CDX Pesticide Submission Portal (PSP)

Biotechnology PIP Exemption Request Application

CDX 00048-OCSPP-000 PSP

May 2023





Pesticide Submission Portal



Pesticide Submissio	n Portal	Help ▼				⊥ Jane Doe, Test Or	g 10 (Primary Subn
	sticide Pr					o data call ins, form consortiums, or utilize pre-submission too	ols (e.g. form
ubmissions and To	ols				Colla	Paperwork Reduction Act Notice	
Registration & Exemptio	ons ▶	Submit regulatory app	lications			1	
Registration Review	•	General Registration		through genetic			
Reregistration	•	Distributor Product		(biotechnology).	_		
Foreign Purchaser Acknowledgement		Pre-Application Biotech PIP Exemption Re	equests	Create Applic	ation		
Statements Pre-Submission Tools	•	Upload e-Submission Pag	kages	-			
The Cubinicolon reeds	ŕ	Upload eDossier Builder I	Packages	>			
iew Recent Packag	es				Colla	se	
ew All Packages.							
Package ID 1		Package Name	11	Modification Date 1.	Status		
6668	BPER-	1528-Thu Oct 20 01:24:15 UTC	2022	10/20/2022	Awaiting User Completion		
howing 1 to 1 of 1 entries							

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

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

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 OMB Control No. 2070-0214 Expiration Date XX/XXX Step 2 Step 3 Step 5 Step 1 Step 4 Package Information **Exemption Information CBI Substantiation Submitter Information** Certification Package & Fees * Package Name Drop a file to attach, or browse. Cover Letter BPER-4528-Thu Oct 20 01:24:15 UTC 2022 Please do not include any Confidential Business Information (CBI) in the Cover * PRIA Fees Payment Amount Description * PRIA Fees Payment Tracking Number Fee Waiver Request Please select a waiver percent - 🗸 **Primary Contact** Copy from CDX * First Name * Email * Last Name * Phone Number

Exemption Information



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

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

p 1	Step 2	Step 3		Step 4	Step 5	
ckage Information	Exemption Information	CBI Substantiation		Submitter Information	n Certific	ation
emption Information						
PreApp-BPER-000001						
* Request Application Name PreApp-BPER-000001		*	Upload Supportin	ng Documentation(s)		СВІ
★ Trait Type				e to attach, or <u>browse</u> .		
		СВІ	for plant-incorpo	must contain information specificated protectants created throupatible plant, and 40 CFR 174.96	gh genetic engineering fro	
* Genus and Species of Recipien	t Plant Other	СВІ	function PIPs.	, ,		
* Entrez Gene ID of the Unmodifie	ed Gene		//RID (if applicable))		
* PIP Exemption Type		□ CBI			? Upload	
174.27 - Loss-of-function PIP	v	_	#	File Name	СВІ	Delete
* Request Type © EPA Confirmation	Self-Determination • Both		1	0 test1.pdf	Y	•
PreApp-BPER-000002						

CBI Substantiation (1 of 2)



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

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

 Step 1
 Step 2
 Step 3
 Step 4
 Step 5

Package Information Exemption Information CBI Substantiation Submitter Information Certification

CBI Substantiation

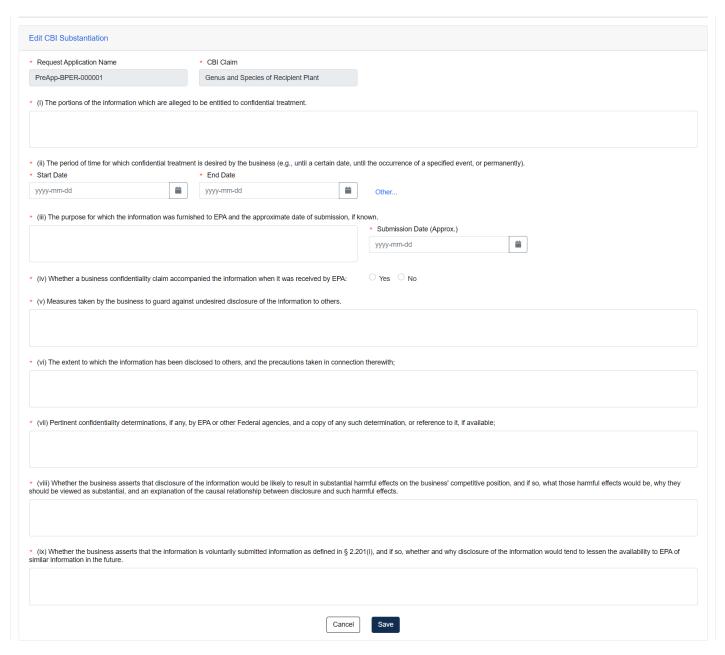
Status	Request Application Name	CBI Claim	Edit
•	PreApp-BPER-000001	0 test1.pdf	ď
•	PreApp-BPER-000001	Genus and Species of Recipient Plant	ď
•	PreApp-BPER-000001	Entrez Gene ID of the Unmodified Gene	ď
•	PreApp-BPER-000002	Genus and Species of Recipient Plant	ď
•	PreApp-BPER-000002	Entrez Gene ID of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

