

How to submit a self-determination or a request for EPA confirmation for exempt genetically engineered plant-incorporated protectants (PIPs)

CDX Central Data Exchange

Pesticide Submission Portal

Tips for Participants



Questions about the Final Rule?

EPA's website

https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/pesticides-exemptions-certain-plant-incorporated-0

- Final rule
- Video of webinar discussing the final rule (including the eligibility determination process)
- Response to public comments received on the proposed rule

Still have questions?

• Please email Mike Mendelsohn (<u>mendelsohn.mike@epa.gov</u>), Chief of the Emerging Technologies Branch

Things to do before submitting a self-determination or EPA confirmation request

Create CDX account & obtain company number

- EPA's CDX is an electronic portal that is used by different programs within the Agency
 - Create CDX account here: <u>https://cdx.epa.gov/</u>
 - Enter "Pesticide Submission Portal" in the "Active Program Services List" when prompted
 - CDX user manual: <u>https://cdx.epa.gov/about/userguide</u>
- Obtain company number in CDX
 - A company number is a unique identifier assigned to a company by EPA
 - For additional information on company numbers, including step-by-step instructions: <u>https://www.epa.gov/pesticide-registration/pesticide-registration-manual-how-obtain-company-number-and-register</u>

Things to do before submitting an EPA confirmation request

Create a Pay.gov account

- Use this portal to pay the PRIA M009 fees for EPA confirmation requests and obtain a payment receipt
- For eligible entities, pay the reduced fee on Pay.gov, and provide the payment receipt, and documents substantiating the fee waiver eligibility with your CDX submission

Determine if you are eligible for a PRIA 5 fee waiver

- Relevant only for EPA confirmation requests, as they are submitted under the PRIA 5 "M009" category (\$3,389 without fee waiver)
- 1. Small businesses

General

eligibility:	If your number of employees is		If your average annual revenue from pesticides is not greater than		You are eligible for a waiver of	
	500 or fewer	and	\$60 million	=	50%	
	500 or fewer	and	\$10 million	=	75%	

• For additional information on PRIA fee waivers and how to submit a request: <u>https://www.epa.gov/pria-fees/pria-fee-waivers-small-businesses</u>

2. Federal and state governments

For additional information on PRIA fee waivers and how to submit a request: <u>https://www.epa.gov/pria-fees/exemptions-federal-and-state-governments-under-pria</u>

The submission process



Pesticide Submission Portal - Landing page

Pesticide Submission Portal Help -

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 N

Submissions and Tools				Collapse
Registration & Exemptions	Submit regulatory applications			
Registration Review	General Registration	•	Request an exemption for PIP(s) derived through genetic engineering (ge	
Descriptorium	Distributor Product	•	technology).	
Reregistration	Pre-Application	•	Create Application	
Foreign Purchaser Acknowledgement Statements	GE Tech PIP Exemption Requests	•		
Pre-Submission Tools	Upload e-Submission Packages	•		
	Upload eDossier Builder Packages	•		

Pesticide Submission Portal - Select PIP exemption submission

Pesticide Submission Portal Help -

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 N

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	Pre-Application		Create	
Foreign Purchaser Acknowledgement Statements	GE PIP Exemption Requests			
Pre-Submission Tools	Upload e-Submission Packages	•		
	Upload eDossier Builder Packages			

Package information

Ste	p 1	Step 2		Step 3		Step 4	
Pa	ckage Information	Exemption Information		Submitter Information		Certification	
Pa	ckage & Fees						
	Package Name GPER-10016-Fri Jun 23 18:30:05 UTC 2023	Four tabs on the top allow quick acc	cess to the	Cover Letter	Drop a file to attach, or <u>browse</u> .		
	PRIA Fees Payment Amount	different parts of the submission				ormation (CBI) in the Cover Letter.	
			0				
	PRIA Fees Payment Tracking Number			Description			
	Fee Waiver Request						
Pr	mary Contact						
	+ First Name			* Email			
	* Last Name			Phone Number		0	

Package information

Step 1	Step 2	Step 3	Step 4
Package Information	Exemption Information	Submitter Information	Certification
Package & Fees			
Package Name GPER-10016-Fri Jun 23 18:30:05 UTC 2023 PRIA Fees Payment Amount PRIA Fees Payment Tracking Number	0	Cover Letter Drop a file to attach, or browse. Please do not include any Confidential Business Infor	mation (CBI) in the Cover Letter.
Fee Waiver Request Primary Contact			
Copy from CDX First Name		* Email	
- Last Name		* Phone Number	

