



Section 5 Notices and Supports User Guide – Primary Authorized Official

Environmental Protection Agency

Office of Pollution Prevention and Toxics

EPA# EPA-705-G-2021-3734

New Chemical Data Collection: OMB Control No. 2070-0012 and EPA ICR No. 0574

Existing Chemical Data Collection: OMB Control No. 2070-0038 and EPA ICR No. 1188

TSCA Fees Payment: OMB Control No. 2070-0208; EPA ICR No. 2569

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1 Introduction

This document presents the user guide for the Office of Pollution Prevention and Toxics (OPPT) Section 5 Notices and Supports application submission process. This document is the user guide for the Primary Authorized Official (AO) user of the Section 5 Notices and Supports application.

The Section 5 Notices and Supports application is the electronic, web-based tool provided by Environmental Protection Agency (EPA) for the submission of Section 5 Notices and Supports data. As a Primary AO, you can create, modify, and/or submit a Section 5 Notices and Supports form. You can also delete Section 5 Notices and Supports forms, create amendments, and download the Copy of Record (CoR).

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0038). Responses to this collection of information are mandatory for certain persons, as specified at 40 CFR 713.7. 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 30 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 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.

For questions concerning the Toxic Substances Control Act (TSCA) Section 5 Notices and Supports software requirements, please contact the Central Data Exchange (CDX) Help Desk at helpdesk@epacdx.net or call 1-888-890-1995 between the hours of 8 am – 6 pm Eastern Standard Time (EST). For questions concerning the TSCA Section 5 Notices and Supports reporting requirements, please contact the TSCA Hotline at TSCA-Hotline@epamail.epa.gov or call 202-554-1404 between the hours of 8:30 am – 5 pm EST.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies. The statements in this document are intended solely as guidance to aid in complying with EPA regulation.

2 System Requirements

To use the Section 5 Notices and Supports application to submit a Section 5 Notices and Supports form, the following are required:

- An e-mail account
- JavaScript enabled web browser
- Internet access
- Adobe Acrobat Reader 5.0 or higher
- CDX username and password

2.1 Supported Browsers

- Vendor supported versions of Internet Explorer (IE) or Edge

Go to the following link to download:

<https://support.microsoft.com/en-us/help/17621/internet-explorer-downloads>

- Vendor supported versions of Mozilla Firefox

Go to the following link to download:

<https://www.mozilla.org/en-US/firefox/new/>

- Vendor supported versions of Safari

Go to the following link to download:

<https://support.apple.com/downloads/>

- Vendor supported versions of Google Chrome

Go to the following link to download:

<http://www.google.com/chrome>

2.2 Screen Resolution

Screen resolution should be set to 1024 x 768 or greater.

3 Primary Authorized Official (AO) Functions

This section describes how to:

- Access the application
- Navigate the Section 5 Notices and Supports ‘Home’ screen
- Assign Supports to complete a form
- Start and complete the Section 5 Notices and Supports forms – Premanufacture Notice (PMN), Biotechnology, Notice of Commencement (NOC), Support, Bona Fide Notices, Alternative Control Measures (ACM) 721.30, and Pre-Notice Communication
- Upload an extensible markup language (XML) file
- Download a Copy of Record
- Create an amendment

The Primary AO is responsible for the submission of original main forms, including PMN, Biotechnology, NOC, Support, Bona Fide, ACM, or Pre-Notice Communication forms. As a Primary AO, you can create a new form. You are also responsible for submitting amendments, unlocking submissions, and deleting forms. You can assign Supports (or other authorized individuals) to edit and complete a form on your behalf. The Primary AO can be thought of as a primary company authorized official, specifically in regards to any sponsored individuals.

You can save the form at any point during the data entry process. The save functionality allows you to return to that same form at any point in the future. You can print the form at any point; however, the ‘Not for Submission’ watermark will be placed on the form anytime the form is printed prior to actual submission.

Exhibit 3-1 displays a table of the capabilities of user roles within the Section 5 Notices and Supports application:

Exhibit 3-1 Section 5 Notices and Supports User Roles Matrix

Legend	Primary Authorized Official		Primary Agent/Consultant		Primary Support		Secondary Authorized Official		Secondary Agent/Consultant		Secondary Support	
	(Primary Company Authorized Official)		(Primary Sponsored Authorized Official)				(Secondary Company Authorized Official)		(Secondary Sponsored Authorized Official)			
	US	non-US	US	non-US	US	non-US	US	non-US	US	non-US	US	non-US
Main forms (PMN, Biotechnology, Bona Fide, ACM, NOC, or Polymer Exemption)												
Create all original main forms	X	X	X	X								
Submit original main forms	X											
Submit original ACM forms	X	X	X	X								
Submit amendments (by editing the main forms)	X	X	X	X								
Unlock all main forms	X	X	X	X								
Edit unlocked main forms	X	X	X	X	X	X						
Delete forms	X	X	X	X								
Assign Supports	X	X										
Receive EPA Communications	X	X	X	X								
Support forms												
Create Support forms	X	X	X	X								
Submit original Support forms	X	X	X	X								
Submit amendment for older cases and other support forms	X	X	X	X								
Unlock support forms	X	X	X	X								
Edit unlocked support forms	X	X	X	X	X	X						
Delete forms	X	X	X	X								
Assign Supports	X	X										
Receive EPA Communications	X	X	X	X								
LOS submissions												
Create LOS for PMN, Biotechnology, or Bona Fide							X	X	X	X		
Submit original LOS for PMN, Biotechnology or Bona Fide							X	X				
Submit amendments to LOS submissions							X	X	X	X		
Unlock LOS for PMN, Biotechnology or Bona Fide							X	X	X	X		
Edit unlocked LOS forms							X	X	X	X	X	X
Delete forms							X	X	X	X		
Assign Supports							X	X				
Receive EPA Communications							X	X	X	X		
Joint submissions												
Create Joint for PMN or Biotechnology							X	X	X	X		
Submit original Joint for PMN or Biotechnology							X					
Submit amendments to Joint forms							X	X	X	X		
Unlock Joint for PMN or Biotechnology							X	X	X	X		
Edit Unlocked Joint forms							X	X	X	X	X	X
Delete forms							X	X	X	X		
Assign Supports							X	X				
Receive EPA Communications							X	X	X	X		

3.1 Log into Section 5 Notices and Supports Application

After you create an account in CDX, click the ‘Primary Authorized Official’ link for the Chemical Safety and Pesticide Programs (CSPP) data flow to navigate to the ‘Chemical Information Submission System’ screen.

Exhibit 3-2 shows a screen capture of the 'Chemical Information Submission System' screen (Scroll 1):

Exhibit 3-2 Chemical Information Submission System Screen (Scroll 1)

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.

Paperwork Reduction Act Notice


Section 5 Notices: Responses to this collection of information are mandatory (40 CFR 721). These collections of information are approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0012 and EPA ICR No. 0574 for new chemical submissions under TSCA section 5; and OMB Control No. 2070-0038 and EPA ICR No. 1188 for existing chemical significant new use notices). The annual public reporting and recordkeeping burden for this collection of information is estimated to average 92 hours per response for PMNs, SNUNs, and LVE and LOREX applications. The public reporting and recordkeeping burden for MCAN application is estimated to average 290 hours per response. The public reporting and recordkeeping burden for NOC submissions is estimated to average 0.8 hours per response.

