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Select Agent Confirmation

Is this a Select Agent Application?

The Agricultural Bioterrorism Protection Act of 2002, as part of the Public Health Security and Bioterrorism Preparedness Response Act of 2002, requires entities that possess, use, or transfer agents or toxins deemed a severe threat to animal or plant health or products must notify and register with APHIS. This law is designed to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies that could threaten public health and safety or American agriculture.

A list of select agents and toxins which the Department of Health and Human Services (HHS) and USDA consider select agents can be viewed at:

http://www.cdc.gov/od/sap/docs/salist.pdf

A list of select agents and toxins which the USDA has considered select agents can be viewed at:

http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_toxinlist.shtml

Additional information regarding the USDA Select Agent Program can be found at:

http://www.aphis.usda.gov/programs/ag_selectagent/

- No. This is NOT an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents.
- Yes. This is an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents.

Continue

CREAPP-0038

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Create/Renew/Amend Application - Choose Application Type for BRS

You have selected **Biotechnology Regulatory Services (BRS)** as the program office. If this is correct, please select the correct application type for the permit you are applying for, then select **Continue**. If you have selected an incorrect program office you may go back by using the browser "Back" button.

BRS Notification of Introduction of Genetically Engineered Plants

A Notification is an alternative streamlined procedure to permitting for the introduction (interstate movement, importation, environmental release) of certain genetically engineered plants that are regulated articles. To make use of the notification alternative, you must introduce a plant species that meets all of the six eligibility criteria, and you must introduce it in accordance with specified performance standards. In addition to the comments below, please refer to the regulations published on March 31, 1993 (see Section VI) and/or contact the Permit Staff, Biotechnology Regulatory Services to determine whether a regulated article is eligible for notification.

O BRS Permit for the Introduction of Genetically Engineered Organisms

Any company, institution, or public sector scientist that wants to import, move or release a genetically modified organisms expressing a plant pest structural sequence, or whose host is a plant pest, or which does not qualify for a Notification process, such as microorganisms and Plant-made Pharmaceutical and Industrial Products require a full APHIS permit. More detailed information about these movements and release are required during the application process, and APHIS evaluations are lengthier than those required under Notifications.

If you are uncertain as to whether the organism qualifies for a Notification or Permit see the links below:

For general information regarding Notifications:

http://www.aphis.usda.gov/biotechnology/notifications.shtml

For general information regarding Permits:

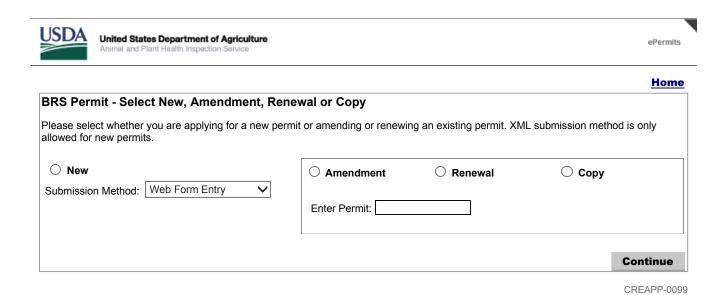
http://www.aphis.usda.gov/biotechnology/permits.shtml

If you are uncertain as to whether the organism is a plant pest or a regulated article, please contact: biotechquery@aphis.usda.gov

or call: 301-851-3935.

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BRS Permit - Courtesy P	Permit Verification
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Courtesy permit for the introduction (importation, interstate movement, release into the environment, or interstate movement/release into the environment) of genetically engineered organisms are not subject to regulation under Part 340 (7 CFR 340).

Are you applying for a courtesy permit?

- Yes. I am applying for a courtesy permit.
- O No. I am applying for a standard permit.

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BRS Permit Introduction Type

In ePermits, you may select from four types of introductions: importation, interstate movement, interstate movement and release, and release. An importation may not be combined with an interstate movement or environmental release. Use the following descriptions to help you determine the type of introduction for this permit.

Select the type of Introduction for this permit.

Note: Changing the Introduction data will result in the loss of all location data (name, address, contact, etc.) previously entered.

