

CDX Pesticide Submission Portal (PSP)

Biotechnology PIP Exemption Request Application

CDX 00048-OCSP-000 PSP

May 2023



Pesticide Submission Portal



Portal Pesticide Submission Portal Help ▾ Jane Doe, Test Org 10 (Primary Submitter)

Pesticide Submission Portal

Welcome to the Office of Pesticide Programs Pesticide Submission Portal. Use the step chart below to create new submissions, respond to data call ins, form consortiums, or utilize pre-submission tools (e.g. form builders and root MRID generation). The View Recent Packages table allows quick access to your most recent submissions.

Submissions and Tools Collapse

- Registration & Exemptions ▶
 - Registration Review ▶
 - Reregistration ▶
 - Foreign Purchaser Acknowledgement Statements ▶
 - Pre-Submission Tools ▶
- Submit regulatory applications
 - General Registration ▶
 - Distributor Product ▶
 - Pre-Application ▶
 - Biotech PIP Exemption Requests ▶**
 - Upload e-Submission Packages ▶
 - Upload eDossier Builder Packages ▶

Request an exemption for PIP(s) derived through genetic engineering (biotechnology).

[Create Application](#)

View Recent Packages Collapse

View All Packages.

Package ID	Package Name	Modification Date	Status
6668	BPER-4528-Thu Oct 20 01:24:15 UTC 2022	10/20/2022	Awaiting User Completion

Showing 1 to 1 of 1 entries

PSP v.2.8.3 [Release Notes](#) CDX Links ▾

OMB Control No. 2070-0214
Expiration Date XX/XXX

PRA Burden Statement: This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. under multiple OMB Control Numbers. Responses to this collection of information are mandatory for certain persons, as specified at 40 CFR 174. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be per response are 0.25 hours to 1.25 hours (2070-0142). Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

Create Passphrase



Create Passphrase

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Please create a passphrase that is at least 8 characters in length and does not exceed 20 characters. To protect your account, your passphrase should contain a combination of letters and numbers. The passphrase you create may include spaces but should not contain special characters (for example, +, ?, and *). Passphrases are also case sensitive. You can associate the same passphrase with multiple submissions.

Your passphrase will be used as an encryption key to protect the contents of your data. Your data cannot be accessed without this passphrase. As the Primary Submitter, you are responsible for remembering your passphrase and distributing it to only authorized agent(s).

You may also create an optional 'Passphrase Hint' that will be associated with this submission. When trying to access this submission in the future, this 'Passphrase Hint' may aid in remembering the passphrase. Please **do not** enter the actual passphrase as the 'Passphrase Hint.'

Or, you can click "Cancel" to return to Home page.

New Passphrase

[Create Passphrase Hint \(Optional\)](#)

Confirm Passphrase

Cancel

Next



Do Not Forget Your Passphrase!

For security reasons, the system administrator does not have access to your passphrase and cannot retrieve it or reset it to a new one. If you have forgotten your passphrase, you must create a new submission.

Package Information



Biotech PIP Exemption Request ▶ BPER-4528-Thu Oct 20 01:24:15 UTC 2022

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Step 1	Step 2	Step 3	Step 4	Step 5
Package Information	Exemption Information	CBI Substantiation	Submitter Information	Certification

Package & Fees

* Package Name

BPER-4528-Thu Oct 20 01:24:15 UTC 2022

* PRIA Fees Payment Amount

* PRIA Fees Payment Tracking Number

Fee Waiver Request

- Please select a waiver percent - ▾

Cover Letter

Drop a file to attach, or [browse](#).

Please do not include any Confidential Business Information (CBI) in the Cover Letter.