TSCA User Fee Payment: Responses to this collection of information are mandatory (40 CFR 700.45). This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0208; EPA ICR No. 2569). The annual public reporting and recordkeeping burden for this collection of information is estimated to range between 5 and 10 minutes per response.

Burden is defined in 5 CFR 1320.3(b). 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. You may send comments regarding the EPA's

Exhibit 3-3 shows a screen capture of the ‘Chemical Information Submission System’ screen (Scroll 2):

Exhibit 3-3 Chemical Information Submission System Screen (Scroll 2)

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

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.

Paperwork Reduction Act Notice

Section 5 Notices: Responses to this collection of information are mandatory (40 CFR 721). These collections of information are approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0012 and EPA ICR No. 0574 for new chemical submissions under TSCA section 5; and OMB Control No. 2070-0038 and EPA ICR No. 1188 for existing chemical significant new use notices). The annual public reporting and recordkeeping burden for this collection of information is estimated to average 92 hours per response for PMNs, SNUNs, and LVE and LOREX applications. The public reporting and recordkeeping burden for MCAN application is estimated to average 290 hours per response. The public reporting and recordkeeping burden for NOC submissions is estimated to average 0.8 hours per response.

TSCA User Fee Payment: Responses to this collection of information are mandatory (40 CFR 700.45). This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0208; EPA ICR No. 2569). The annual public reporting and recordkeeping burden for this collection of information is estimated to range between 5 and 10 minutes per response.

Burden is defined in 5 CFR 1320.3(b). 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. You may send comments regarding the EPA'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. Please include the OMB Control No. in any correspondence. Send only comments to this address.

Navigation: To access the Section 5 Notices and Supports ‘Home’ screen, select ‘TSCA Section 5 Notices and Supports – ePMN’ from the submission type drop-down menu and click the ‘OK’ button.

3.2 Home Screen Navigation

You can access the Section 5 Notices and Supports ‘Home’ screen by selecting ‘TSCA Section 5 Notices and Supports – ePMN’ from the submission type drop-down menu on the ‘Chemical Information Submission System’ screen and clicking the ‘OK’ button.

The Section 5 Notices and Supports ‘Home’ screen is the first screen within the Section 5 Notices and Supports application. It provides you with links and tabs to access the ‘Section 5 Notices and Supports Forms,’ ‘User Management,’ and ‘Resources’ screens. To navigate to any of these screens, click the corresponding screen link (highlighted in blue text), or click the screen tab (located within the application header). The links and tabs provide the same functionality.

There is a ten (10) minute logout timer for this application; the application will automatically log you out after ten minutes of inactivity and navigate you back to the CDX login screen.

- **Forms:** Click the ‘Forms’ tab or link to navigate to the ‘Section 5 Notices and Supports Forms’ screen. You can create, modify, or delete a Section 5 Notices and Supports form using the ‘Section 5 Notices and Supports Forms’ screen. For additional details about the ‘Section 5 Notices and Supports Forms’ screen, please refer to **Section 3.4**.
- **User Management:** Click the ‘User Management’ link or tab to navigate to the ‘User Management’ screen. You can manage the access rights of Supports per form alias using the ‘User Management’ screen. For additional details about the ‘User Management’ screen, please refer to **Section 3.3**.
- **Resources:** Click the ‘Resources’ link or tab to navigate to the ‘Resources’ screen. You can find the Section 5 Notices and Supports user guide, as well as useful links for guidance documents on the ‘Resources’ screen. For additional details about the ‘Resources’ screen, please refer to **Section 18**.

Exhibit 3-4 shows a screen capture of the Section 5 Notices and Supports ‘Home’ screen:

Exhibit 3-4 Section 5 Notices and Supports Home Screen

Home Forms **User Management** Resources

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

HOME ?

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 1 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.

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Navigation: Click the ‘User Management’ link or tab to access the ‘User Management’ screen to assign Supports or Primary Agents/Consultants (if applicable).

3.3 User Management

You can access the ‘User Management’ screen by clicking the ‘User Management’ link on the Section 5 Notices and Supports ‘Home’ screen or by clicking the ‘User Management’ tab from the application header.

On the ‘User Management’ screen, you have the ability to assign one or more Supports or Primary Agents/Consultants to have access to modify any of the Section 5 Notices and Support forms you have created.

Form Alias: A form alias will not be available in this drop-down menu until one has been created. Select a form alias from the drop-down menu to begin assigning Supports or Primary Agents/Consultants. Once a form alias has been selected, the ‘Assign Users’ group box will update to display only the Supports or Primary Agents/Consultants who have identified you as their AO during CDX registration, or a user you have specified that is able to submit on your behalf.

Form Information: This field set displays information pertaining to the form you selected from the ‘Form Alias’ drop-down menu.

- **Form Alias:** Displays the form alias that a form is given.
- **TS Number:** Displays the toxic substances (TS) number that is entered for that specific form (if applicable).
- **Form Type/SubType:** Displays the type of form, which may include ‘Primary PMN,’ ‘Biotechnology,’ ‘NOC,’ ‘Support,’ ‘Bona Fide,’ ‘ACM,’ or ‘Pre Communication.’ This field also displays the subtype of the form, if applicable. NOC, Bona Fide, ACM, and Pre-Notice Communication forms do not have subtype values.
- **Last Modified:** Displays the date and time the form was last modified.

Assign Users: This box shows all the Supports or Primary Agents/Consultants you can assign to complete a Section 5 Notices and Supports form for the form alias selected. To move support persons from the ‘Unassigned’ group box to the ‘Assigned’ group box, highlight an individual or multiple Support(s) or Primary Agent(s)/Consultant(s) and click the ‘add >>’ button.