Selection	Introduction Type	Description	Number of Locations
0	Importation	Importation into the United States from another country. Importations may not be combined with another type of introduction.	1 point of origin, 1 destination
0	Interstate Movement	Movement within the United States.	1 or more points of origin, 1 or more destinations, and 1 or more release locations.
0	Interstate Movement and Release	Movement within the United States and release of the article into the environment.	1 or more points of origin, 1 or more destinations, and 1 or more release locations.
0	Release	Release of the article into the environment. An environmental release may be combined with an interstate movement.	1 or more release locations.

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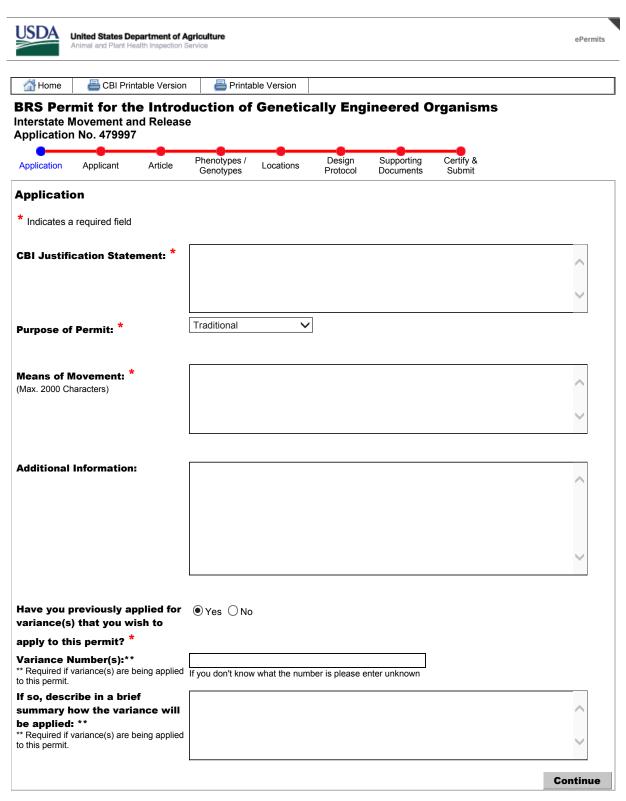
BRS Permit - CBI Verification
Confidential Business Information (CBI) is financial or commercial information the applicant does not want disclosed for competitive reasons.
For more information on CBI, please view the "General Document Preparation Guidelines for submission to BRS" section entitled "Confidential Business Information (CBI) in Submissions to BRS" at http://www.aphis.usda.gov/brs/pdf/Doc_Prep_Guidance.pdf
Does this application contain CBI? ○ Yes ○ No
Tips for Entering CBI Data While completing your permit application, please remember to surround information which you want to protect as CBI with square brackets ([]). For example, a construct component containing information to protect would appear as follows:
terminator: nopaline [synthase (nos) 3']
The CBI-deleted version of this construct component would automatically be generated by ePermits using the square brackets to display it:
terminator: nopaline []
If you try to use another separator for CBI besides square brackets ([]), your CBI will not be protected.
Continue

