

TSCA Section 5 Biotech

EPA Form No. 6300-07

OMB Control No. 2070-0038

Expiration 12/31/2025

CHEMICAL INFORMATION SUBMISSION SYSTEM

TSCA Section 5 Notices and Supports - ePMN

OK

Section 5 of TSCA, EPA's New Chemicals Program, helps manage the potential risk to human health and the environment from chemicals prior to entry to the marketplace. Anyone who plans to manufacture or import a new chemical substance (i.e. one not listed on the TSCA inventory) for a non-exempt commercial purpose is required by Section 5 of TSCA to provide EPA with notice before initiating the activity. A Premanufacture Notice, or PMN, must be submitted at least 90 days prior to the manufacture or import of the chemical. Additional notice types which use the PMN form are listed to reflect different circumstances under which a chemical may be manufactured or imported such as Significant New Use Notices (SNUN), Low Volume Exemptions (LVE), Test Market Exemption Applications (TMEA), and Low Volume and Low Release Exemptions (LoREX). Biotechnology notice forms will be used to submit Microbial Commercial Activity Notices (MCAN), TSCA Experimental Release Applications (TERA), Tier 1 Exemptions, Tier 2 Exemptions, and Biotechnology Test Market Exemption Applications (Biotechnology TMEA). For a PMN or MCAN, the manufacturing or importing company must also notify EPA via a Notice of Commencement within 30 days after the start of the first manufacture or import of the chemical for non-exempt commercial purposes. To determine if a substance is on the TSCA inventory, and therefore excluded from the requirement to provide premanufacturing notification, a submitter may submit a Bona Fide Intent to Manufacture notice ("Bona Fide Notice"). For questions regarding TSCA Section 5 Notices, a pre-submission inquiry can be submitted.

Please note: The public reporting and recordkeeping burden for this collection of information is estimated to average 93 hours per response for PMN, SNUN, LVE, and LOREX applications (TMEA is estimated to average 88 hours per response), including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The public reporting and recordkeeping burden for this collection of information is estimated to average 290 hours per response for MCAN applications and the NOC is estimated to average 0.8 hours per response. 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, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed EPA Form (7710-25) (PMN) or Form 6300-14 (Biotechnology) or Form 7710-56 (NOC) to this address.

The software includes submission forms, embedded help files and a downloadable user manual to guide you through the Section 5 Notices and Supports submission process. Click OK to complete a Section 5 Notices and Supports reporting form, using the Section 5 Notices and Supports software. If you are not reporting on Section 5 Notices and Supports, please select a different application in the drop-down menu.

Paperwork Reduction Act Notice

OMB Control No. 2070-0038
Expiration 12/31/2025

EPA Form No. 6300-07

Paperwork Reduction Act Notice

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., and assigned OMB Control No. 2070-0038. Responses to this collection of information are mandatory for certain persons who engage in the covered activities as specified in section 5 of the Toxic Substances Control Act and EPA implementing regulations (40 CFR parts 720 through 725). 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, which varies based on the activity, is estimated to be between 17 to 526 hours per response. 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 Director of the Information Engagement Division, Office of Mission Support, 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.

Authority

The Government Paperwork Elimination Act (GPEA) (44 U.S.C. 3504) provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3) (Ref. 2), provides that any requirement in title 40 of the CFR to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency published a document in the **Federal Register** announcing that EPA is prepared to receive certain documents in electronic form. For more information about CROMERR, go to <http://www.epa.gov/cromerr>.

Forms

The TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting rule requires anyone who intends to manufacture (which includes import) a new chemical substance (i.e., one not listed on the TSCA Inventory) for a non-exempt commercial purpose or to manufacture or process a chemical substance for a significant new use previously designated by EPA to provide EPA with notice before initiating the activity.

Use the following forms to report new chemicals to EPA: Premanufacture Notice form (EPA Form 7710-25) should be used to submit PMNs, LVEs, SNUNs, LOREXs, TMEAs, Modifications for LVEs and LoREX submissions; Biotechnology Notice form (EPA Form 6300-14) should be used to submit MCANs, TERAs, Tier I Exemptions, Tier 2 Exemptions, and Biotechnology TMEAs; Notice of Commencement form (NOC, EPA Form 7710-56) should be used to submit Notices of Commencement for PMNs and MCANs; ACM 40 CFR 721.30 form (TBD) should be used to report proposed Alternative Control Measures for published SNURs; or Bona Fide Notice (TBD) for any requests to determine if a chemical is on the TSCA inventory. The Support form is used to submit supplemental information for Premanufacture and Biotechnology notices, such as Test Data, Correspondences, and Amendments to older submissions.

To determine if a substance is on the TSCA inventory, and therefore excluded from the requirement to provide premanufacturing notification, a submitter may submit a Bona Fide Intent to Manufacture notice ('Bona Fide Notice'). For questions regarding TSCA Section 5 Notices, a pre-submission inquiry can be submitted.

User Management

Manage the access rights of Support persons (including Agents/Consultants) for each Section 5 Notices and Support form.

Resources

Displays links to helpful guidance documents and websites for TSCA and Section 5.

Authorized Official

An Authorized Official has the ability to create, delete, amend, unlock, and submit all Section 5 Notices and Support forms electronically to EPA. The Authorized Official also has the ability to assign Supports (including Agents/Consultants) to individual forms.

OMB Control No. 2070-0038
Expiration 12/31/2025

EPA Form No. 6300-07

Exhibit 3-5 User Management Screen



Logged in as: Jane Doe, Primary Authorized Official

Log Out

[Home](#) [Forms](#) [User Management](#) [Resources](#)

USER MANAGEMENT

The Authorized Official is responsible for restricting a Support's access to select forms by assigning or un-assigning them to each form alias. The Support can access and edit only those documents for which the Authorized Official has granted access. Select the form to manage from the drop-down menu and assign a Support to the form by highlighting the individual and clicking the **add** link. To un-assign a Support, highlight the individual and click the **remove** link. To highlight and assign or un-assign multiple Supports, hold down the Ctrl or Shift keys on the keyboard and click each Support before clicking the 'add>>' or '<<remove' link. You must click the **'Save'** button after each change in user assignment.

Form Alias:

Assign Users

Unassigned

Assigned

add >>
<< remove

[CDX Homepage](#) | [MyCDX Homepage](#) | [EPA Homepage](#) | [Terms and Conditions](#) | [Privacy Notice](#) | [CDX Helpdesk: \(888\) 890-1995](#)



Logged in as: Jane Doe, Primary Authorized Official

Log Out

HomeFormsUser ManagementResources

SECTION 5 NOTICES AND SUPPORTS FORMS

- If submitting a form for the first time in the Section 5 Notices and Supports application, select the form type from the drop-down menu and click **Start New Form**.
- Only one Polymer Exemption submission per year should be filed per organization.
- To edit an In Progress form, click the form alias link in the Alias column in the table below.
- To access and edit a form previously submitted through CDX, unlock the form by clicking the lock (🔒) icon and enter the passphrase when prompted. All additional changes made to the form will be submitted as an amendment.
- To download a copy of record for a submitted form, click the green arrow (⬇️) icon and enter the passphrase when prompted.
- You may delete any form that has not yet been submitted by clicking the delete (❌) icon.
- All columns may be sorted by clicking the column header.