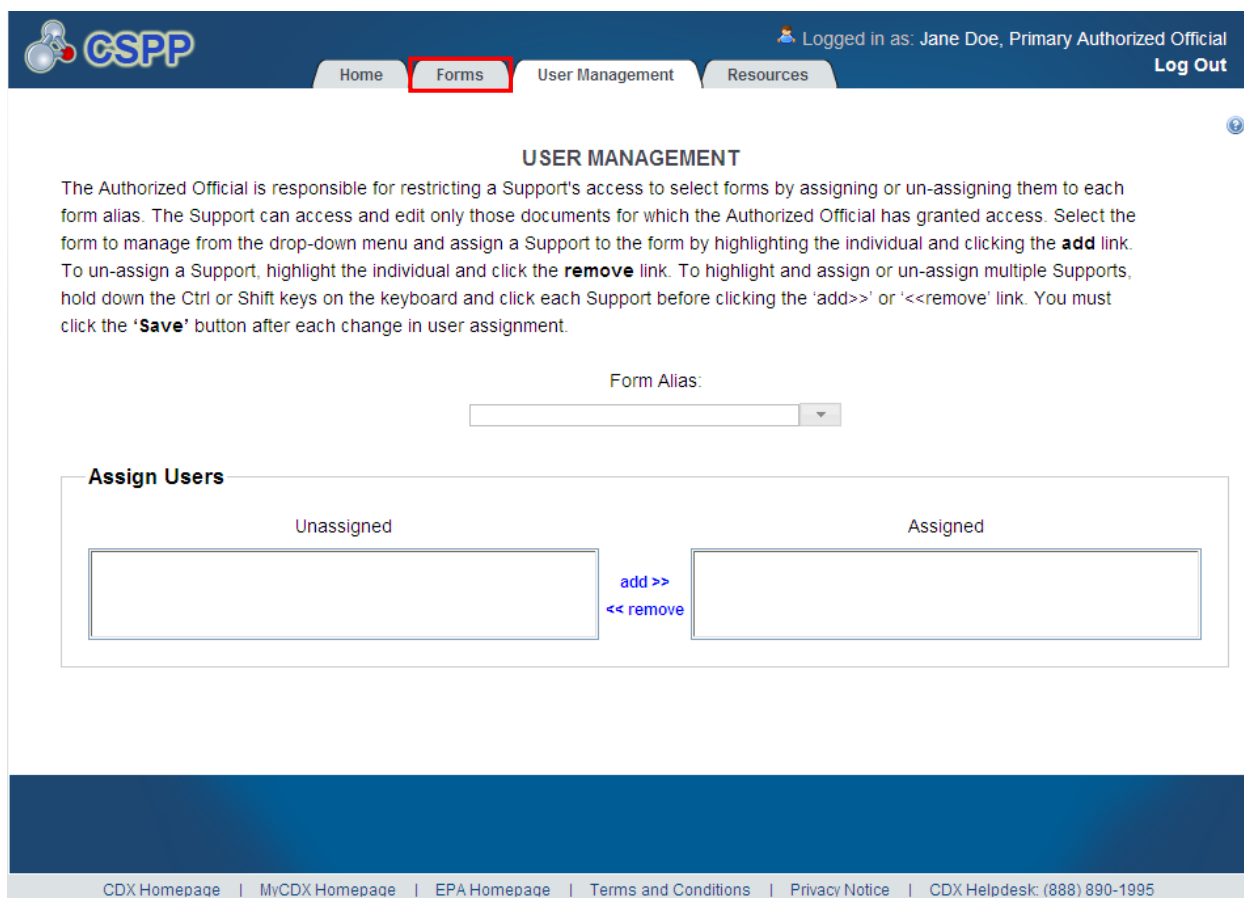
- **Unassigned:** This box/field contains the registered Support(s) and/or Primary Agent(s)/Consultant(s) associated with the AO who can potentially be assigned to access and edit the selected form. To move support persons from the ‘Unassigned’ group box to the ‘Assigned’ group box, highlight an individual or multiple support persons and click the ‘add >>’ button. To highlight multiple support persons hold down the <Ctrl> key on your keyboard while clicking each Support and/or Primary Agent/Consultant. To highlight multiple consecutive support persons, hold down the <Shift> key on your keyboard while clicking the first and last Support and/or Primary Agent/Consultant in the list.
- **Assigned:** This box/field contains the registered Support(s) and/or Primary Agent(s)/Consultant(s) given permission, by the AO, to access and edit the selected form. This group box shows all support persons assigned to complete the Section 5 Notices and Supports form for a single form alias. To move Supports and/or Primary Agents/Consultants from the ‘Assigned’ group box to the ‘Unassigned’ group box highlight individual or multiple support persons and click the ‘<< remove’ button. To highlight multiple support persons hold down the <Ctrl> key on your keyboard while clicking each Support and/or Primary Agent/Consultant. To highlight multiple consecutive support persons, hold down the <Shift> key on your keyboard while clicking the first and last Support and/or Primary Agent/Consultant in the list.

- **Add >>:** Click the button to move Supports and/or Primary Agents/Consultants from the ‘Unassigned’ box to the ‘Assigned’ box.
- **<< Remove:** Click the button to move Supports and/or Primary Agents/Consultants from the ‘Assigned’ box to the ‘Unassigned’ box.

When you have finished assigning the Supports and/or Primary Agents/Consultants, click the ‘Save’ button that displays after selecting a form to save the selection.

Exhibit 3-5 shows a screen capture of the ‘User Management’ screen:

Exhibit 3-5 User Management Screen



Navigation: Click the ‘Forms’ tab located within the application header to navigate to the ‘Section 5 Notices and Supports Forms’ screen.

3.4 Section 5 Notices and Supports Forms

You can access the ‘Section 5 Notices and Supports Forms’ screen by clicking the ‘Forms’ link from the Section 5 Notices and Supports ‘Home’ screen, or by clicking the ‘Forms’ tab located within the application header.

Only one Section 5 Notices and Supports form is created per form alias, which helps differentiate between forms. Each column within the table of the ‘Section 5 Notices and Supports Forms’ screen can be sorted by clicking the individual column headers.

Start New Form: To create a new Section 5 Notices and Supports form, select one of the following options from the ‘Form Type’ drop-down menu and click the ‘Start New Form’ button: ‘Premanufacture Notice (PMN),’ ‘Support,’ ‘Notice of Commencement (NOC),’ ‘Biotechnology,’ ‘Bona Fide,’ ‘Alternative Control Measures (ACM),’ or ‘Pre-Notice Communication.’ You are required to create a passphrase that will be associated with that particular form. Make sure to create a passphrase that you will remember, as it cannot be retrieved or reset. Refer to **Section 3.5** for further instructions on creating a passphrase.

Edit an ‘In Progress’ Form: To modify an existing Section 5 Notices and Supports form, click the ‘Alias’ link for a form with a status of ‘In Progress.’ You are required to enter the passphrase associated with that particular form to access and edit the form. It is possible for more than one user to modify a form simultaneously; the user that clicks the ‘Save’ button first will have his/her changes saved. Refer to **Section 16** for further instructions on viewing and modifying a form that is ‘In Progress.’

Amend a submitted form: To edit an already submitted Section 5 Notices and Supports form (i.e., to create an amendment), you must first unlock the particular submission by clicking the ‘Lock’ icon (🔒) under the ‘Action’ column. You will be required to enter the passphrase associated with that particular submission to gain access and continue amending the submission. All further changes that are made will be submitted as an amendment. Refer to **Section 16** for further instructions on creating an amendment.

The ‘Section 5 Notices and Supports Forms’ screen displays the following columns of information:

- **Alias:** Displays the form alias you provided on the ‘General Form Information’ screen within a PMN, Biotechnology, NOC, or Support form; the ‘General Document Information’ screen within a Bona Fide Notice; or the ‘Contact Information’ screen within an ACM form. The ‘Alias’ column will display a default alias comprised of a form type, date stamp, and time stamp in the following format: <Form Type-YYYYMMDD-HH:MM:SS Time Zone> if you accept the system-generated ‘Form Alias’ on the first screen in a Section 5 Notices and Supports form. A form alias is helpful when a user or company has multiple forms and/or when you must differentiate between forms. Click the form alias link to navigate to the ‘Enter Passphrase’ screen to access a form.
- **Type:** Displays the form type pertaining to the reported chemical substance or mixture. This column can contain the following values: ‘Primary PMN,’ ‘Biotechnology,’ ‘Support,’ ‘NOC,’ ‘Bona Fide,’ or ‘ACM.’
- **Subtype:** Displays the form subtype pertaining to the form type for the reported chemical substance or mixture.
 - This column contains one of the following values for a PMN form: ‘MOCK_SUBMISSION,’ ‘LOREX_MODIFICATION,’ (Low Release/Low Exposure Exemption Modification) ‘LVE_MODIFICATION,’ (Low Volume Exemption Modification) ‘LOREX,’ ‘LVE,’ ‘TMEA,’ (Test Marketing Exemption Application) ‘SNUN,’ (Significant New Use Notice) or ‘PMN.’
 - This column contains the following values for a Biotechnology form: ‘MCAN,’ (Microbial Commercial Activity Notice) ‘TERA,’ (TSCA Experimental Release