CREAPP-0065

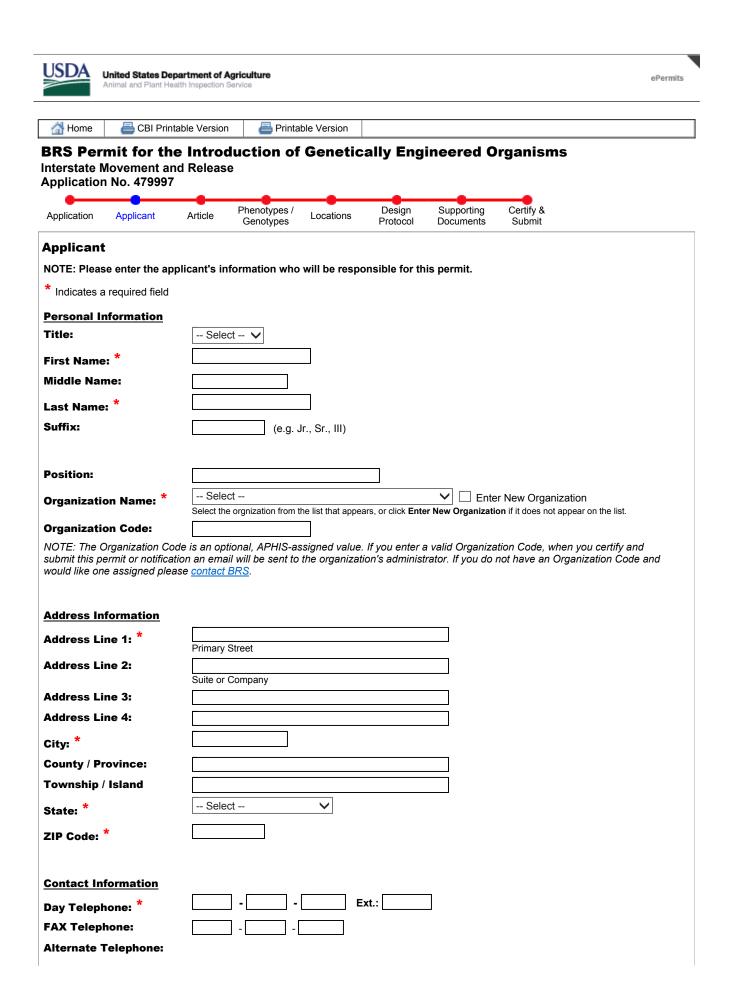


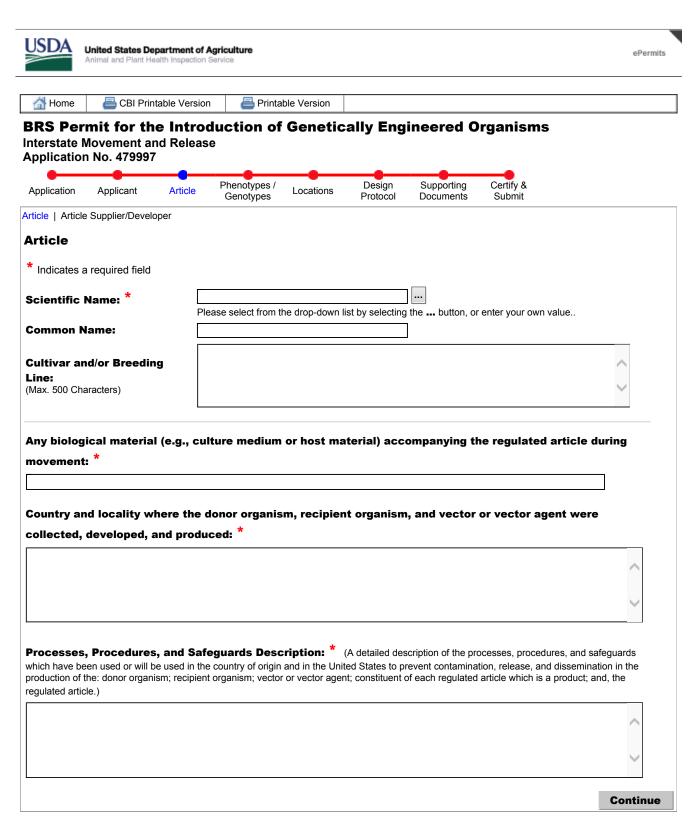
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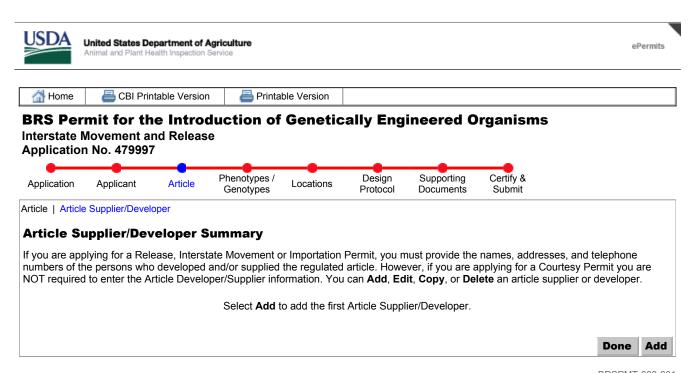