40 items found

Page 2 of 2

Go to: 1, 2

Items Per Page: 25

Alias	Type	Subtype	Case Number	Status	Modify Date	Submission Date	Action
Primary PMN-20180827-17:38:28 EDT	Primary PMN	PMN	P-18-0314	Submitted	08/27/2018	08/27/2018	⬇️🔒
Primary PMN-20180920-12:01:11 EDT	Primary PMN	PMN	P-18-0366	Submitted	09/20/2018	09/20/2018	⬇️🔒
Primary PMN-20180929-15:48:48 EDT	Primary PMN	TMEA		In Progress	09/29/2018		❌

CDX Homepage

MyCDX Homepage

EPA Homepage

Terms and Conditions

Privacy Notice

CDX Helpdesk: (888) 890-1995



Logged in as: Jane Doe, Primary Authorized Official

Log Out

Home

Forms

User Management

Resources

Primary PMN-20180918-16:42:41 EDT	Primary PMN	LVE	L-18-0046	Submitted	09/19/2018	09/19/2018	 
Primary PMN-20180919-15:27:10 EDT	Primary PMN	PMN	P-18-0364	Submitted	09/19/2018	09/19/2018	  
Primary PMN-20180919-15:38:18 EDT	Primary PMN			In Progress	09/29/2018		
Primary PMN-20180929-11:34:42 EDT	Primary PMN						
Polymer Exemption-20160707-15:20:37 EDT	Polymer Exemption		Y-16-0020	Submitted	08/27/2016	08/27/2016	  
Biotechnology-20180913-16:44:55 EDT	Biotechnology	MCAN	J-18-0378, J-18-0379, J-18-0380	Submitted	09/14/2018	09/14/2018	 
Biotechnology-20180929-12:23:11 EDT	Biotechnology	Biotechnology_TME		In Progress	09/29/2018		
NOC-20171012-10:25:02 EDT	NOC			In Progress	10/12/2017		
Primary PMN-20180307-12:19:46 EST	Primary PMN	SNUN		In Progress	09/29/2018		
Primary PMN-20180930-10:51:56 EDT	Primary PMN	PMN	P-18-0390	Submitted - Awaiting Payment	09/30/2018	09/30/2018	  

Export options:  CSV |  Excel |  XML |  PDF

Select the form type and then click **Start New Form**

Form Type:

Premanufacture Notice (PMN)

Start New Form

CDX Homepage

MyCDX Homepage

EPA Homepage

Terms and Conditions

Privacy Notice

CDX Helpdesk: (888) 890-1995

OMB Control No. 2070-0038
Expiration 12/31/2025

EPA Form No. 6300-07

Exhibit 3-8 Create Passphrase Screen



Logged in as: Jane Doe, Primary Authorized Official
[Log Out](#)

CREATE PASSPHRASE

Please create a passphrase that is at least 8 characters in length. To better protect your form, your passphrase should contain a combination of letters and numbers. Your passphrase may include spaces, but should not contain special characters (for example, +, and *).

New Passphrase:

Confirm New Passphrase:

As an Authorized Official, you are responsible for remembering your passphrase and distributing it to only authorized individuals. Your passphrase will be used as an encryption key to protect the contents of your data. As an Authorized Official, you are responsible for remembering your passphrase and distributing it to only authorized Supports.

Note: If you lose or forget your passphrase, you will not be able to access your Section 5 Notices and Supports Form to print, submit, or make changes. You will need to complete a new Section 5 Notices and Supports Form and create a new passphrase for the form. For security reasons, the system administrator will not have access to your passphrase and will not be able to retrieve it or reset it.

Cancel

Next

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

Exhibit 3-10 Attach Documents Pop-Up Window

ATTACH DOCUMENTS

Type and Subtype
Select the type and subtype of the attachment

Type:

Attachment
Select the file to attach

File:

Description
Provide a description of the attachment
***Please do not include any CBI information in the description of the file information.*

Number of Pages pages

CBI Check to claim the attachment as CBI ☒

Sanitized Attachment
Select the sanitized file to attach

File:

Attachments containing CBI data require a sanitized copy of the attachment not containing any CBI data.

Exhibit 3-11 Enter Passphrase Screen



Logged in as: Jane Doe, Primary Authorized Official
[Log Out](#)

ENTER PASSPHRASE

Please enter your form passphrase and click **Next**

Forgot 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 complete a new Section 5 Notices and Supports Form and create a new passphrase for the chemical substances you intend to import or manufacture.

[Cancel](#) [Next](#)

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

OMB Control No. 2070-0038
Expiration 12/31/2025

EPA Form No. 6300-07

Biotechnology
Primary Authorized Official
Biotechnology-20180914-
15:06:48 EDT

- General Form Information
- Fees Certification
- Joint Submission
 - Joint Submission 1
 - Joint Submitter Information
 - Joint Submission Information
 - Remove
 - Add Joint Submission
- Letter Of Support
 - Letter of Support 1
 - Letter of Support Submitter Information
 - Letter of Support Submission Information
 - Remove
 - Add Letter Of Support
- Technical Contact Information
- Optional Cover Letter
- Submitting Official Information
- CBI Substantiation
 - Instructions for Substantiating CBI Claims

Support
Primary Authorized Official
Support-20170720-13:06:36 EDT

- General Form Information
- Original Submitter Information
- Submitting Official Information
- CBI Substantiation
 - Instructions for Substantiating CBI Claims



Logged in as: Jane Doe, Primary Authorized Official

Log Out

HomeFormsUser ManagementResources

Biotechnology
Primary Authorized Official

Biotechnology-20180914-15:06:48 EDT

General Form Information

Fees Certification

Joint Submission

Joint Submission 1

Joint Submitter Information

Joint Submission Information

Remove

Add Joint Submission

Letter Of Support

Letter of Support 1

Letter of Support Submitter Information

Letter of Support Submission Information

Remove

Add Letter Of Support

Technical Contact Information

Optional Cover Letter

Submitting Official Information

Biotechnology (Biotechnology-20180914-15:06:48 EDT) > General Form Information

GENERAL FORM INFORMATION

You may enter an alias for easier form identification or the system will provide a time stamp.

Form Alias: Biotechnology-20180914-15:06:48 ED

III. Type of Submission:

MCAN (Microbial Commercial Activity Notice)

TS Number:

IV. Text/Comments CBI:

Please describe the submission and/or attachment.

Please provide your Biotech submission information in one or more attachments.

Attach Document

File Name	Description	Pages	CBI	Actions
Check here if you are filing a consolidated Biotechnology form:	☒	Number of Microorganisms: (2-20)		
Check here if you are filing a joint Biotechnology form:	☒			
Check here if you have a Letter of Support pending:	☒			

Next

Validate

Save

Preview

Submit

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

OMB Control No. 2070-0038
Expiration 12/31/2025

EPA Form No. 6300-07

The screenshot displays the GSPP web application interface. At the top, a navigation bar includes the GSPP logo, a user login status 'Logged in as: Jane Doe, Primary Authorized Official', and a 'Log Out' button. Below the navigation bar, a breadcrumb trail shows the path: 'Biotechnology (Biotechnology-20181011-17:41:44 EDT) > Fees Certification'. The main content area is titled 'FEES CERTIFICATION' and contains instructions: 'Please select the Fees Certification statement that applies. Note that the Fees Certification selections below can not be modified using the submission amendment process.' Below this, a section titled 'Fees Certification' asks the user to 'Select the following Fees Certification statement that applies:' and provides three radio button options. The first option is 'The Company named in Part I will remit the fee of \$16,000.00 as specified in 40 CFR 700.45 (c)'. The second option is 'The Company named in Part I is a "small business concern" as defined under 40 CFR 700.43 and will remit the fee of \$2,800.00 as specified in 40 CFR 700.45(c)'. The third option is 'This joint submission includes at least one Company which is a "small business concern" and at least one Company which is not a "small business concern," as defined under 40 CFR 700.43. The \$16,000.00 fee will be remitted with the joint submission. Any remaining balance due for this joint submission is to be paid by the secondary submitter(s)'. A footnote at the bottom of the main content area states: '*The criteria for a "small business concern" has been changed in the final fees rule. View the updated definition of a small business concern. A PDF version of the final fees rule is available at https://www.epa.gov/sites/production/files/2018-09/documents/2018-09-27_prepubcopy_tsc-fees-finalrule.pdf.' At the bottom of the main content area, there are two buttons: 'Previous' and 'Next', with the 'Next' button highlighted with a red border. On the left side of the interface, a sidebar menu shows the submission structure, including 'General Form Information', 'Fees Certification', 'Joint Submission', 'Joint Submission 1', 'Letter Of Support', 'Letter of Support 1', 'Technical Contact Information', 'Optional Cover Letter', and 'Submitting Official Information'. At the bottom of the interface, a dark blue bar contains four icons with labels: 'Validate' (checkmark), 'Save' (floppy disk), 'Preview' (computer monitor), and 'Submit' (submit button). Below this bar, a footer contains links to 'CDX Homepage', 'MyCDX Homepage', 'EPA Homepage', 'Terms and Conditions', 'Privacy Notice', and 'CDX Helpdesk: (888) 890-1995'.