- Application) ‘TIER1,’ ‘TIER2,’ or ‘Biotechnology_TME’ (Biotechnology Test Market Exemption).
- This column contains the following values for a Support form: ‘Amendment,’ ‘Test Data,’ ‘Transfer Of Ownership,’ ‘Withdrawal Request,’ ‘Suspension Request,’ or ‘Other Correspondence.’
 - NOC forms, ACM forms, Bona Fide Notices, and Pre-Notice Communication forms do not have subtypes.
- **Case Number:** Displays the form case number pertaining to the reported chemical substance or mixture after EPA receives the submission. In all cases, the ‘XX’ represents the fiscal year in which the form was submitted, and the ‘XXXX’ represents the order in which the form was received. A consolidated submission will generate sequential case numbers for each chemical identified within the form and will display all case numbers associated with that specific form. If the form has not been submitted and received, the ‘Case Number’ field remains blank.
 - A PMN submission can have the following case number formats: P-XX-XXXX for PMN, SN-XX-XXXX for SNUN, L-XX-XXXX for LVE, LM-XX-XXXX for LVE Modifications, X-XX-XXXX for LOREX, XM-XX-XXXX for LOREX Modifications, T-XX-XXXX for TMEA, and I-XX-XXXX for Mock PMN notice types.
 - A Biotechnology form can have the following case number formats: J-XX-XXXX for MCAN, R-XX-XXXX for TERA, G-XX-XXXX for Tier I Exemption, and H-XX-XXXX for Tier II.
 - Bona Fide forms will have a case number format of BF-XX-XXXX.
 - ACM forms will have a case number format of ACM-XX-XXXX.
 - NOC and Support forms will display user-specified case numbers.
 - Pre-Notice Communication forms will have a case number format of PC-XX-XXXX.
 - **Status:** Displays the status of the Section 5 Notices and Supports form. The values will display as either ‘In Progress’ or ‘Submitted.’
 - **Modify Date:** Displays the date the form was last modified.
 - **Submission Date:** Displays the date the form was submitted to EPA via CDX. This date populates only after the form has been submitted.
 - **Action:** Click the ‘Copy of Record’ icon (📄) to access the ‘Copy of Record’ screen. The ‘Copy of Record’ icon (📄) displays only after the form has been completed. Refer to **Section 15** for further instructions on downloading the Copy of Record. Click the ‘Delete’ icon (✖) to delete any form with a status of ‘In Progress.’ This column also displays a ‘Lock’ icon (🔒) for all forms that have been submitted and are not ‘In Progress.’ Only an AO or Primary Agent/Consultant can unlock a form by clicking the ‘Lock’ icon (🔒) and unlocking the form. The form will remain unlocked and display the ‘Unlocked’ icon (🔓) until the form is resubmitted by the AO. Click the red ‘Download and Pay Unpaid Invoices’ icon (\$) to access the ‘Copy of Record’ screen to pay the fee. The ‘Download and Pay Unpaid Invoices’

icon displays only after personnel sends an invoice. After a user pays the invoice, the icon disappears.

- **Items Per Page:** Select a value ('25,' '50,' '75,' or '100') from this drop-down menu to specify the number of forms to display on a single page.
- **Export Options:** Displays 'CSV,' 'Excel,' 'XML,' and 'PDF' links for you to export the 'Section 5 Notices and Supports Forms' screen in one of the specified formats as a Comma-Separated Values (CSV) file, XML file, an Excel spreadsheet, XML file, or portable document format (PDF). The export options section will not display until a form is created.
- **Form Type:** Select the form type that you would like to create from the drop-down menu. This drop-down menu contains the following values: 'Premanufacture Notice (PMN),' 'Support,' 'Notice of Commencement (NOC),' 'Biotechnology,' 'Bona Fide,' 'Alternative Control Measures (ACM),' and 'Pre-Notice Communication.' This drop-down menu is only available to Primary Authorized Officials and Primary Agents/Consultants.
- **Start New Form:** Click this button to start a new form after selecting a form type and navigate to the 'Create Passphrase' screen.

Exhibit 3-6 shows a screen capture of the ‘Section 5 Notices and Supports Forms’ screen:

Exhibit 3-6 Section 5 Notices and Supports Forms Screen (Scroll 1)

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.

40 items found
Page 2 of 2
Go to: [1](#), [2](#)
Items Per Page:

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		❌

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Exhibit 3-7 shows a screen capture of the ‘Section 5 Notices and Supports Forms’ screen:

Exhibit 3-7 Section 5 Notices and Supports Forms Screen (Scroll 1)

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

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

Export options: [CSV](#) | [Excel](#) | [XML](#) | [PDF](#)

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

Form Type:

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Navigation: Select a form type from the ‘Form Type’ drop-down menu and click the ‘Start New Form’ button to navigate to the ‘Create Passphrase’ screen.

3.5 Create Passphrase

To start a new Section 5 Notices and Supports form, select a form type from the ‘Form Type’ drop-down menu, and click the ‘Start New Form’ button on the ‘Section 5 Notices and Supports Forms’ screen to navigate to the ‘Create Passphrase’ screen, which allows you to create a passphrase and associate that passphrase with your newly created form.

The application uses the passphrase as an encryption key to protect the contents of the form. You are responsible for remembering the passphrase and distributing it to the appropriate individuals.

If you forget the passphrase, you will not have access to the form and will not be able to view, print, submit, or make changes. If you lose or forget the passphrase, you must create a new form and passphrase. For security reasons, the system administrator does not have access to the passphrase and will not be able to retrieve it or reset it to a new one.

New Passphrase: To associate a passphrase with a form, enter a passphrase that is at least eight (8) characters in length. 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 *). You can associate the same passphrase with multiple forms.

You will be responsible for remembering the passphrase and distributing it to only authorized Supports for an individual form. If you forget the passphrase, you will not be able to access the Section 5 Notices and Supports form to print, submit, or make changes.

Exhibit 3-8 shows a screen capture of the ‘Create Passphrase’ screen for a Primary Authorized Official:

Exhibit 3-8 Create Passphrase Screen

Navigation: Create a passphrase and click the ‘Next’ button to navigate to the ‘General Form Information’ screen in a PMN, Biotechnology, NOC, or Support form. Click the ‘Next’ button to

navigate to the 'General Document Information' screen in a Bona Fide Notice. Click the 'Next' button to navigate to the 'Contact Information' screen in an ACM form.

3.6 Attach Documents

The 'Attach Document' button displays on various screens within a Section 5 Notices and Supports form, and provides functionality for you to attach supporting documents where needed. Click the 'Attach Document' button displayed on a screen to access the 'Attach Documents' pop-up window. You can attach a file and enter a description, number of pages, and indicate CBI status. The size of the file that can be attached is unlimited; however, the application prevents a user from uploading an empty document.

The system allows you to claim an uploaded document as CBI. If you claim a document as CBI, the system requires you to upload a sanitized version of the attached document. If you wish to change a CBI attachment to be non-CBI by un-checking the 'CBI' checkbox, a warning appears to notify you that un-checking the 'CBI' checkbox will delete the sanitized file. If you neglect to populate a required field and click the 'OK' button, an error message will display to indicate the missing field and the application will delete the previously attached file.