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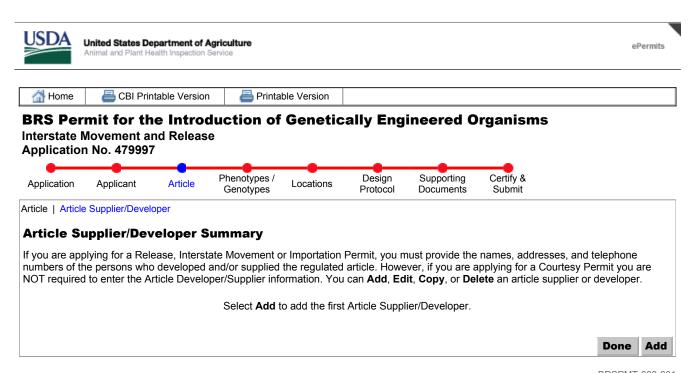


BRSPMT-003-200



BRSPMT-003-201

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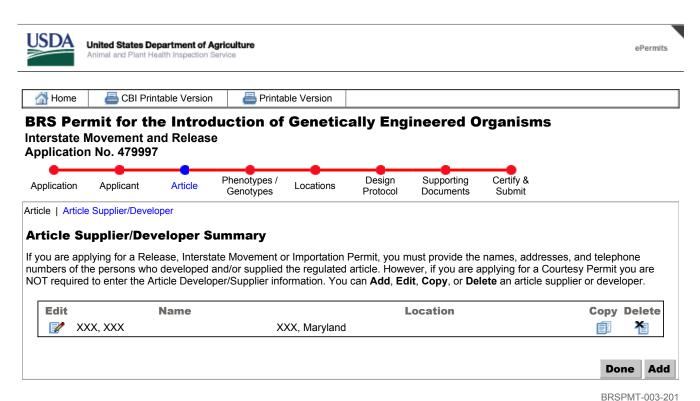
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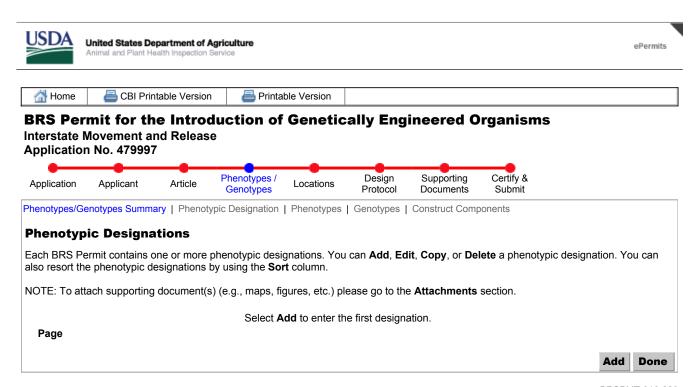
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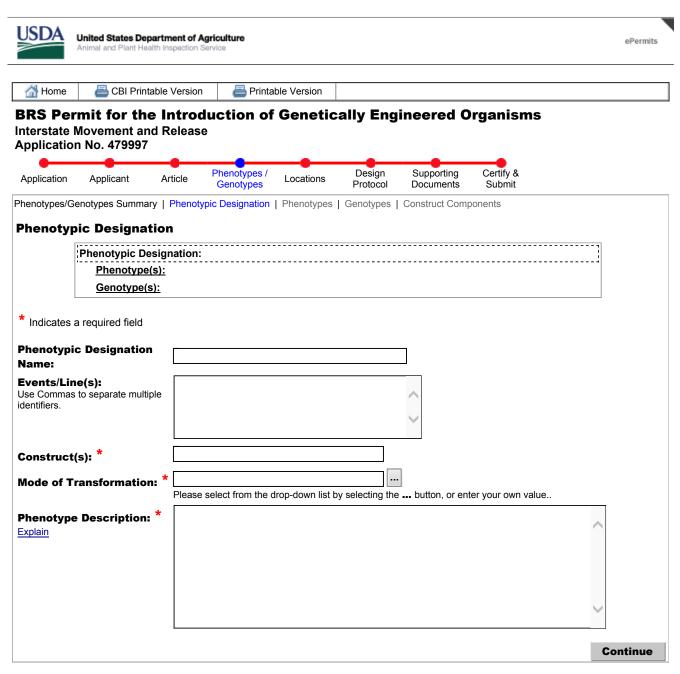