Description

Primary Contact

[Copy from CDX](#)

* First Name

* Last Name

* Email

* Phone Number

Next

Exemption Information



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Step 1 Step 2 Step 3 Step 4 Step 5

Package Information Exemption Information CBI Substantiation Submitter Information Certification

Exemption Information

PreApp-BPER-000001

* Request Application Name
PreApp-BPER-000001

* Trait Type
 CBI

* Genus and Species of Recipient Plant
 Other... CBI

* Entrez Gene ID of the Unmodified Gene
 CBI

* PIP Exemption Type
174.27 - Loss-of-function PIP

* Request Type
 EPA Confirmation Self-Determination Both

* Upload Supporting Documentation(s) CBI
Drop a file to attach, or [browse](#).
Documentation must contain information specified in 40 CFR 174.95(a)-(d) for plant-incorporated protectants created through genetic engineering from a sexually compatible plant, and 40 CFR 174.96(a) and (b) for loss-of-function PIPs.

MRID (if applicable)

#	File Name	CBI	Delete
1	0 test1.pdf	Y	<input type="button" value="Delete"/>

PreApp-BPER-000002

[+Add Another](#)

CBI Substantiation (1 of 2)



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Step 1	Step 2	Step 3	Step 4	Step 5
Package Information	Exemption Information	CBI Substantiation	Submitter Information	Certification

CBI Substantiation

Status	Request Application Name	CBI Claim	Edit
✓	PreApp-BPER-000001	0 test1.pdf	
!	PreApp-BPER-000001	Genus and Species of Recipient Plant	
!	PreApp-BPER-000001	Entrez Gene ID of the Unmodified Gene	
!	PreApp-BPER-000002	Genus and Species of Recipient Plant	
!	PreApp-BPER-000002	Entrez Gene ID of the Unmodified Gene	

[Edit CBI Substantiation](#)

[Previous](#) [Next](#)

CBI Substantiation (2 of 2)



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[Edit CBI Substantiation](#)

* Request Application Name: PreApp-BPER-000001

* CBI Claim: Genus and Species of Recipient Plant

* (i) The portions of the information which are alleged to be entitled to confidential treatment.

* (ii) The period of time for which confidential treatment is desired by the business (e.g., until a certain date, until the occurrence of a specified event, or permanently).

* Start Date:

* End Date: [Other...](#)

* (iii) The purpose for which the information was furnished to EPA and the approximate date of submission, if known.

* Submission Date (Approx.):

* (iv) Whether a business confidentiality claim accompanied the information when it was received by EPA: Yes No

* (v) Measures taken by the business to guard against undesired disclosure of the information to others.

* (vi) The extent to which the information has been disclosed to others, and the precautions taken in connection therewith;

* (vii) Pertinent confidentiality determinations, if any, by EPA or other Federal agencies, and a copy of any such determination, or reference to it, if available;

* (viii) Whether the business asserts that disclosure of the information would be likely to result in substantial harmful effects on the business' competitive position, and if so, what those harmful effects would be, why they should be viewed as substantial, and an explanation of the causal relationship between disclosure and such harmful effects.

* (ix) Whether the business asserts that the information is voluntarily submitted information as defined in § 2.201(i), and if so, whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.

Submitter Information



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Step 1

Step 2

Step 3

Step 4

Step 5

Package Information

Exemption Information

CBI Substantiation

Submitter Information

Certification

Submitter Information

i The information below has been pre-populated from CDX registration. If the information listed is incorrect please make the appropriate edits to your user information in CDX registration.

* First Name:

Jane

* Last Name:

Doe

* Phone Number:

* Email Address:

* Organization Name:

CDX Testing Company

* Company Number:

98765

* Address 1:

123 Test ST

Address 2:

* City:

Tulsa

* State:

OK

* Country:

US

* ZIP Code:

74116

Previous

Next

Certification



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Step 1

Step 2

Step 3

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Step 5

Package Information

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Certification

Certification

I, **Jane Doe**, as the duly authorized agent of **CDX Testing Company**, am submitting this Plant-Incorporated Protectant Exemption Eligibility Determination consistent with the provisions of 40 CFR part 174. I hereby certify that the plant-incorporated protectant(s) known as **PIP Name A**, **PIP Name B** is/are eligible under 40 CFR § 174.21 to be exempt from the requirements of FIFRA, except as provided under 40 CFR §§ 174.71 and 174.73.