Biotechnology
Primary Authorized Official
Biotechnology-20181011-17:41:44 EDT

General Form Information
Fees Certification
Joint Submission
Joint Submission 1
Joint Submitter Information
Joint Submission Information
Remove
Add Joint Submission
Letter Of Support
Letter of Support 1
Letter of Support Submitter Information
Letter of Support Submission Information
Remove
Add Letter Of Support
Technical Contact Information
Optional Cover Letter
Submitting Official Information

Biotechnology (Biotechnology-20181011-17:41:44 EDT) > Fees Certification

FEES CERTIFICATION

Please select the Fees Certification statement that applies. Note that the Fees Certification selections below can not be modified using the submission amendment process.

Fees Certification

Select the following Fees Certification statement that applies:

- ☐ The Company named in Part I will remit the fee of \$16,000.00 as specified in 40 CFR 700.45 (c).
- ☐ The Company named in Part I is a "small business concern" as defined under 40 CFR 700.43 and will remit the fee of \$2,800.00 as specified in 40 CFR 700.45(c).
- ☐ This joint submission includes at least one Company which is a "small business concern" and at least one Company which is not a "small business concern," as defined under 40 CFR 700.43. The \$16,000.00 fee will be remitted with the joint submission. Any remaining balance due for this joint submission is to be paid by the secondary submitter(s).

*The criteria for a "small business concern" has been changed in the final fees rule. View the updated definition of a small business concern. A PDF version of the final fees rule is available at https://www.epa.gov/sites/production/files/2018-09/documents/2018-09-27_prepubcopy_tsc-fees-finalrule.pdf.

Previous Next

Validate Save Preview Submit

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

The screenshot displays the GSPP interface for a Biotechnology submission. The top navigation bar includes 'Home', 'Forms', 'User Management', and 'Resources'. The user is logged in as 'Jane Doe, Primary Authorized Official' with a 'Log Out' option. The left sidebar shows a tree view of the submission process, including 'General Form Information', 'Fees Certification', 'Joint Submission', and 'Letter Of Support'. The main content area is titled 'FEES CERTIFICATION' and contains instructions to select a statement that applies. There are four radio button options for fee certification. Below the options is a link to the updated definition of a small business concern. At the bottom of the main area are 'Previous' and 'Next' buttons. The footer contains a blue bar with 'Validate', 'Save', 'Preview', and 'Submit' buttons, and a grey bar with links to 'CDX Homepage', 'MyCDX Homepage', 'EPA Homepage', 'Terms and Conditions', 'Privacy Notice', and 'CDX Helpdesk: (888) 890-1995'.

Biotechnology
Primary Authorized Official
Biotechnology-20181011-17:41:44 EDT

Home Forms User Management Resources Logged in as: Jane Doe, Primary Authorized Official Log Out

Biotechnology (Biotechnology-20181011-17:41:44 EDT) > Fees Certification

FEES CERTIFICATION

Please select the Fees Certification statement that applies. Note that the Fees Certification selections below can not be modified using the submission amendment process.

Fees Certification

Select the following Fees Certification statement that applies:

- ☐ The Company named in Part I will remit the fee of \$4,700.00 as specified in 40 CFR 700.45(c).
- ☐ The Company named in Part I is a "small business concern" as defined under 40 CFR 700.43 and will remit the fee of \$940.00 as specified in 40 CFR 700.45(c).
- ☐ This joint submission includes at least one Company which is a "small business concern" and at least one Company which is not a "small business concern," as defined under 40 CFR 700.43. The \$4,700.00 fee will be remitted with the joint submission. Any remaining balance due for this joint submission is to be paid by the secondary submitter(s).
- ☐ The company named in Part I is submitting a sustainable futures TME. The company has graduated from EPA's Sustainable Futures program and is therefore exempt from fees for this sustainable futures TME.

**The criteria for a "small business concern" has been changed in the final fees rule. [View the updated definition of a small business concern](https://www.epa.gov/sites/production/files/2018-09/documents/2018-09-27_prepubcopy_tsca-fees-finalrule.pdf). A PDF version of the final fees rule is available at https://www.epa.gov/sites/production/files/2018-09/documents/2018-09-27_prepubcopy_tsca-fees-finalrule.pdf.*

Previous Next

Validate Save Preview Submit

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995



SMALL BUSINESS CONCERN DEFINITION

40 CFR 700.43

Small business concern means a manufacturer or processor who meets the size standards identified in the table below. The number of employees indicates the maximum allowed for a manufacturer or processor to be considered small. If the North American Industry Classification System (NAICS) code of a manufacturer or processor is not represented in the table below, it will be considered small if it has 500 or fewer employees. When calculating the number of employees, a manufacturer or processor must include the employees of all companies they "own or control," as defined by 40 CFR 704.3. The number of employees are calculated as the average number of people employed for each pay period of the business' latest 12 calendar months, regardless of hours worked or temporary status.

Potentially Affected NAICS	NAICS Description	Small Business Concern Size Standards (# of employees)
324110	Petroleum Refineries	1500 or fewer
325110	Petrochemical Manufacturing	1000 or fewer
325120	Industrial Gas Manufacturing	1000 or fewer
325130	Synthetic Dye and Pigment Manufacturing	1000 or fewer
325180	Other Basic Inorganic Chemical Manufacturing	1000 or fewer
325193	Ethyl Alcohol Manufacturing	1000 or fewer
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	1250 or fewer
325199	All Other Basic Organic Chemical Manufacturing	1250 or fewer
325211	Plastics Material and Resin	1250 or fewer



Logged in as: Jane Doe, Primary Authorized Official

Log Out

HomeFormsUser ManagementResources

Biotechnology
Primary Authorized Official
Biotechnology-20170731-
12:05:42 EDT

General Form Information

Joint Submission

Joint Submission 1

Joint Submitter Information

Joint Submission Information

Add Joint Submission

Letter Of Support

Add Letter Of Support

Technical Contact Information

Optional Cover Letter

Submitting Official Information

CBI Substantiation

Instructions for Substantiating CBI Claims

Biotechnology (Biotechnology-20170731-12:05:42 EDT) > Joint Submitter Information

JOINT SUBMITTER INFORMATION

?

Please enter the information for the joint submitter who will be responsible for supporting the information on the form. Check to claim information as CBI.

Check here to claim this information as CBI: ☐

First Name:

Last Name:

Position:

Company Name:

Phone Number:
(Do not enter any dashes (-) in Phone Number field above.)

Phone Extension:

Email Address:

Mailing Address 1:
Street address, P.O. box, company name, etc.

Mailing Address 2:
Apartment, suite, etc.