After you upload a document to be attached, the 'Attach Documents' pop-up window will close and the document's information will display in a table format on the screen. Depending on the screen, the attachment table may display the section of the page the file is associated with, the file name and file extension of the document, a description of the document, the number of pages in the document, and if the document was claimed CBI. The system allows you to delete unwanted documents by clicking the 'Delete' icon (✖) located under the 'Actions' column. To view, open, or edit previously attached documents, click the appropriate file name of the document within the 'File Name' column of the document table to view previously entered document information.

- **Type:** Select the document type from the drop-down menu of the document that you upload. For additional information regarding document types, refer to Exhibit 3-9. This is a required field.
- **Subtype:** Select the document subtype from the drop-down menu of the document that you upload. For additional information regarding document subtypes, refer to Exhibit 3-9. This is a required field when displayed.
- **Attachment:** Click the 'Browse' button to generate the 'File Upload' window to search for a document on your hard drive. The application prevents the upload of empty documents. The attached file can be one of the following file types: .pdf, .ppt, .pptx, .xls, .xlsx, .doc, .docx, .rtf, .txt, .gif, .jpg, .png, .bpm, .fas, .gbk, or .embl.
- **Description:** Enter a description associated with the attached document. Submitters should not include any CBI information in the document description. This is a required field.
- **Number of Pages:** Enter the number of pages in a document. This is a required field.
- **Check to claim the attachment as CBI:** Check the 'CBI' checkbox to claim the attached document as confidential. Un-checking the 'CBI' checkbox for a CBI document generates a warning notifying you that un-checking the CBI claim will delete the sanitized file.

- **Sanitized Attachment:** Click the ‘Browse’ button to generate the ‘File Upload’ window to search for a document on your hard drive. The attached file can be one of the following file types: .pdf, .ppt, .pptx, .xls, .xlsx, .doc, .docx, .rtf, .txt, .gif, .jpg, .png, .bpm, .fas, .gbk, or .embl. For any attached document claimed as CBI, you will be required to attach a sanitized version of the document.
- **Cancel:** Click the ‘Cancel’ button to cancel the attach document process.
- **OK:** Click the ‘OK’ button to attach and link the document uploaded on the ‘Attach Documents’ window to the form. If a field is missing, a warning message will display notifying you that all attachments must be re-attached and the missing field must be populated.

Exhibit 3-9 shows a table of the document types and subtypes for each Section 5 Notices and Supports form:

Exhibit 3-9 Section 5 Document Types and Subtypes

Form Type	Document Type	Document Subtypes
PMN, Support	Aquatic Ecotoxicity	<ul style="list-style-type: none"> • Algae Toxicity • Fish Acute Toxicity • Fish Chronic Toxicity • Invertebrate Acute Toxicity • Invertebrate Chronic Toxicity
	Chemical Structure Diagram	<ul style="list-style-type: none"> • Not applicable (N/A)
	Correspondence	<ul style="list-style-type: none"> • N/A
	Fate	<ul style="list-style-type: none"> • BCF/BAF (bioconcentration factors / bioaccumulation factors) • Biodegradation • Fugacity • Hydrolysis • Monitoring data (e.g., air, water, soil, biota, human) • Partitioning (e.g., Koc, Kd, Kow, Koa, Henry's law constant) • Photolysis
	GPC	<ul style="list-style-type: none"> • N/A
	Genetic Toxicity	<ul style="list-style-type: none"> • Chromosomal Aberrations Assay • Genetic Mutation Assay • Unscheduled DNA (Deoxyribonucleic acid) Synthesis

Form Type	Document Type	Document Subtypes
	Health Toxicity	<ul style="list-style-type: none"> • Acute Toxicity • Carcinogenicity • Combined Repeated-Dose/Developmental/Reproductive Toxicity • Dermal Irritation • Developmental Toxicity • Eye Irritation • Immunotoxicity • Neurotoxicity • Pharmacokinetics/Metabolism • Repeated-Dose Toxicity • Reproductive Toxicity • Sensitization
	IES Report	<ul style="list-style-type: none"> • N/A
	Other	<ul style="list-style-type: none"> • A free text field generates for a user to provide a description of the document type
	Process Diagram - Other	<ul style="list-style-type: none"> • N/A
	Process Diagram – Submitter	<ul style="list-style-type: none"> • N/A
	Safety Datasheet	<ul style="list-style-type: none"> • MSDS/SDS (material safety data sheet / safety data sheet) • Technical Datasheet
	Terrestrial Ecotoxicity	<ul style="list-style-type: none"> • Avian Toxicity • Invertebrate Toxicity • Plant Toxicity
	CBI Substantiation	<ul style="list-style-type: none"> • N/A
Biotechnology	Published Literature	<ul style="list-style-type: none"> • N/A
	Regs and Certifications	<ul style="list-style-type: none"> • N/A
	ID	<ul style="list-style-type: none"> • Identification (ID) Sequence Data • Other ID Data • Strain History

Form Type	Document Type	Document Subtypes
	Construct	<ul style="list-style-type: none"> • Construct Methodology • Construct Data • Gene Sequence Data • Plasmid Data
	Effects	<ul style="list-style-type: none"> • Human Health Effects • Environmental Effects • Pathogenicity Data • Antibiotic Resistance • Metabolism • Allergenicity Data
	MSDS	<ul style="list-style-type: none"> • N/A
	Manufacturing Details	<ul style="list-style-type: none"> • N/A
	Use Details	<ul style="list-style-type: none"> • N/A
	Inactivation Data	<ul style="list-style-type: none"> • N/A
	CBI Substantiation	<ul style="list-style-type: none"> • N/A
	Other	<ul style="list-style-type: none"> • A free text field generates for a user to provide a description of the document type
Bona Fide	Spectrum of Substance	<ul style="list-style-type: none"> • N/A
	Statement of Commercialization	<ul style="list-style-type: none"> • N/A
	Statement of Research and Development	<ul style="list-style-type: none"> • N/A
	CBI Substantiation	<ul style="list-style-type: none"> • N/A
	Other	<ul style="list-style-type: none"> • A free text field generates for a user to provide a description of the document type
NOC	CBI Substantiation K	<ul style="list-style-type: none"> • N/A
	CBI Substantiation	<ul style="list-style-type: none"> • N/A
ACM	N/A	<ul style="list-style-type: none"> • N/A
	CBI Substantiation	<ul style="list-style-type: none"> • N/A
	Other	<ul style="list-style-type: none"> • A free text field generates for a user to provide a description of the document type

Exhibit 3-10 shows a screen capture of the ‘Attach Documents’ pop-up window that displays within the majority of forms:

Exhibit 3-10 Attach Documents Pop-Up Window

Navigation: Click the ‘Cancel’ button or ‘X’ icon in the upper right-hand corner to cancel the document attachment process. Click the ‘OK’ button to attach the document to the form and navigate back to the original screen from which the document attachment process was initiated.

3.7 Enter Passphrase

To edit a form click the ‘Alias’ link for a Section 5 Notices and Supports form with a status of ‘In Progress’ on the ‘Section 5 Notices and Supports Forms’ screen. The ‘Enter Passphrase’ screen requires you to enter the passphrase that is associated with the form.

Enter Passphrase: Enter the passphrase that you originally created and associated with the form.