Package & Fees

Step 1	Step 2	Step 3	Step 4
Package Information	Exemption Information	Submitter Information	Certification
Package & Fees			
Package Name		Cover Letter	Drop a file to attach, or browse.
Step 2 type Information tage & Fees Package Name SPER-10016-Fri Jun 23 18:30:05 UTC 2023 PRIA Fees Payment Amount Type "N/A" if self-determination PRIA Fees Payment Tracking Number Type "N/A" if self-determination or multiple EPA confirmation requests Fee Waiver Request ary Contact Extreme CDX First Name Last Name			Please do not include any Confidential Business Information (CBI) in the Cover Letter.
PRIA Fees Payment Amount		-	
Type N/A If self-determination		Description	
 PRIA Fees Payment Tracking Number Type "N/A" if self-determination or multiple FPA confirma 	tion requests 2		

Primary Contact

Step 1	Step 2	Step 3	Step 4
	Exemption Information	Submitter Information	Certification
Package & Fees			
Primary Contact			
Copy from CDX First Name Last Name		Email Phone Number	0

Go to step 2

Step	1	Step 2		Step 3	Step 4
		Exemption Information		Submitter Information	Certification
	kage & Fees				
	Package Name GPER-10016-Fri Jun 23 18:30:05 UTC 2023			Cover Letter	
	PRIA Fees Payment Amount			Description	
	PRIA Fees Payment Tracking Number				
) Fee Waiver Request				
Prin	nary Contact				
	First Name				
				Step 3 Submitter Information Cover Letter Description Email Phone Number Information	
	Last Name			* Phone Number	

N xt

Step 1	Step 2		Step 3	Step	4	
Package Information	Exemption Information		Submitter Information	Cert	ification	
Exemption Information						
PreApp-GPER-000001						
Request Application Name PreApp-GPER-000001			Upload Supporting Documentation(s)			СВІ
PIP Name		СВІ	Drop a file to attach, or <u>browse</u> . Documentation must contain information specified in 40 CFI	R 174.95(a)-(d) for plant-incorporate	d protectants created through genetic	
Genus and Species of Recipient Plant	✓ Other	СВІ	engineering from a sexually compatible plant, and 40 CFR 1	174.96(a) and (b) for loss-of-function	PIPs.	
Entrez Gene ID of the Unmodified Gene		CBI	Document Type Please select one -		~	
PIP Exemption Type			Document Sub-Type			
- Please select one -	~		- Please select one -		~	
FIFRA & FFDCA	~	Single statute exemption	MRID (if applicable)	0	Upload	
			# File Name	Document Type	MRID	CBI Delete
+Add Another						

Previous Next

		Step 3	Step 4	
kage Information Exemption Information		Submitter Information	Certification	
mption Information				
PreApp-BPER-000001				
Request Application Name		- Upload Supporting Documentation(s)		O CBI
PreApp-BPER-000001				0.000
PIP Name		Drop a file to attach, or <u>browse</u> .		
Test PIP	СВІ		created through	
Genus and Species of Recipient Plant		CBI substantiation m	nust be made for	
Lycopersicon esculentum (Tomato) V Other	CBI <	 every element claim 	ed CBI in the	
Entrez Gene ID of the Unmodified Gene		submitted MRID.		
00000	СВІ		~	
PIP Exemption Type		· · · · · · · · · · · · · · · · · · ·		•
174.26(a)(1) - Insertion	~	A new tab will appea	ar with a form of a total of t	9
* Request Type		substantiating quest	ions that must be answere	d for each
EPA Confirmation Self-Determination Both		individual CBI claim	and PIP. Those questions ca	an also be
Statute under which exempt	Single statute exemption	found at 40 CED 174	0	
FIFKA& FFDCA		Tound at 40 CFR 174	.9.	

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Step 1	Step 2		Step 3	Step 4
Package Information			Submitter Information	Certification
Exemption Information				
* Request Application Name			* Upload Supporting Documentation(s)	
PreApp-GPER-000001				CBI
- PIP Name			Drop a file to attach, or browse.	
		CBI	Documentation must contain information specified in 40 CFR 174.95(a)-(d) for plant-in engineering from a sexually compatible plant, and 40 CFR 174.96(a) and (b) for loss-	
 Genus and Species of Recipient Plant 				
	✓ Other	CBI		
Entrez Gene ID of the Unmodified Gene			* Document Type	
		CBI	- Please select one -	~
- PIP Exemption Type			* Document Sub-Type	
- Please select one -	~		- Please select one -	×
Statute under which exempt			MRID (if applicable)	
FIFRA only	~	Single statute exemption		C Upload
FIFRA only FFDCA only			# File Name Document Type	MRID CBI Delete