City:

State:

Postal Code:

Country:

Previous

Next



Validate



Save



Preview



Submit

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995



Logged in as: Jane Doe, Primary Authorized Official

Log Out

HomeFormsUser ManagementResources

Biotechnology
Primary Authorized Official
Biotechnology-20170731-
12:05:42 EDT

General Form Information

Joint Submission

Joint Submission 1

Joint Submitter Information

Joint Submission Information

Add Joint Submission

Letter Of Support

Add Letter Of Support

Technical Contact Information

Optional Cover Letter

Submitting Official Information

CBI Substantiation

Instructions for Substantiating CBI Claims

Biotechnology (Biotechnology-20170731-12:05:42 EDT) > Joint Submission Information

JOINT SUBMISSION INFORMATION

Please include instructions you wish the joint submitter to see. Clicking the link below will relay the information in this text box to your joint submitter via unencrypted e-mail.

Unique Identifier for Joint Submission: 804c9b14-17c5-48ad-bdd2-1ca570e32d73

This is the unique identification number for your joint submitter. [Notify the Secondary Submitter of the Joint Submission.](#)

The Secondary Submitter will need this identification number to complete the form. It is your responsibility to ensure that your secondary submitter understands how to complete the Biotechnology form and sends the information to EPA by the end of the submission period. The information collected in the primary and secondary form(s) will be linked by the unique identifier. The form will not undergo a review process until all forms have been received.

Previous

Next

✓

Validate

Save

Preview

Submit

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995



OMB Control No. 2070-0038
Expiration 12/31/2025

From:	Jane.Doe@test.com
CC:	
To:	Enter email addresses separated by semicolons (;) or commas (,). Click in this box to start entering email addresses.
Subject:	2015 Biotechnology
Message:	As the Authorized Official of TEST COMPANY, I have identified you as a Secondary Submitter of a joint submission for this 2015 Biotechnology form. Please use the Section 5 Notices and Supports application to provide the correct information for the necessary items in this form. See the instructions below for accessing the Section 5 Notices and Supports application. You will need to use the unique identification number to access and complete the Biotechnology form for the joint submission. Unique Identifier d2b7815d-71d8-4a8e-a406-1ab118df2b4b Information about the Section 5 programs, how to access the Section 5 Notices and Supports application, and instructions for reporting under the Section 5 rule are available at www.epa.gov/oppt/newchems/. For additional information or if you believe you have received this email in error, please contact me.
Additional Comments:	
Send	

EPA Form No. 6300-07



Logged in as: Jane Doe, Primary Authorized Official
[Log Out](#)

HomeFormsUser ManagementResources

Biotechnology
Primary Authorized Official
Biotechnology-20171010-
13:50:24 EDT

General Form Information

Joint Submission

Joint Submission 1

Joint Submitter Information

Joint Submission Information

Remove

Add Joint Submission

Letter Of Support

Letter of Support 1

Letter of Support Submitter Information

Letter of Support Submission Information

Add Letter Of Support

Technical Contact Information

Optional Cover Letter

Submitting Official Information

CBI Substantiation

Instructions for Substantiating CBI Claims

Biotechnology (Biotechnology-20171010-13:50:24 EDT) > Letter of Support Submitter Information

LETTER OF SUPPORT SUBMITTER INFORMATION

?

Please enter the information for the letter of support submitter who will be responsible for supporting the information on the form. Check to claim information as CBI.

Check here to claim this information as CBI: ☐

First Name:

Last Name:

Position:

Company Name:

Phone Number:
(Do not enter any dashes (-) in Phone Number field above.)

Phone Extension:

Email Address:

Mailing Address 1:
Street address, P.O. box, company name, etc.

Mailing Address 2:
Apartment, suite, etc.

City:

State:

Postal Code:

Country:

PreviousNext

Validate

Save

Preview

Submit

[CDX Homepage](#) | [MyCDX Homepage](#) | [EPA Homepage](#) | [Terms and Conditions](#) | [Privacy Notice](#) | [CDX Helpdesk: \(888\) 890-1995](#)

EPA Form No. 6300-07

The screenshot shows the CSPP (Chemical Safety and Hazard Investigation) web application interface. The user is logged in as Jane Doe, a Primary Authorized Official. The page title is "LETTER OF SUPPORT SUBMISSION INFORMATION". The left sidebar contains a navigation menu with options like "General Form Information", "Fees Certification", "Joint Submission", "Letter Of Support", "Technical Contact Information", "Optional Cover Letter", and "Submitting Official Information". The main content area includes a text box for instructions to the Letter of Support submitter, a unique identifier for the submission (501d098b-23fc-415d-b895-4ef5bc91f9bf), and a detailed explanation of the unique identifier's purpose. At the bottom, there are buttons for "Previous", "Next", "Validate", "Save", "Preview", and "Submit". The "Next" button is highlighted with a red box.

CSPP

Logged in as: Jane Doe, Primary Authorized Official
Log Out

Home Forms User Management Resources

Biotechnology
Primary Authorized Official
Biotechnology-20181003-15:49:55 EDT

Biotechnology (Biotechnology-20181003-15:49:55 EDT) > Letter of Support Submission Information

LETTER OF SUPPORT SUBMISSION INFORMATION

Please include instructions you wish the Letter of Support submitter to see. Clicking the link below will relay the information in this text box to your Letter of Support submitter via **unencrypted e-mail**.

Unique Identifier for Letter of Support Submission: 501d098b-23fc-415d-b895-4ef5bc91f9bf

This is the unique identification number for your Letter of Support submitter. The Secondary Submitter will need this identification number to complete the form. [Notify the Secondary Submitter of the Letter of Support submission.](#)

It is your responsibility to ensure that your secondary submitter understands how to complete the Biotechnology form and sends the information to EPA by the end of the submission period. The information collected in the primary and secondary form(s) will be linked by the unique identifier. The form will not undergo a review process until all forms have been received.

Previous Next

Validate Save Preview Submit

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995



OMB Control No. 2070-0038
Expiration 12/31/2025

From:	Jane.Doe@test.com
CC:	
To:	Enter email addresses separated by semicolons (;) or commas (.). Click in this box to start entering email addresses.
Subject:	2015 Biotechnology
Message:	As the Authorized Official of TEST COMPANY, I have identified you as a Secondary Submitter of a letter of support submission for this 2015 Biotechnology form. Please use the Section 5 Notices and Supports application to provide the correct information for the necessary items in this form. See the instructions below for accessing the Section 5 Notices and Supports application. You will need to use the unique identification number to access and complete the Biotechnology form for the letter of support submission. Unique Identifier 58220b1e-4c6f-4cad-99f4-464d2da527c8 Information about the Section 5 programs, how to access the Section 5 Notices and Supports application, and instructions for reporting under the Section 5 rule are available at www.epa.gov/oppt/newchems/. For additional information or if you believe you have received this email in error, please contact me.
Additional Comments:	
Send	

EPA Form No. 6300-07



Logged in as: Jane Doe, Primary Authorized Official

Log Out

HomeFormsUser ManagementResources

Biotechnology
Primary Authorized Official

Biotechnology-20171010-
13:50:24 EDT

Joint Submission Information

Remove

Add Joint Submission

Letter Of Support

Letter of Support 1

Letter of Support Submitter Information

Letter of Support Submission Information

Remove

Add Letter Of Support

Technical Contact Information

Optional Cover Letter

Submitting Official Information

CBI Substantiation

Instructions for Substantiating CBI Claims

Biotechnology (Biotechnology-20171010-13:50:24 EDT) > Technical Contact Information

?

TECHNICAL CONTACT INFORMATION

To add a new Technical Contact click the **Add Technical Contact** button.

Add Technical Contact

Last Name	First Name	Address	CBI	Actions
PreviousNext				

✓Validate

Save

Preview

Submit

CDX Homepage

MyCDX Homepage

EPA Homepage

Terms and Conditions

Privacy Notice

CDX Helpdesk: (888) 890-1995



ADD TECHNICAL CONTACT

Please enter information for the technical contacts that will be contacted to answer questions regarding information in the form. Check to claim information as CBI or click the 'Copy CDX Registration' button to populate from CDX (if applicable).