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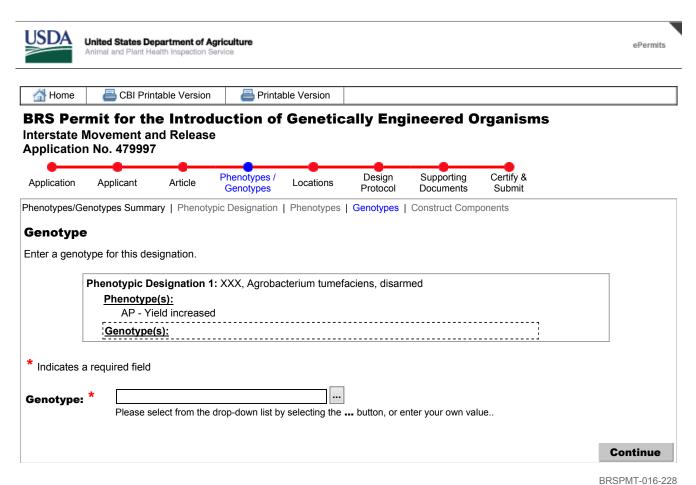
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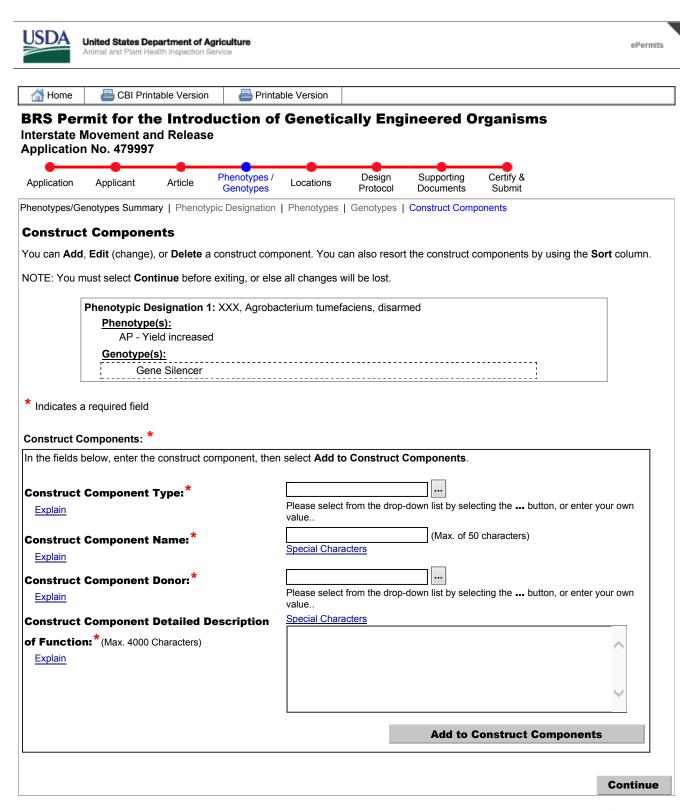
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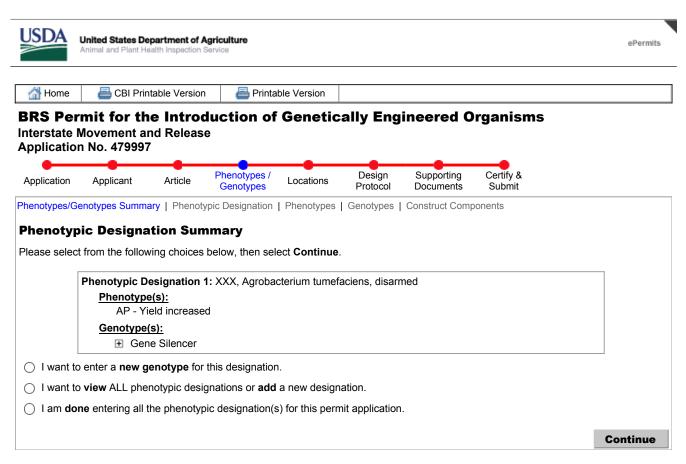
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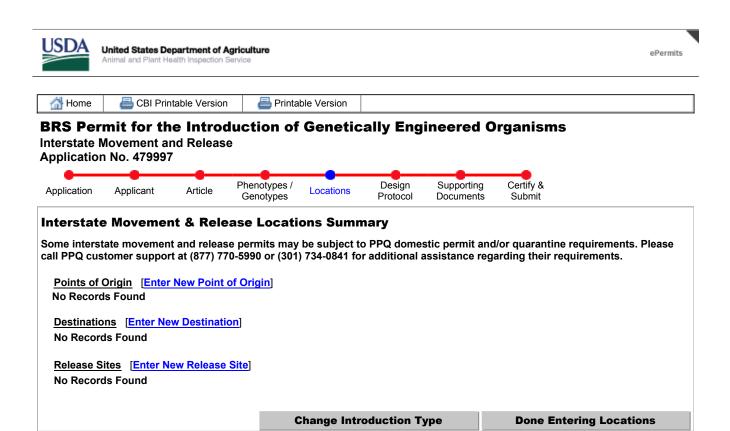
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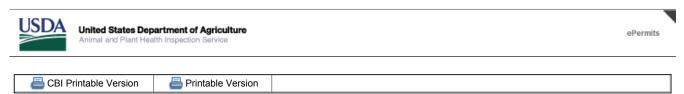


