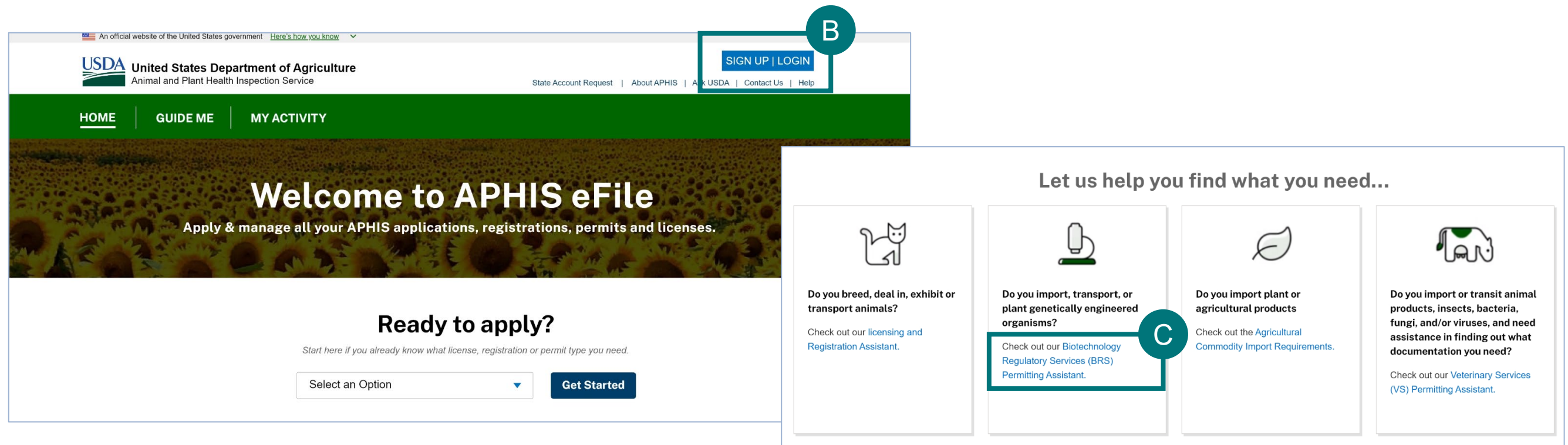
Step 1: Access the BRS Permitting Assistant

A Navigate to <https://efile.aphis.usda.gov/s/> in **Google Chrome**. 

B Although it is not required, you may choose to Login or Register at this time.

- Guests may use the BRS Permitting Assistant to explore regulatory requirements for an organism.
- Please note that you will need to login to begin an application.
- Instructions for registration can be found here: <https://www.aphis.usda.gov/help/eFile/efile-first-time-user-setup.pdf>

C Scroll to the Find What You Need section and select the **Biotechnology Regulatory Services (BRS) Permitting Assistant** link.



The screenshot shows the APHIS eFile website interface. At the top, there is a header with the USDA logo and navigation links. A callout 'B' points to a 'SIGN UP | LOGIN' button. Below the header is a green navigation bar with 'HOME', 'GUIDE ME', and 'MY ACTIVITY' options. The main content area features a large banner with the text 'Welcome to APHIS eFile' and 'Apply & manage all your APHIS applications, registrations, permits and licenses.' Below this is a section titled 'Ready to apply?' with a dropdown menu labeled 'Select an Option' and a 'Get Started' button. To the right, there is a section titled 'Let us help you find what you need...' with four cards. Callout 'C' points to the 'Biotechnology Regulatory Services (BRS) Permitting Assistant' link in the second card.

Step 2: Complete the BRS Permitting Assistant

Complete the **Permitting Assistant** to begin the application process.

A Enter the **organism details** into the appropriate search fields.

Note: **Under What are you applying for:**

- Select Help Me Decide to explore your organism's regulatory requirements.
- Select Permit if you know you want to apply for a permit.

B Select the **Search button**.

The screenshot shows the 'Step 1: Enter Your Organism Details & Search' interface. It features several input fields: 'Organism' (with 'Drosophila melanogaster' and a 'See List of Organisms' link), 'Intended Use' (set to 'Traditional'), 'What are you applying for' (set to 'Help Me Decide'), and 'Movement Type' (set to 'Import'). Below these are 'Organism Category' (Arthropod), 'Select Agent' (No), and 'Plant Pest' (Yes). A 'Search' button is at the bottom right. Callouts include: 'A' pointing to the search fields, 'B' pointing to the Search button, and three informational boxes: one about 'i' icons for tool tips, one about 'See List' hyperlinks, and one about contacting BRS.eFile@usda.gov if the organism is not found.

Step 2: Complete the BRS Permitting Assistant

SEARCH PAGE

- A Select the appropriate response for each **Attribute Filter** to refine your organism search results, if applicable.

Note: For best results **complete ALL attribute filters** in top to bottom order until there is **only ONE result** remaining in the Outcome area.

Some of the filters are selection-order dependent, meaning that your first selection may limit which filters you select next.