Click here to copy your information from CDX Registration: [Copy CDX Registration](#)

Check here to claim this information as CBI: ☐

First Name:

Last Name:

Position:

Company Name:

Phone Number:

(Do not enter any dashes (-) in Phone Number field above.)

Phone Extension:

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country:

[Cancel](#)

[OK](#)

OMB Control No. 2070-0038
Expiration 12/31/2025

EPA Form No. 6300-07

The screenshot displays the CSPP (Chemical Safety and Hazard Investigation) web application interface. At the top, a navigation bar includes links for Home, Forms, User Management, and Resources, along with a 'Log Out' button. The user is logged in as 'Jane Doe, Primary Authorized Official'. The main content area is titled 'Biotechnology (Biotechnology-20171010-13:50:24 EDT) > Optional Cover Letter'. Below this, the form is titled 'OPTIONAL COVER LETTER' and contains a text area for writing a cover letter. A checkbox labeled 'Check here to claim this information as CBI:' is present. At the bottom of the form are 'Previous' and 'Next' buttons. A left sidebar shows a tree view of the application's structure, including sections like 'Letter Of Support' and 'CBI Substantiation'. A bottom action bar contains icons for 'Validate' (a green checkmark), 'Save' (a floppy disk), 'Preview' (a computer monitor), and 'Submit' (a database cylinder). The footer includes links to the CDX Homepage, MyCDX Homepage, EPA Homepage, Terms and Conditions, Privacy Notice, and CDX Helpdesk.

Navigation: Click the 'Validate' icon (✓) located in the bottom action bar to validate the form.
Click the 'Save' icon (💾) located in the bottom action bar to perform a global save on the form.
Click the 'Preview' icon (🖥️) located in the bottom action bar to view a PDF preview of the

Biotechnology
Primary Authorized Official

Biotechnology-20170731-
12:05:42 EDT

- General Form Information
- Joint Submission**
 - Joint Submission 1**
 - Joint Submitter Information
 - Joint Submission Information
 - Remove
 - Add Joint Submission
- Letter Of Support**
 - Letter of Support 1**
 - Letter of Support Submitter Information
 - Letter of Support Submission Information
 - Remove
 - Add Letter Of Support
- Technical Contact Information
- Optional Cover Letter
- Submitting Official Information
- CBI Substantiation**
 - Instructions for Substantiating CBI Claims

Home
Forms
User Management
Resources

SUBMITTING OFFICIAL 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.

This confirmation is required to proceed with the submission process

Please confirm that you are the legally responsible party from ☐ the submitting company

CBI:	☒
First Name:	Jane
Middle Initial:	
Last Name:	Doe
Job Title:	Not Applicable
Company Name:	TESTORG
Phone Number:	
Email Address:	
Mailing Address 1:	TEST
Mailing Address 2:	
City:	TEST
State:	AL
Postal Code:	12345
Country:	US

Previous
Next

Validate

Save

Preview

Submit

CDX Homepage
MyCDX Homepage
EPA Homepage
Terms and Conditions
Privacy Notice
CDX Helpdesk: (888) 890-1995

EPA Form No. 6300-07



Logged in as: Jane Doe, Primary Authorized Official

Log Out

HomeFormsUser ManagementResources

Support
Primary Authorized Official

Support-20170720-13:06:36 EDT

General Form Information
Original Submitter Information
Submitting Official Information
CBI Substantiation
Instructions for Substantiating CBI Claims

Support (Support-20170720-13:06:36 EDT) > General Form Information

GENERAL FORM INFORMATION

The form alias is an optional field that changes the form name on the **Forms Screen**. Its purpose is to make it easier to distinguish between multiple forms. If an alias is not selected, the field will default to the date it was created. The form alias may be changed at any time.

Form Alias:

I. Original Notice Submission Information

Case Number:

TS Number:

IV. Type of Support

Check if requested by EPA/Contractor: ☐

V. Description or Explanation of Support CBI: ☒

Attach Document

File Name	Description	Subtype	Pages	CBI	Actions
-----------	-------------	---------	-------	-----	---------

Next

Validate

Save

Preview

Submit

CDX Homepage

MyCDX Homepage

EPA Homepage

Terms and Conditions

Privacy Notice

CDX Helpdesk: (888) 890-1995

OMB Control No. 2070-0038
Expiration 12/31/2025

EPA Form No. 6300-07

CSPP

Logged in as: Jane Doe, Primary Authorized Official [Log Out](#)

Home Forms User Management Resources

Support
Primary Authorized Official
Support-20170731-12:13:21 EDT

General Form Information
Original Submitter Information
Submitting Official Information
CBI Substantiation
Instructions for Substantiating CBI Claims

Support (Support-20170731-12:13:21 EDT) > Original Submitter Information

ORIGINAL SUBMITTER INFORMATION

Please enter the information of the Authorized Official who submitted the original PMN/Biotech/Bona Fide form for which you are filing a Support document.

Click here to copy your information from CDX Registration: [Copy CDX Registration](#)

Check here to claim this information as CBI: ☐

First Name:

Last Name:

Position:

Company Name:

Phone Number:
(Do not enter any dashes (-) in Phone Number field above.)

Phone Extension:

Email Address:

Mailing Address 1:
Street address, P.O. box, company name, etc.

Mailing Address 2:
Apartment, suite, etc.

City:

State:

Postal Code:

Country:

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

[Validate](#) [Save](#) [Preview](#) [Submit](#)

[CDX Homepage](#) | [MyCDX Homepage](#) | [EPA Homepage](#) | [Terms and Conditions](#) | [Privacy Notice](#) | [CDX Helpdesk: \(888\) 890-1995](#)

OMB Control No. 2070-0038
Expiration 12/31/2025

Navigation: Click the 'Validate' icon (✓) located in the bottom action bar to validate the form. Click the 'Save' icon (💾) located in the bottom action bar to save the overall form. Click the 'Preview' icon (🖨️) located in the bottom action bar to generate a PDF preview of the form.

EPA Form No. 6300-07



Logged in as: Jane Doe, Primary Authorized Official

Log Out

HomeFormsUser ManagementResources

Support

Primary Authorized Official

Support-20170731-12:13:21 EDT

General Form Information

Original Submitter Information

Submitting Official Information

CBI Substantiation

Instructions for Substantiating CBI Claims

SUBMITTING OFFICIAL 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.

CBI:

☒

First Name:

Jane

Middle Initial:

Last Name:

Doe

Job Title:

Not Applicable

Company Name:

TESTORG

Phone Number:

Email Address:

Mailing Address 1:

TEST

Mailing Address 2:

City:

TEST

State:

AL

Postal Code:

12345

Country:

US

Previous

Next



Validate



Save



Preview



Submit

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995



Logged in as: Jane Doe, Primary Authorized Official

Log Out

HomeFormsUser ManagementResources

Bona Fide (Bona Fide-20171010-14:35:14 EDT) > Class 1 or 2/Biotechnology Chemical Substances

CLASS 1 OR 2/BIOTECHNOLOGY CHEMICAL SUBSTANCES

Class 1 or 2/Biotechnology Chemical Substances

Chemical Identification Information

Expand All | Collapse All

Cancel

Class of Substance:

☐ Class 1 ☐ Class 2/Biotechnology

Click the button below to search EPA's Substance Registry Services (SRS) for the desired chemical.

Add Chemical ID

CASRN:

Chemical Name:

Generic Name:

ID Method

☐ Method 1 (CAS Inventory Expert Service) ☐ Method 2 (Other Method)

Attach IES Report

File Name	Description	Actions			
Molecular Formula: (optional)					
Chemical Structure Diagram: (optional)					
Include an attachment for the chemical structure diagram below.					
Attach Chemical Structure					
<table><thead><tr><th>File Name</th><th>Description</th><th>Actions</th></tr></thead><tbody></tbody></table>			File Name	Description	Actions
File Name	Description	Actions			

Save

Click the Add New Chemical button to add chemical name and structural information for a new chemical.