Exhibit 3-11 shows a screen capture of the ‘Enter Passphrase’ screen:

Exhibit 3-11 Enter Passphrase Screen

Navigation: Enter the passphrase that you originally created and associated with the form and click the ‘Next’ button to navigate to the ‘General Form Information’ screen in a PMN, Biotechnology, NOC, or Support form. Click the ‘Next’ button to navigate to the ‘General Document Information’ screen in a Bona Fide Notice. Click the ‘Next’ button to navigate to the ‘Contact Information’ screen in an ACM form.

3.8 Navigation Tree

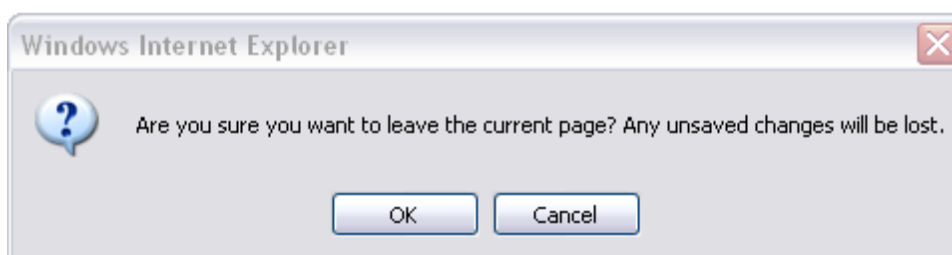
The navigation tree is located on the left hand side of each screen. It allows you to navigate between the various screens within the application and the different sections of the form. You can perform the following functions using the navigation tree:

- **Open and close the navigation tree:** A navigation arrow that opens and closes the navigation tree is located to the right of the navigation tree to provide more visual form space. Click the arrow (◀) on the open navigation tree to close the navigation tree and increase the space of the form content. Likewise, click the arrow (▶) on the closed navigation tree to open the navigation tree.
- **Collapse and expand folders:** Each section of the form falls under a collapsible folder within the navigation tree, which allows you to save space or easily view items in the navigation tree. When a folder is expanded, you can click the minus sign (-), the ‘Folder’ icon (📁), or the folder title link to collapse that section of the navigation tree. When a folder is collapsed, you can click the plus sign (+), the ‘Folder’ icon (📁), or the folder title link to expand that section of the navigation tree. When you place your cursor over a folder title link, it will highlight in red.

- **Navigate between screens:** You can use the navigation tree to navigate between the various screens within the application and the different sections of the form. A ‘Form’ icon (📄) denotes each section of a form. Click a ‘Form’ icon (📄) or a section title link to navigate between screens. You are required to save all information entered on a particular screen before navigating to the next screen or all entered information will be lost. A prompt will appear after you click a link in the navigation tree indicating, ‘Are you sure you want to leave the current page? Any unsaved changes will be lost.’ Click the ‘OK’ button to navigate to the requested screen without saving any of the data in the previous screen. Click the ‘Cancel’ button to close the prompt and remain on the current screen.

Exhibit 3-12 shows a screen capture of the navigation prompt pop-up window:

Exhibit 3-12 Navigation Prompt Pop-Up Window



- **Add Joint Submission:** Click the ‘Add Joint Submission’ link located under the ‘Joint Submission’ folder within the navigation tree to add a Joint Submission. A maximum of two Joint Submissions can be added to a PMN form.
- **Add Letter of Support:** Click the ‘Add Letter of Support’ link located under the ‘Letter of Support’ folder within the navigation tree to add a Letter of Support (LOS). An unlimited number of Letters of Support can be added to a PMN form.
- **Add Consolidated Chemical:** Click the ‘Add Consolidated Chemical’ link within the navigation tree to add a chemical within a consolidated submission and select the ‘Class 1 or 2 Chemical Substance’ or ‘Polymer’ radio button on the ‘Chemical Identification’ screen. A maximum of six (6) separate chemical folders can be added to a PMN form. The ability to add a consolidated chemical within a PMN form is unavailable when creating a PMN amendment.
- **Delete chemical folders:** Click the ‘Delete’ icon (✖) that displays at the bottom of each chemical folder within the navigation tree of a PMN form to delete specific chemical folders. When a chemical folder is deleted, all information entered within the deleted chemical folder is lost and cannot be retrieved. Click the ‘Add Consolidated Chemical’ link and fill in all corresponding data to add a new chemical report. This delete functionality is not applicable to the Biotechnology, NOC, Support, Bona Fide Notice, or ACM forms, and is unavailable when amending a PMN form.
- **Copy chemical folders:** Click the ‘Copy’ icon (📄) that displays at the bottom of each chemical folder within the navigation tree of a PMN form to copy a specific chemical folder. When a chemical folder is copied, the chemical name, Chemical Abstracts Service Registry Number (CASRN), and attached documents are removed from the copied chemical. This

copy functionality is not applicable to the Biotechnology, NOC, Support, Bona Fide, or ACM forms, and is unavailable when amending a PMN form.

- **Delete ‘Submitter Controlled Operations’ or ‘Operations Controlled By Others’ folders:** Click the ‘Delete’ icon (✖) that displays at the bottom of each ‘Submitter Controlled Operations’ or ‘Operations Controlled by Others’ folder within the navigation tree to delete a specific operations folder. When a ‘Submitter Controlled Operations’ or ‘Operations Controlled by Others’ folder is deleted, all information entered within the deleted operation is lost and cannot be retrieved. Click the ‘Add Operation’ link under the appropriate operations folder and fill in all corresponding data to add a new ‘Submitter Controlled Operations’ or ‘Operation Controlled by Others’ folder. The delete functionality is not applicable while a user is navigating on a screen within the ‘Operations Controlled by Others’ folder. This delete functionality is not applicable to the Biotechnology, NOC, Support, Bona Fide Notices, or ACM forms.
- **Upload XML:** The system displays an ‘Upload XML’ button in the navigation tree to allow a user to upload an XML file into a PMN form or joint PMN form, or to export an existing PMN form into an XML file format. A user may also upload eTSCA thick client files into a PMN form. If an XML file is uploaded into an existing form, the contents of that XML file overwrite the contents within the PMN form. For more information about the upload XML functionality, refer to **Section 4.1.36**.

Exhibit 3-13 shows a screen capture of the Premanufacture Notice navigation tree (Scroll 1):

Exhibit 3-13 Premanufacture Notice (PMN) Navigation Tree (Scroll 1)

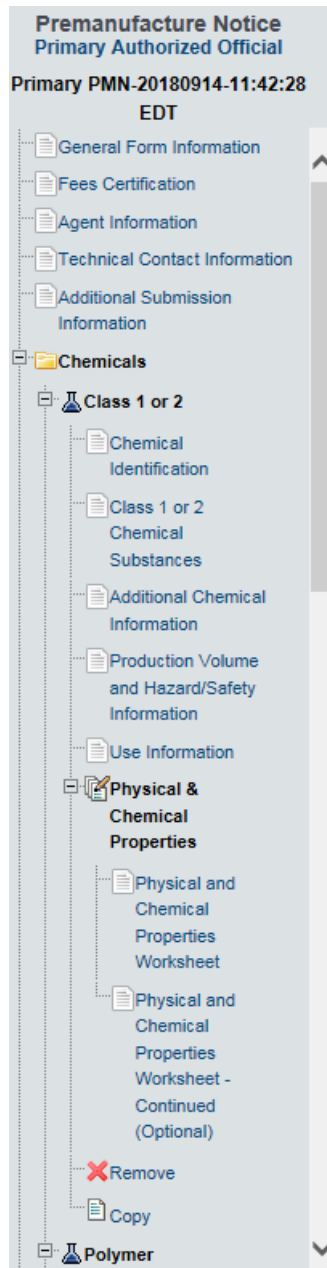


Exhibit 3-14 shows a screen capture of the Premanufacture Notice navigation tree (Scroll 2):