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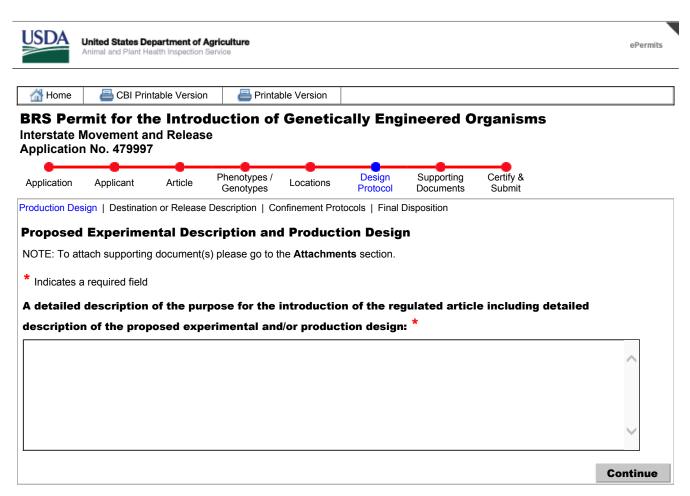


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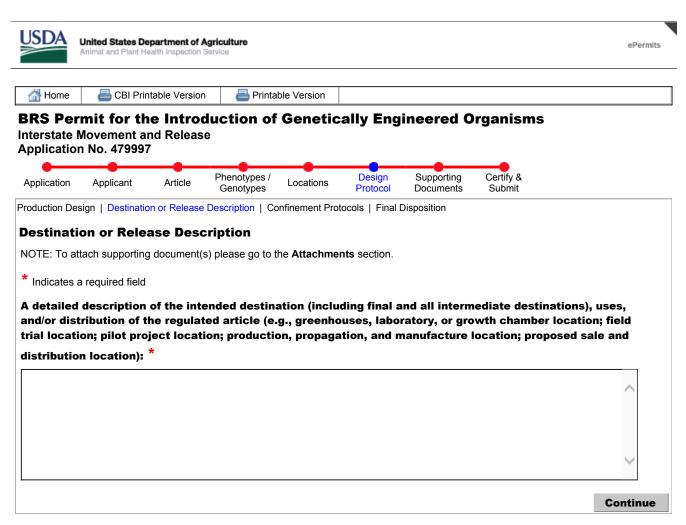