Add New Chemical

Previous

Next

Bona Fide

Primary Authorized Official

Bona Fide-20171010-14:35:14 EDT

General Document Information

Primary Contact Information

Technical Contact Information

Statement of Intent

Letter of Support

Letter of Support Submitter Information

Letter of Support Submission Information

Chemical

Chemical Identification Information

Chemical Alias

Class 1 or 2/Biotechnology Chemical Substances

Use Information

Site Information

Submitter Site Identification

Document Management

Optional Cover Letter

Submitting Official Information

CBI Substantiation

Instructions for Substantiating CBI Claims

Validate

Save

Preview

Submit

CDX Homepage

MyCDX Homepage

EPA Homepage

Terms and Conditions

Privacy Notice

CDX Helpdesk: (888) 890-1995

OMB Control No. 2070-0038
Expiration 12/31/2025

EPA Form No. 6300-07



Logged in as: Jane Doe, Primary Authorized Official

Log Out

Home

Forms

User Management

Resources

Bona Fide

Primary Authorized Official

Bona Fide-20170807-09:41:08 EDT

Letter of Support

Letter of Support Submitter Information

Letter of Support Submission Information

Chemical

Chemical Identification Information

Chemical 211751

Class 1 or 2/Biotechnology Chemical Substances

Class 2/Biotechnology Substances

Use Information

Site Information

Submitter Site Identification

Document Management

Optional Cover Letter

Submitting Official Information

CBI Substantiation

Instructions for Substantiating CBI Claims

Bona Fide (Bona Fide-20170807-09:41:08 EDT) > Class 2/Biotechnology Substances

CLASS 2/BIOTECHNOLOGY SUBSTANCES

Class 2/Biotechnology Substance Details

Fill in below for a class 2/biotechnology substance. (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition (where appropriate).

Precursor Substances

Search SRS Click the Search SRS button on the left to search or enter a precursor substance.

Chemical Name	CASRN	Action
---------------	-------	--------

Nature of Reaction

Range of Composition (Optional)

Validate

Save

Preview

Submit

CDX Homepage

MyCDX Homepage

EPA Homepage

Terms and Conditions

Privacy Notice

CDX Helpdesk: (888) 890-1995

Expiration 12/31/2025



Logged in as: Jane Doe, Primary Authorized Official

Log Out

Home

Forms

User Management

Resources

Bona Fide

Primary Authorized Official

Bona Fide-20170807-09:41:08 EDT

Letter of Support

Letter of Support Submitter Information

Letter of Support Submission Information

Chemical

Chemical Identification Information

Chemical 211751

Class 1 or 2/Biotechnology Chemical Substances

Class 2/Biotechnology Substances

Use Information

Site Information

Submitter Site Identification

Document Management

Optional Cover Letter

Submitting Official Information

CBI Substantiation

Instructions for Substantiating CBI Claims

Chemical Name

CASRN

Action

Nature of Reaction

Range of Composition (Optional)

Optional Attachments

Attach Document

File Name

Description

Action

Previous

Next

Validate

Save

Preview

Submit

CDX Homepage

MyCDX Homepage

EPA Homepage

Terms and Conditions

Privacy Notice

CDX Helpdesk: (888) 890-1995

EPA Form No. 6300-07

		NON-CBI SUBMISSION	
BIO2018P1		Form Approved. O.M.B. Nos. 2070-0012 and 2070-0038	
EPA Biotech Form			
Biotech Form Report Number			Mark (X) if anything is CBI ☐
I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for protection for any confidential information made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that the person submitting the claim has: (i) taken reasonable measures to protect the confidentiality of the information; (ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law; (iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering. Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.			
I. SUBMITTER IDENTIFICATION INFORMATION			CBI ☐
First Name		Last Name	
Position		Company	
Mailing Address (Number & Street)			
City		State	Postal Code
e-mail		Telephone (include area code)	
Ia. JOINT SUBMITTER -- If you are submitting this notice as part of a joint submission, mark (X) ☐			CBI ☐
First Name		Last Name	
Position		Company	
Mailing Address (Number & Street)			
City		State	Postal Code

EPA Form No. 6300-07

EPA Support Form						
Support Form Report Number				Mark (X) if anything is CBI		☐
I. ORIGINAL NOTICE SUBMISSION IDENTIFICATION						
Report Number		TS Number		Case Number		
Original Submission Date						
Original Submission Media Type						
II. ORIGINAL NOTICE SUBMITTER IDENTIFICATION						☐
Authorized Official Name		(first)		(last)		
Position				Company Name		
Mailing Address (Number & Street)						
City		State		Postal Code		
e-mail				Telephone (include area code)		
III. CURRENT SUPPORT DOCUMENT IDENTIFICATION INFORMATION						☐
Name		(first)		(last)		
Position				Company Name		
Mailing Address (Number & Street)						
City		State		Postal Code		
Province				Country		
e-mail				Telephone (include area code)		
IV. TYPE OF SUPPORT (Check One)						
☐		Transfer of Ownership				
☐		Suspension Request				
☐		Withdrawal Request				
☐		Other Correspondence				
☐		TEST DATA (Health/Eco/Fate)				
☐		Amendment (Changes made to PMN pages 1-13, MSDS or Physical/Chemical properties)				
Check if requested by EPA/ contractor						☐
EPA person/ contractor						
Submitter Signature						

OMB Control No. 2070-0038
Expiration 12/31/2025



SECTION 5 NOTICES AND SUPPORTS VALIDATION

Errors:

- **General Form Information**
 - ❗ [A Type of Notice is required.](#)
- **Technical Contact Information**
 - ❗ [Contact is required.](#)
- **Additional Submission Information**
 - ❗ [Values are required.](#)
- **Chemicals**
 - ❗ At least one chemical must be provided.
- **Joint Submission 1**
 - **Joint Submitter Information**
 - ❗ [First Name is required.](#)
 - ❗ [Last Name is required.](#)
 - ❗ [Company Name is required.](#)
 - ❗ [Phone Number is required.](#)
 - ❗ [Mailing Address 1 is required.](#)
 - ❗ [City is required.](#)
 - ❗ [Country is required.](#)
- **LOS Submission 1**
 - **Letter of Support Submitter Information**
 - ❗ [First Name is required.](#)
 - ❗ [Last Name is required.](#)
 - ❗ [Company Name is required.](#)
 - ❗ [Phone Number is required.](#)

[City is required.](#)
[Country is required.](#)

- **LOS Submission 1**
 - **Letter of Support Submitter Information**
 - [First Name is required.](#)
 - [Last Name is required.](#)
 - [Company Name is required.](#)
 - [Phone Number is required.](#)
 - [Mailing Address 1 is required.](#)
 - [City is required.](#)
 - [Country is required.](#)
 - **Site Information**
 - ['Do you have sites controlled by the submitter?' is required.](#)
 - ['Do you have sites controlled by others?' is required.](#)
 - **Submitting Official Information**
 - [Legal Verification is required to proceed with the submission process.](#)
 - **CBI Substantiation**
 - [CBI Substantiation attachment is required.](#)

Warnings:

- **Joint Submission 1**
 - **Joint Submitter Information**
 - [Email Address is not required, but is suggested for this contact.](#)
 - **Joint Submission Information**
 - [You did not notify the Secondary Submitter of the joint submission.](#)
- **LOS Submission 1**
 - **Letter of Support Submitter Information**
 - [Email Address is not required, but is suggested for this contact.](#)
 - **Letter of Support Submission Information**
 - [You did not notify the Secondary Submitter of the letter of support submission.](#)

Exhibit 14-3 Biotech Certification Screen



Logged in as: Jane Doe, Primary Authorized Official
Log Out

BIOTECH CERTIFICATION

I certify that to the best of my knowledge and belief:

The company named in this submission intends to manufacture, import, or process for a commercial purpose, other than in small quantities solely for research and development, the microorganism identified in this submission. All information provided in this submission is complete and truthful as of the date of submission. I am including with this submission all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by 40 CFR 725.160 or 725.260.