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Step 2		Step 3		Step 4		
Exemption Information		Submitter Information		Certification		
		* Upload Supporting Documentation(5)		-	CBL
		Drop a file to attach, or b	owse.			
	CBI	Documentation must contain in engineering from a sexually co	formation specified in 40 CFR 174.95(a)-(d) for plant- mpatible plant, and 40 CFR 174.96(a) and (b) for loss	incorporated protectants created through g s-of-function PIPs.	genetic	
✓ Other	CBI					
		+ Document Type				
	CBI	- Please select one -		~		
		Document Sub-Type				
		- Mease select one -		× ·		
~	Single statute exemption	MRID (if applicable)		Deland		
				opicau		
		# File Nar	ne Document Type	MRID	CBI	Delete
	Step 2 Exemption Information Other	Step 2 Exemption Information CBI CBI CBI CBI CBI CBI CBI CBI CBI CB	Step 2 Step 3 Exemption Information Submitter Information • Upload Supporting Documentation() • Upload Supporting Documentation() • Origon a file to attach, or br • Other • Other • Other • Other • Document Type • Please select one - • Document Sub-Type • Please select one - • Document Sub-Type • Please select one - • Discument Sub-Type • Please select one - • MRID (if applicable) • File Name	Step 2 Step 3 Exemption Information Submitter Information • Upload Supporting Documentation(s) • Upload Supporting Documentation(s) • Drop a file to attach, or browne: • Drop a file to attach, or browne: • Other • Other • Other • Document Type • Please select one - • Document Study.Type • Please select one - • Document Type • Please select one - • Document Type • Please select one - • Document Type • Please select one - • Please select one - <td>Step 2 Step 3 Step 4 Exemption Information Certification Certification Certification • Upload Supporting Documentation(s) • Upload Supporting Documentation(s) • Upload Supporting Documentation(s) • Operation information specified in 40 CFR 174 55(a).(d) for plan-line(operated protectants created through a sequely compatible plant, and 40 CFR 174 55(a).(d) for plant-line(operated protectants created through a sequely compatible plant, and 40 CFR 174 55(a).(d) for loss-offunction PIPs. • Operation • Operation • Document Type • Document Sub-Type • Document Sub-Type • Plants ested one - • MRID (# applicable) # File Name Document Type</td> <td>Step 2 Step 3 Step 4 Exemption information Outlification Outlification</td>	Step 2 Step 3 Step 4 Exemption Information Certification Certification Certification • Upload Supporting Documentation(s) • Upload Supporting Documentation(s) • Upload Supporting Documentation(s) • Operation information specified in 40 CFR 174 55(a).(d) for plan-line(operated protectants created through a sequely compatible plant, and 40 CFR 174 55(a).(d) for plant-line(operated protectants created through a sequely compatible plant, and 40 CFR 174 55(a).(d) for loss-offunction PIPs. • Operation • Operation • Document Type • Document Sub-Type • Document Sub-Type • Plants ested one - • MRID (# applicable) # File Name Document Type	Step 2 Step 3 Step 4 Exemption information Outlification Outlification

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				Step 3	Step 4	
				Submitter Information	Certification	
Type of request	Documents to be submitted	Document type	Document sub-type			
Self- determination	None required	-	-	Upload Supporting Documentation(s)		СВІ
EPA confirmation request	Supporting documentation (40 CFR 174.95)	Correspondence	Other	Drop a file to attach, or <u>browse</u> . Documentation must contain information specified in 40 CFR 174.95(a)-(d) for pl genetic engineering from a sexually compatible plant, and 40 CFR 174.96(a) and	ant-incorporated protectants created through ((b) for loss-of-function PIPs.	
	Pay.gov receipt	Miscellaneous	Other	Document Type		
	PRIA fee waiver request (if applicable)	Miscellaneous	Other	Correspondence Document Sub-Type Other	~ 	
	EPA Form 8570-1	Form	Form 8570-1	# File Name Document Type	MRID CBI	Delete

Step 1	Step 2		Step 3	Step 4	
Package Information	Exemption Information		Submitter Information	Certification	
Exemption Information					
Request Application Name PreApp-BPER-000001			- Upload Supporting Documentation(s)		СВІ
- PIP Name		СВІ	Drop a file to attach, or <u>browse</u> . Documentation must contain information specified in 40 CFR 174.95(a)-(d) for		
Genus and Species of Recipient Plant Please select one -	✓ Other	СВІ	genetic engineering from a sexually compatible plant, and 40 CFR 174.96(a) a		
Entrez Gene ID of the Unmodified Gene		СВІ	 Document Type Study 	~	
PIP Exemption Type Please select one -	~		 Document Sub-Type Study 	~	
 Statute under which exempt FIFRA & FFDCA 	~	Single statute exemption	* MRID (if applicable)	C Upload	
			# File Name Document Type	MRID CBI	Delete
+Add Another					