I understand that it is a violation of 18 U.S.C. § 1001 to willfully make any false statement to the EPA. I further understand that if this self-determination is not consistent with the provisions of 40 CFR part 174, this plant-incorporated protectant product may not be exempt from the requirements of FIFRA, and I and/or **CDX Testing Company** may be subject to enforcement and penalties under FIFRA sections 12, 13, and 14, 7 U.S.C. §§ 136j, 136k, and 136l. Moreover, I also understand that if this determination is not consistent with 40 CFR part 174, the residues of this plant-incorporated protectant may not be exempt from the requirement of a tolerance under the FFDCa, and that I and/or **CDX Testing Company**, as well as foods containing such residues, may be subject to enforcement and penalties under Chapter III of the FFDCa, 21 U.S.C. 331 et seq.

Moreover, I also understand that any information not claimed as Confidential Business Information pursuant to 40 CFR 174.9 constitutes a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of FIFRA, with no further notice to the submitter.

This confirmation is required to proceed with the submission process.

I certify to the above statements.

Certification is required.

Previous

Start Submission Process

Submission Process – Validation & PDF Generation



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Validation

Click an error link to navigate to the page containing the validation issue. All errors must be fixed before submission can occur.

No validation errors were found.

PDF Generation

Select the 'PDF Preview' button to preview the submission PDF. Please do not send a copy of the PDF to EPA. Select the 'Sign, Encrypt, Submit' button to launch the CDX eSignature Widget to electronically sign and complete the submission. Select the 'Cancel' button to stop the submission process and return to the submission.

PDF Preview

Sign, Encrypt, Submit

Cancel

Submission Process – Certification



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A screenshot of a web application interface. The background is a dark grey panel with the following sections:

- Validation**: A heading followed by the text "Click an error link to navigate to the page containing...". Below this, it says "No validation errors were found."
- PDF Generation**: A heading followed by instructions: "Select the 'PDF Preview' button to preview the submission...". Below this, it says "Click the 'Sign, Encrypt, Submit' button to launch the submission process and return to the submission."
- At the bottom, there are three buttons: "PDF Preview" (dark blue), "Sign, Encrypt, Submit" (light grey), and "Cancel" (dark red).

Overlaid on top of this interface is a white modal dialog box with a thin grey border. The modal contains the following text:

I certify, under penalty of law that the information provided in this document is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.

At the bottom of the modal are two buttons: "Accept" (green) and "Decline" (green).

Submission Process – CROMERR (e-Signature) Widget

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eSignature Widget ×

1. Authentication

Log into CDX

User:
[REDACTED]

Password:
[REDACTED]

Show Password

Welcome [REDACTED]

2. Verification

Question:
What is the first and middle name of your oldest sibling?

Answer:
[REDACTED]

Show Answer

Correct Answer

3. Sign File

Submission Process – Success Confirmation



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Validation
Click an error link to navigate to the page containing the validation issue. All errors must be fixed before submission can occur.

No validation errors were found.

PDF Generation
Select the 'PDF Preview' button to preview the CDX eSignature Widget to electronically sign the submission. Select the 'Sign, Encrypt, Submit' button to launch the submission process and return to the submission.

Success
The submission was sent to EPA. The Copy of Record link to allow for the download of the Copy of Record and signature for this submission will appear in the forms list when EPA receives and processes your submission.

PDF Preview Sign, Encrypt, Submit OK

Confirmation Email



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helpdesk@epacdx.net

CDX PSP Package Transmitted to OPP

To [REDACTED]

EXTERNAL SENDER: Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Your PSP package ([REDACTED]) for CDX Testing Company (98765) has been successfully transmitted to OPP.

Below are the application(s) included in this package and their tracking number(s):

[REDACTED]

Company Name: CDX Testing Company

Company Number: 98765

If you have questions concerning this message, you may contact the CDX Help Desk by email at helpdesk@epacdx.net or by calling the CDX Technical Support Staff through our toll free telephone support on (888) 890-1995 between Monday through Friday from 8:00 am to 6:00 pm EST/EDT. For International callers, the CDX Help Desk can also be reached at (970) 494-5500.

CDX Homepage

<https://cdx.epa.gov>

United States Environmental Protection Agency - Central Data Exchange