Cancel

I Certify

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995



Logged in as: Jane Doe, Primary Authorized Official
[Log Out](#)

SUBMISSION PROCESS: VALIDATION?


Validation



Make Payment



PDF Generation



CROMERR



Submit


Running validation on your data

Processing. Please wait...
(Please disable any pop-up blockers within your internet browser settings to allow for the validation pop-up to be displayed if validation errors are present.)

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

Exhibit 14-5 Make a Payment Screen



Logged in as: Jane Doe, Primary Authorized Official
[Log Out](#)

MAKE A PAYMENT


Validation


Make Payment


PDF Generation


CROMERR


Submit

If this is pending a joint and/or LOS submission(s), please enter an amount greater than 0 and less than or equal to the total payment amount. If you are not paying all or a portion of the amount due, check the 'Proceed without paying' checkbox to continue without paying. An email will be sent to notify the identified secondary submitter(s) if there is a remaining balance.

Total Due: \$16000.00
Payment Amount:

☐ Proceed without paying.

Make a Payment

Cancel

Continue

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

CSPP PAYMENT PROCESSOR



Payment Method

☒ Credit/Debit Card

☐ ACH Payment

Payer Information

Payment Amount

\$8000.00

Card Number *

Expiration Date *

01 / 2018

Security Code *

Account Holder Name *

First Name

Last Name

☐ Use a company name

Billing Address *

Address 1*

Address 2

City/State/Zip Code *

City

AK

Zip

Submit Payment

OMB Control No. 2070-0038
Expiration 12/31/2025

CSPP PAYMENT PROCESSOR



Payment Method

☐ Credit/Debit Card

☒ ACH Payment

Bank Account Transaction

Payment Amount

\$8000.00

Account Type *

Business Checking

Check Number

Account Holder Name *

First Name

Last Name

☐ Use a company name

Routing Number *

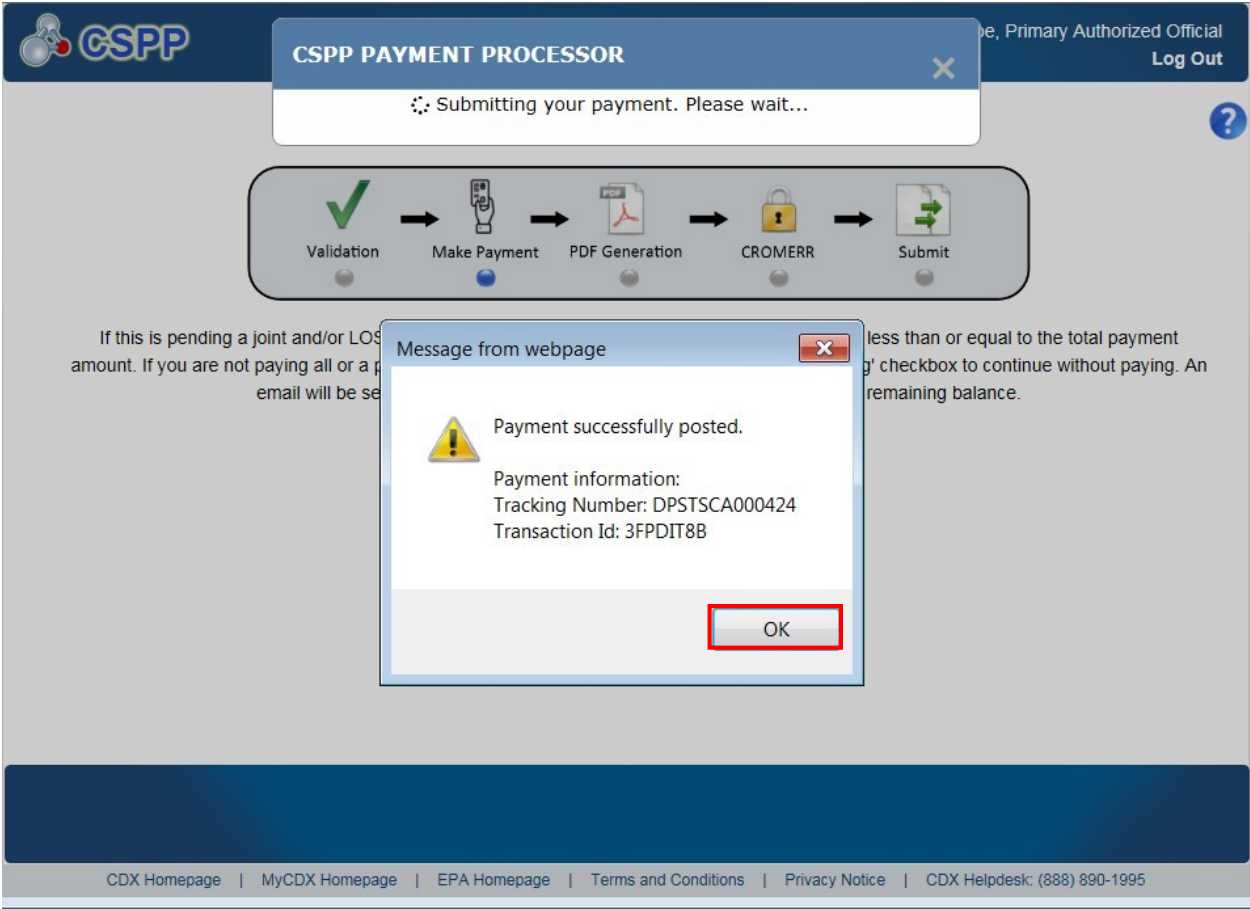
Account Number *

Confirm Account Number *

Submit Payment

OMB Control No. 2070-0038
Expiration 12/31/2025

Exhibit 14-8 Successful Payment



 Logged in as: Jane Doe, Primary Authorized Official
[Log Out](#)

SUBMISSION PROCESS: PDF GENERATION

?

Your PDF preview transaction was successfull



[View PDF](#) [Continue](#)

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995



Logged in as: Jane Doe, Primary Authorized Official
[Log Out](#)

CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) LOGIN

Validation

Make Payment

PDF Generation

CROMERR

Submit

Please login with your CDX password:

CancelNext

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

Exhibit 14-17 Submit to CDX Screen



Logged in as: Jane Doe, Primary Authorized Official
Log Out

SUBMIT TO CDX


Validation

→


Make Payment

→


PDF Generation

→


CROMERR

→


Submit

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for protection for any confidential information made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that the person submitting the claim has:

(i) taken reasonable measures to protect the confidentiality of the information;

(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

Cancel

Confirm

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995



Logged in as: Jane Doe, Primary Authorized Official
[Log Out](#)

CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) SUBMISSION?