Edit CBI Substantiation



CBI Substantiation (2 of 2)





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

Submitter Information



OMB Control No. 2070-0214

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

Expiration Date XX/XXXStep 5 Step 2 Step 3 Step 4 Step 1 **Submitter Information Package Information Exemption Information CBI** Substantiation Certification Submitter Information 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: Address 1: Jane 123 Test ST Last Name: Address 2: Doe Phone Number: · City: Tulsa Email Address: State: OK Organization Name: Country: **CDX Testing Company** US · Company Number: ZIP Code: 98765 74116

Previous Next

Certification



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

Step 1 Step 2 Step 3 Step 4

OMB Control No. 2070-0214 Expi**sstions**Date XX/XXX

Package Information Exemption Information CBI Substantiation Submitter Information Certification

Certification

I, <u>Jane Doe</u>, as the duly authorized agent of <u>CDX Testing Company</u>, 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 <u>PIP Name B</u> 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 <u>CDX Testing Company</u> 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 <u>CDX Testing Company</u>, 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



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

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

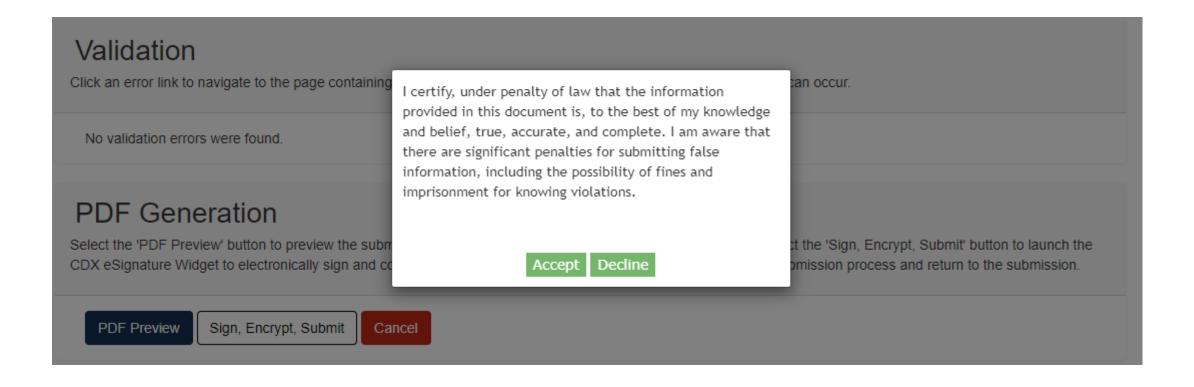
Sign, Encrypt, Submit

Cancel

Submission Process – Certification



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



Submission Process – CROMERR (e-Signature) Widget CDX

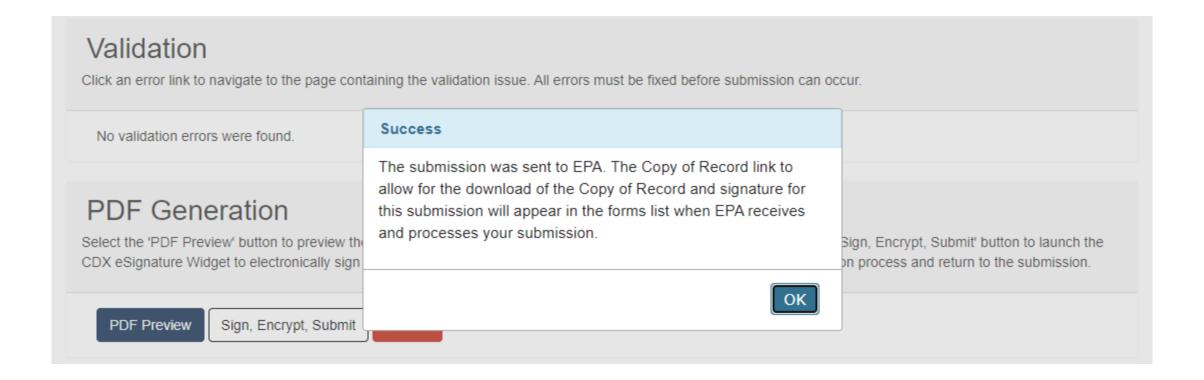
OMB Control No. 2070-0214 Expiration Date XX/XXX

Valid	eSignature Widget			×
Click an e	1. Authentication	2. Verification	3. Sign File	
	Log into CDX	Question:	Cian	
No vali	User:	What is the first and middle name of your oldest sibling?	Sign	
_	Password:	Answer:		_
PDF	•••••	•••••		
Select the	Show Password	Show Answer		ch the
CDX eSiç	Welcome	Correct Answer		sion.
PDF				_

Submission Process – Success Confirmation

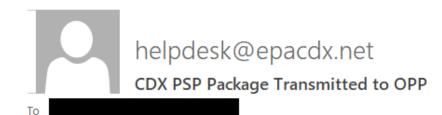


OMB Control No. 2070-0214 Expiration Date XX/XXX



Confirmation Email





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

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 () 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):

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