Previous Next

Step 1	Ctop 0	Step 2		Stop 4	
Step 1	Step 2	Step 0		Step 4	
Package Information	Exemption Information	Submitter Information		Certification	
Exemption Information					
	MRID Guidance & Root MRID Generator		×		
 Request Application Name 	MRID Guidance				
PreApp-BPER-000001	The same root MRID cannot be used across multiple submissions. In o	ther words, if you use the root MRID '123456' for one submission, you cannot \boldsymbol{u}	use it for another		CBI
- PIP Name	 submission and must instead generate a new root. The first MRID always ends in '00' and must be assigned to the transmission of the transmission of	ttal document that describes the purpose of the submission and lists all of the i	included studies by title		
	and MRID. MRIDs ending in '01' through '99' are available for assignment to support	rting studies.	r pl		
Genus and Species of Recipient Plant	 If a submission includes more than 99 studies, you will need more than List studies on the transmittal document in MRID order without any bread 	and			
- Please select one -	Additional information can be found via the EPA website: https://www.ep	a.gov/pesticide-registration/study-formatting-and-supplemental-information.			
* Entrez Gene ID of the Unmodified Gene	Enter the number of root MRIDs you need below, then click "Generate Root	MRIDs".			
	Each application must have its own root MRID.			~	
* PIP Exemption Type	Number of Root MRIDs	Generate Bott MRIDs MRID	Actions		
- Please select one -				~	
Statute under which exempt		Showing 1 to 1 of	1 entries		
FIFRA & FFDCA			Ok	(?) Upload	
		# File Name	Document Type	MRID CBI	Delete
+Add Another					
Previous Next					

Step 1	Step 2		Step 3	Step 4
Package Information	Exemption Information		Submitter Information	Certification
Exemption Information				
* Request Application Name			* Upload Supporting Documentation(s)	
PreApp-GPER-000001				
- PIP Name			Drop a file to attach, or <u>browse</u> .	
			Documentation must contain information specified in 40 CFR 174.95(a)-(d) for plant-in engineering from a sexually compatible plant, and 40 CFR 174.96(a) and (b) for loss-o	
* Genus and Species of Recipient Plant	✓ Other	CBI		
 Entrez Gene ID of the Unmodified Gene 			* Document Type	
		CBI	- Please select one -	~
- PIP Exemption Type			* Document Sub-Type	
- Please select one -	~		- Please select one -	~
* Statute under which exempt			MRID (if applicable)	
FIFRA & FFDCA	~	Single statute exemption		Upload
			# File Name Document Type	MRID CBI Delete
+Add Amother				
Previous				

Go to step 3

Step 1	Step 2		Step 3	Step 4
Package Information			Submitter Information	Certification
Exemption Information				
- Request Application Name PreApp-GPER-00001			* Upload Supporting Documentation(s)	Сві
- PIP Name			Drop a file to attach, or browse.	
 Genus and Species of Recipient Plant 		CBI	Documentation must contain information specified in 40 CFR 174.95(a)-(d) for pla engineering from a sexually compatible plant, and 40 CFR 174.96(a) and (b) for l	
	 ✓ Other 	CBI		
- Entrez Gene ID of the Unmodified Gene		C CBI	Document Type	
PIP Exemption Type			Prease service one - Document Sub-Type	
- Please select one -	~		- Please select one -	~
Statute under which exempt			MRID (if applicable)	
FIFRA & FFDCA	~	Single statute exemption		Upload
			# File Name Document Typ	pe MRID CBI Delete
Previous				

Submitter information

Step 1	Step 2	Step 3	Step 4				
Package Information	Exemption Information	Submitter Information	Certification				
Submitter Information							
		-					
First Name:		Address 1:					
Jane		111 Test St					
Last Name:		Address 2:					
Doe							
Phone Number:		City:					
###-####		Test city					
Email Address:		State:					
jane.doe@testcompany		DC					
Organization Name:		Country:					
GEPER Test Company LLC		US					
Company Number:		ZIP Code:					
123		20001					

Previous Next

Go to step 3

Step 1	Step 2	Step 3	Step 4				
Package Information	Exemption Information		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:					
		111 Test St					
- Last Name:		Address 2:					
- Phone Number:		* City:					
		Test city					
- Email Address:		* State:					
Organization Name:		* Country:					
GEPER Test Company LLC							
- Company Number:		* ZIP Code:					
123		20001					



Certification

Step 1	Step 2	Step 3	Step 4
Package Information	Exemption Information	Submitter Information	Certification

Certification

I, Jane Doe, as the duly authorized agent of <u>GEPER Test Company LLC</u>, an 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>Test PIP</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>GEPER Test Company LLC</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>GEPER Test Company LLC</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 Sub. hission Process

Submit your CDX-related questions



Questions?



How to submit a self-determination or a request for EPA confirmation for exempt genetically engineered plant-incorporated protectants (PIPs)



Pesticide Submission Portal