Validation

→


Make Payment

→


PDF Generation

→


CROMERR

→


Submit

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

[Finish](#)

[CDX Homepage](#) | [MyCDX Homepage](#) | [EPA Homepage](#) | [Terms and Conditions](#) | [Privacy Notice](#) | [CDX Helpdesk: \(888\) 890-1995](#)

Exhibit 15-1 Download Copy of Record Screen

OMB Control No. 2070-0038
Expiration 12/31/2025

DOWNLOAD COPY OF RECORD

You can now download the Copy of Record for the ePMN submission



Download Copy of Record:

File Name	Action
Copy of Record	

Download Communication Documents:

Communication Type	File Name	File Size	Status	Download
--------------------	-----------	-----------	--------	----------

Fee Payment:

Payment Amount	Payment Date	Status	Transaction ID	Tracking Number
\$16,000.00	2018-09-17	Paid	3FPDKCB2	DPSTSCA000465

Invoice Payment Documents:

Payment Communication Type	File Name	File Status	Download	Payment Amount	Due Date	Payment Status	Payment Received Date	Make a Payment
Fee Payment	CdxCommunication91917e1d-bf15-4212-b2b5-8237354d1a85.pdf			\$10,000.00	2018-12-21	Unpaid	No Payment Information Available	Pay Your Invoice Now

Home





Logged in as: Jane Doe, Primary Authorized Official

Log Out

HomeFormsUser ManagementResources

SECTION 5 NOTICES AND SUPPORTS FORMS

- If submitting a form for the first time in the Section 5 Notices and Supports application, select the form type from the drop-down menu and click **Start New Form**.
- Only one Polymer Exemption submission per year should be filed per organization.
- To edit an In Progress form, click the form alias link in the **Alias** column in the table below.
- To access and edit a form previously submitted through CDX, unlock the form by clicking the lock () icon and enter the passphrase when prompted. All additional changes made to the form will be submitted as an amendment.
- To download a copy of record for a submitted form, click the green arrow () icon and enter the passphrase when prompted.
- You may delete any form that has not yet been submitted by clicking the delete () icon.
- All columns may be sorted by clicking the column header.

Page 1 of 1

3 items found.

Items Per Page: 25

Alias	Type	Subtype	Case Number	Status	Modify Date	Submission Date	Action
Primary PMN-20170712-16:25:43 EDT	Primary PMN	PMN		In Progress	07/12/2017		
Primary PMN-20170802-12:01:13 EDT	Primary PMN	LOREX_MODIFICATION		 Submitted	10/02/2017	10/02/2017	 
Polymer Exemption-20160707-15:20:37	Polymer Exemption		Y-16-0020	 Submitted	08/27/2016	08/27/2016	 

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

Exhibit 16-4 Enter Passphrase Screen

 Logged in as: Jane Doe, Primary Authorized Official
[Log Out](#)



ENTER PASSPHRASE

Please enter your form passphrase and click **Next**

Forgot 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 complete a new Section 5 Notices and Supports Form and create a new passphrase for the chemical substances you intend to import or manufacture.

[Cancel](#) [Next](#)

[CDX Homepage](#) | [MyCDX Homepage](#) | [EPA Homepage](#) | [Terms and Conditions](#) | [Privacy Notice](#) | [CDX Helpdesk: \(888\) 890-1995](#)



Logged in as: Jane Doe, Primary Authorized Official
Log Out

CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) LOGIN

Please login with your CDXweb password:

Cancel

OK

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995



Logged in as: Jane Doe, Primary Authorized Official
[Log Out](#)

[Home](#)
[Forms](#)
[User Management](#)
[Resources](#)

SECTION 5 NOTICES AND SUPPORTS FORMS

- If submitting a form for the first time in the Section 5 Notices and Supports application, select the form type from the drop-down menu and click **Start New Form**.
- Only one Polymer Exemption submission per year should be filed per organization.
- To edit an In Progress form, click the form alias link in the Alias column in the table below.
- To access and edit a form previously submitted through CDX, unlock the form by clicking the lock (🔒) icon and enter the passphrase when prompted. All additional changes made to the form will be submitted as an amendment.
- To download a copy of record for a submitted form, click the green arrow (📄) icon and enter the passphrase when prompted.
- You may delete any form that has not yet been submitted by clicking the delete (✖) icon.
- All columns may be sorted by clicking the column header.

26 items found

Page 1 of 2
 [Go to: 1, 2](#)

Items Per Page: 25

Alias	Type	Subtype	Case Number	Status	Modify Date	Submission Date	Action
Primary PMN-20180907-13:44:14 EDT	Primary PMN	PMN	P-18-0342	Submitted	09/07/2018	09/07/2018	📄 🔒
Primary PMN-20180918-16:42:41 EDT	Primary PMN	TMEA		In Progress	09/18/2018		✖
Primary PMN-20170712-16:25:43 EDT	Primary PMN	PMN		In Progress	07/12/2017		✖
Primary PMN-20180423-14:22:10 EDT	Primary PMN	PMN	P-18-0183	Submitted	05/16/2018	05/16/2018	📄 🔒
Primary PMN-20180914-11:42:28 EDT	Primary PMN	PMN	P-18-0361	In Progress	09/17/2018	09/17/2018	📄 📄 🔒
Polymer Exemption-	Polymer Exemption			In Progress	04/24/2018		✖

[CDX Homepage](#) |
 [MyCDX Homepage](#) |
 [EPA Homepage](#) |
 [Terms and Conditions](#) |
 [Privacy Notice](#) |
 [CDX Helpdesk: \(888\) 890-1995](#)

? OMB Control No. 2070-0038
 Expiration 12/31/2025

EPA Form No. 6300-07

Navigation: After clicking the 'Lock' icon (🔒), a prompt will display to confirm the

RESOURCES

Section 5 Notices and Supports User Guide

This guide describes each screen of the Section 5 Notices and Supports software and provides information on how to use the system to complete a Section 5 Notices and Supports form. The guide also contains instructions for registering with CDX, submitting the Section 5 Notices and Supports form, and amending a previous submission. You can download and print the guide for quick reference.

[User Guide](#)

Helpful Web Links

Click the link provided below to access additional information related to the Regulatory Impact Analysis for the Regulation of Microbial Products of Biotechnology: Government Costs.

[Regulatory Impact Analysis for the Regulation of Microbial Products of Biotechnology: Government Costs](#)

Click the link provided below to access additional information related to TSCA Biotechnology Regulations.

[Microbial Products of Biotechnology: Final Rule \(62 FR 17910\)](#)

Click the link provided below to access additional information related to Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms.

[Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms](#)

Click the link provided below to access additional information related to the Central Data Exchange (CDX).

[CDX Homepage](#)

Click the link provided below to access additional information related to the Toxic Substances Control Act (TSCA) Chemical Substances Inventory.

[TSCA Chemical Substances Inventory](#)

Click the link provided below to access additional information related to Substance Registry Services.

[Substance Registry Services \(SRS\)](#)

Click the link provided below to access additional information related to the Facility Registry System.

[Facility Registry System \(FRS\)](#)

Click the link provided below to access additional information related to Inventory Expert Services.

[CAS Inventory Expert Services](#)



Logged in as: Jane Doe, Primary Authorized Official
[Log Out](#)

HomeFormsUser ManagementResources

[Family Registry System \(FRS\)](#)

Click the link provided below to access additional information related to Inventory Expert Services.
[CAS Inventory Expert Services](#)

Click the link provided below to access additional information related to the National Pollutant Discharge Elimination System.
[National Pollutant Discharge Elimination System \(NPDES\)](#)

Click the link provided below to access additional information related to the New Chemicals Program.
[New Chemicals Program Homepage](#)

Click the link provided below to access information related to the status of Section 5 Notices.
[Status of Section 5 Notices](#)

Click the link provided below to access the instruction manual for reporting under the Toxic Substances Control Act §5 New Chemicals Program.
[Instruction Manual for Reporting Under the TSCA§5 New Chemicals Program](#)

Click the link provided below to access questions and answers for the New Chemicals Program under the Toxic Substances Control Act.
[Questions & Answers for the New Chemicals Program](#)

Click the link provided below to access information and guidance for new chemical submitters relating to new chemical notices, preparation of Pre-manufacture Notices, Significant New Use Notices, Exemption notices, EPA scientific approaches, and best practices.
[Points to Consider When Preparing TSCA New Chemical Notifications](#)

For technical assistance, please call CDX helpdesk at (888) 890-1995. For assistance on how to fill out the forms (content) or for policy questions, please call (202) 554-1404 Monday to Friday 8:30 a.m. - 5:00 p.m. EST or e-mail the TSCA Hotline at TSCA-Hotline@epamail.epa.gov.

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995