BRS Permit for the Introduction of Genetically Engineered Organisms

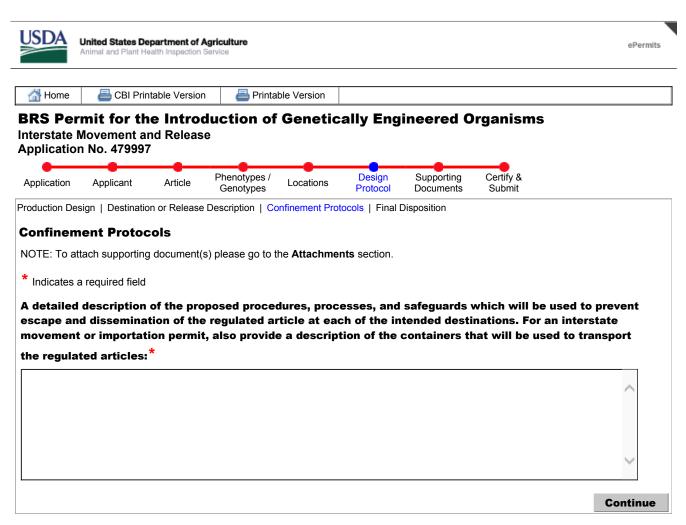
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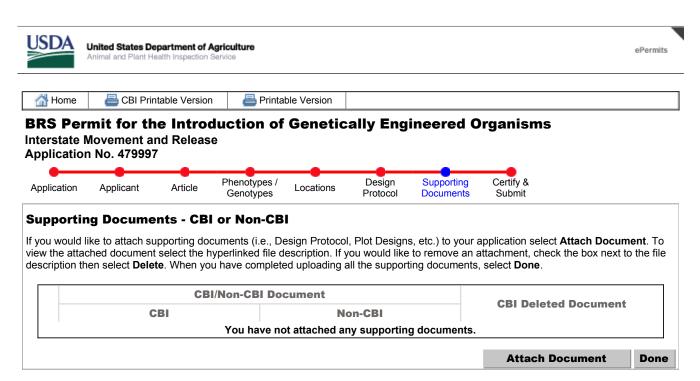
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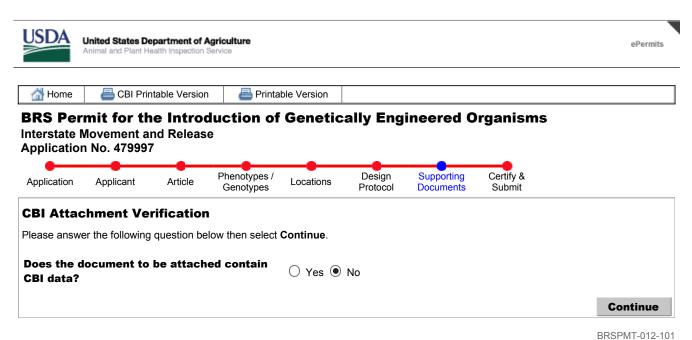
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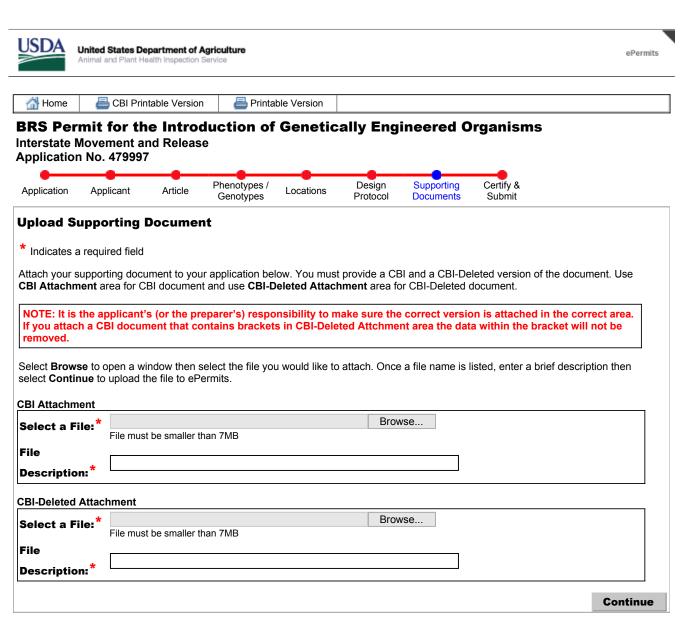
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lease/monitoring area for sites versites to the second or endangered species ection 1531, Endangered Species	r the area requiring monitoring (or the area within the boundaries of the possible where the release has yet to be determined) within designated critical habitat for a listed or within habitat proposed for designation under the Endangered Species Act (16 U.S. s Act (ESA) of 1973, as amended)? (For information see: RS critical hab guide permit.pdf) Yes No
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