Step 2: Select Attributes

2 filters applied [Clear All](#)

A

Use the “X” to remove an individual filter and “Clear All” to remove all selected filters.

Is the organism being moved as a secure shipment? | Yes

Is the organism's introduced genetic material designed to propagate through a population by biasing the inheritance rate? | Yes

Is the organism being moved as a secure shipment?

Yes (1)
 No (0)
 I Don't Know (0)

Is the organism's introduced genetic material designed to propagate through a population by biasing the inheritance rate?

Yes (1)
 No (0)
 I Don't Know (0)

Step 2: Complete the BRS Permitting Assistant

SEARCH PAGE

- A Complete the attribute filters until **one result** remains. **Review the information** on the Outcome Card.
- B **Select Add Outcome** to add the result as a single outcome. You may revisit Step 1 of the Permitting Assistant to perform another search and add more than one outcome before proceeding.
- C Once you have selected and added your outcome(s), select **Next Step** to **Review and Confirm Outcomes**.

Step 3: Select Your Outcome

Showing 1 of 1 Outcomes

Show 3 results per page | Sort by: Outcome

A

B

Drosophila melanogaster
Arthropod | PR-099631

Your Organism is Not Exempt
You may apply for a permit at this time. Please **Add Outcome** to proceed with a permit application.

Permit Required: Yes

Eligible for Confirmation Request: No

+ Add Outcome

Step 3: Select Your Outcome

Showing 1 of 1 Outcomes

Show 3 results per page | Sort by: Outcome

C

Drosophila melanogaster
Arthropod | PR-099631

Your Organism is Not Exempt
You may apply for a permit at this time. Please **Add Outcome** to proceed with a permit application.

Permit Required: Yes

Eligible for Confirmation Request: No

X Remove Outcome

To remove an outcome, select the Remove Outcome button.

Step 3: Review and Confirm Outcomes


Review and Confirm your Outcomes on the Request Summary page.

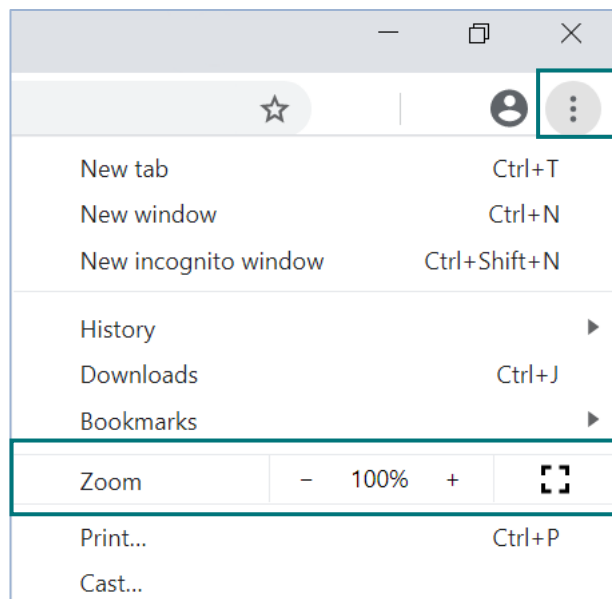
- A** To conduct another search and add additional outcomes, select **Go Back and Add More Outcomes**.
- B** The list of the outcomes you added will display within each of the sections that apply.
- C** Use the Trash Can icon to delete items from your summary page.
- D** If you would like to receive a link to your Request Summary, enter your email then select **Send**.
- E** If your request resulted in any permit applications, select the **Proceed to Application** to complete the permit application.

The screenshot shows a web interface for reviewing outcomes. At the top, there are tabs for 'Permit Required (1)', 'Confirmation Request', 'No Permit Required', 'Contact BRS', and 'Not Regulated'. The main section is titled '1. BRS Application' and shows a list of outcomes. The first outcome is 'Drosophila melanogaster' (Arthropod | PR-099631). It is marked as 'Available for you to apply for Import' and 'Permit Required' (Yes). A note states: 'Your Organism is Not Exempt You may apply for a permit at this time. Please Add Outcome to proceed with a permit application.' A trash can icon is visible next to the outcome. On the right, there is a 'Summary of Requests' section showing counts for various request types. At the bottom right, there is a form to 'Email a Copy of the Overall Summary' with an email input field and a 'Send' button. Callouts A-E highlight specific UI elements: A (Go Back and Add More Outcomes button), B (BRS Application section), C (Trash Can icon), D (Email form), and E (Proceed to Applications button).

APPENDIX

System Setup

- **Browser** – For the best user experience, please use Google Chrome 
- **Emails** – Add no-reply.aphis.efile@usda.gov to your address book so that any Request Summaries sent from the BRSPA do not go to your junk box
- **Zoom** – 100%



Contact

If you require assistance with your **applications or BRS' Permitting Assistant**, please contact:

Biotechnology Regulatory Services

(301) 851-3300

BRS.eFile@usda.gov

If you require **technical assistance**, please contact:

USDA Help Desk

help@usda.gov

For access to the most recent version of this user guide, and for other APHIS eFile support materials, visit <https://www.aphis.usda.gov/aphis/banner/help/efile/efile-training>