Exhibit 3-14 Premanufacture Notice (PMN) Navigation Tree (Scroll 2)

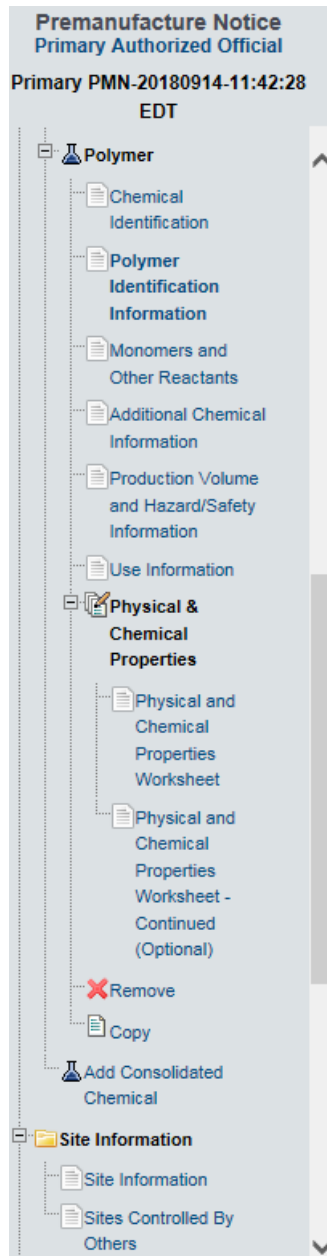


Exhibit 3-15 shows a screen capture of the Premanufacture Notice navigation tree (Scroll 3):

Exhibit 3-15 Premanufacture Notice (PMN) Navigation Tree (Scroll 3)



Exhibit 3-16 shows a screen capture of the Premanufacture Notice navigation tree (Scroll 4):

Exhibit 3-16 Premanufacture Notice (PMN) Navigation Tree (Scroll 4)

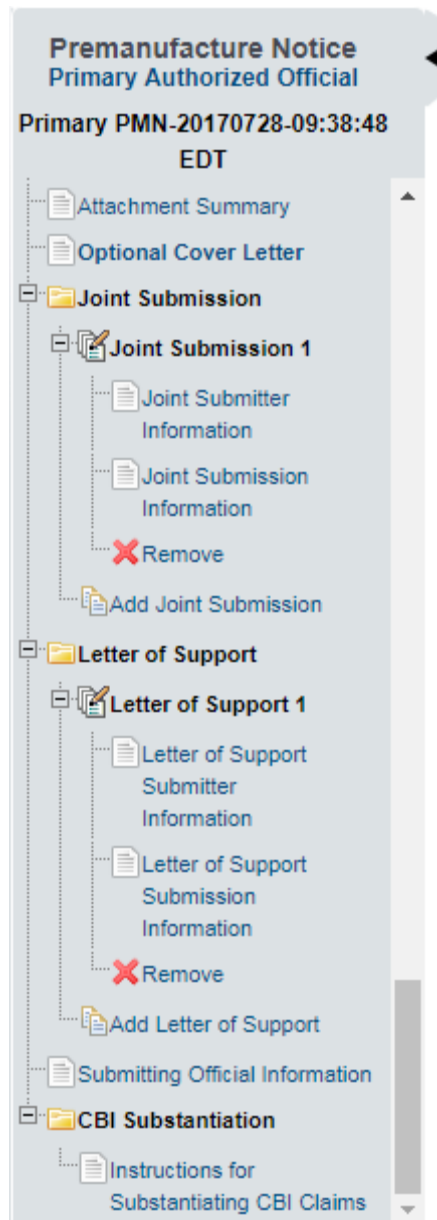


Exhibit 3-17 shows a screen capture of the Biotechnology navigation tree:

Exhibit 3-17 Biotechnology Navigation Tree

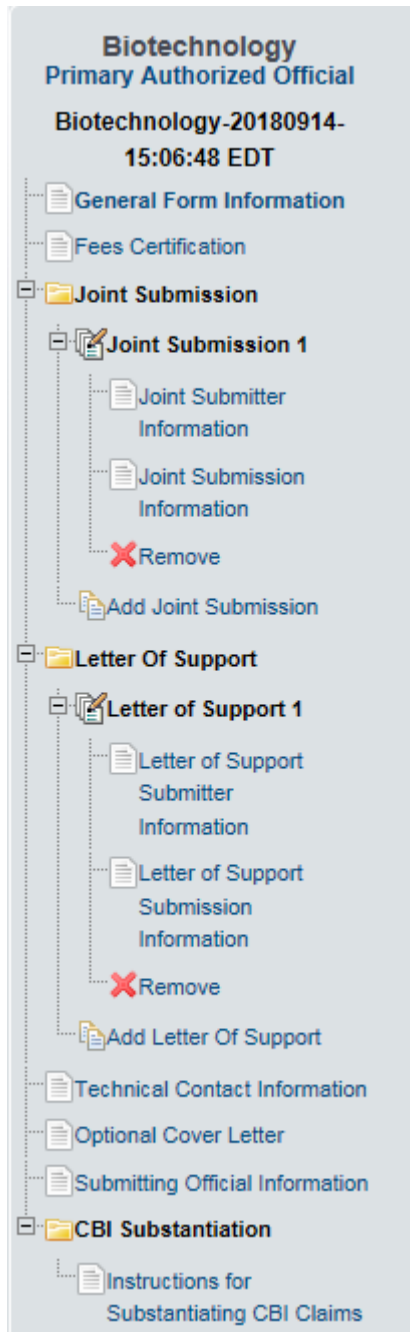


Exhibit 3-18 shows a screen capture of the NOC navigation tree:

Exhibit 3-18 Notice of Commencement (NOC) Navigation Tree

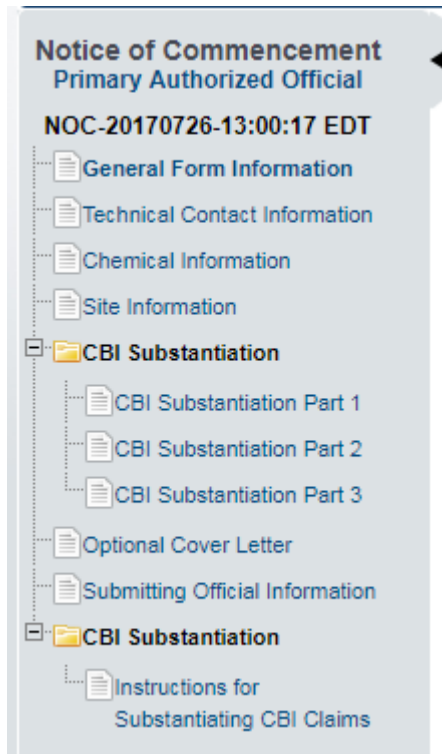


Exhibit 3-19 shows a screen capture of the Support navigation tree:

Exhibit 3-19 Support Navigation Tree

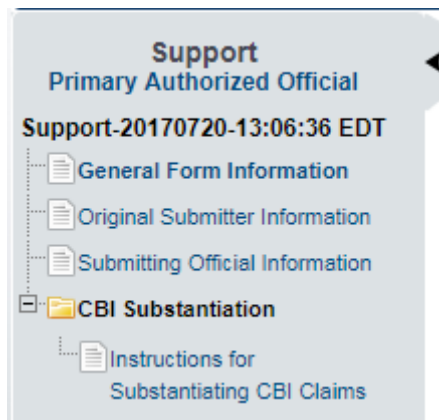


Exhibit 3-20 shows a screen capture of the Bona Fide navigation tree (Class 1 or 2/Biotechnology Chemical Substance):

Exhibit 3-20 Bona Fide Navigation Tree (Class 1 or 2/Biotechnology Chemical Substance)

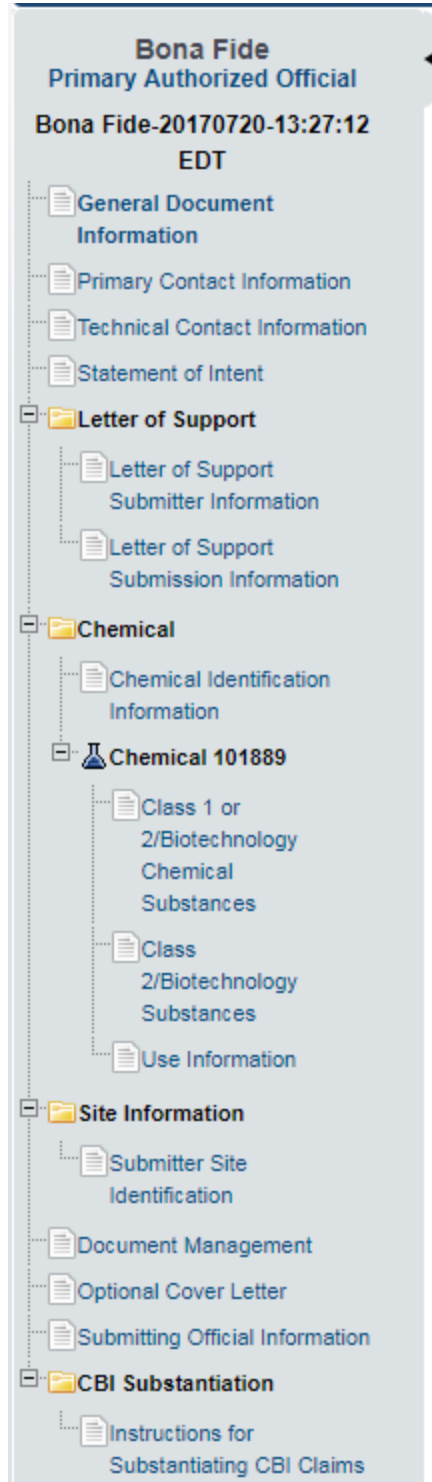


Exhibit 3-21 shows a screen capture of the Bona Fide navigation tree (Polymer):

Exhibit 3-21 Bona Fide Navigation Tree (Polymer)

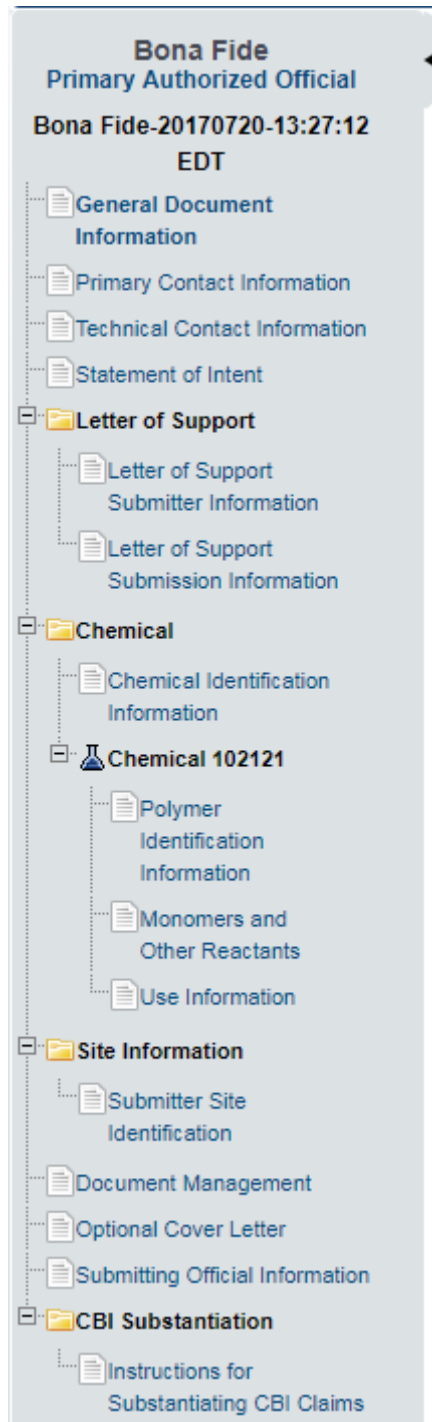
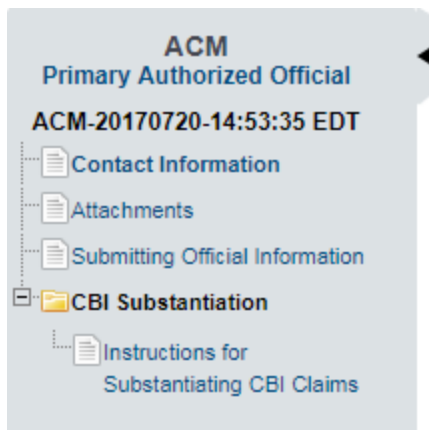


Exhibit 3-22 shows a screen capture of the ACM navigation tree:

Exhibit 3-22 Alternative Control Measures (ACM) Navigation Tree



3.9 Action Bar

The action bar is located at the bottom of the form on each screen. You can perform the following functions using the action bar:

The following exhibits, Exhibit 3-23, Exhibit 3-24, Exhibit 3-25, and Exhibit 3-26, show screen captures of the action bar:

- Validate:** Click the ‘Validate’ icon (✓) at any stage of completing a Section 5 Notices and Supports form. A ‘Section 5 Notices and Supports Validation’ pop-up window generates when you click the ‘Validate’ icon (✓) if you disable the pop-up blocker within your internet browser. The ‘Section 5 Notices and Supports Validation’ pop-up window displays a report of all warning messages and validation errors. On screens that display an expandable/collapsible field set, you must click the ‘Save’ button displayed within the expandable/collapsible field set to save the information entered within the field set before the ‘Validate’ functionality initiates. Refer to **Section 11** for more information on validating a form.

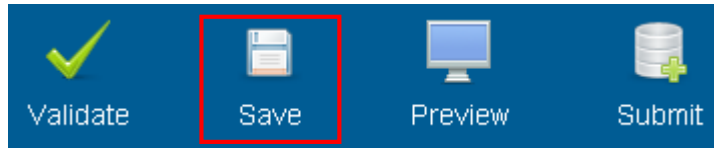
Exhibit 3-23 Action Bar - Validate



- Save:** Click the ‘Save’ icon (floppy disk) at any stage of completing a Section 5 Notices and Supports form to save the form. To generate and access links to other pages of the form within the navigation tree, you must click the ‘Save’ icon (floppy disk) within the action bar. After you click the ‘Save’ icon (floppy disk), you will receive a prompt indicating that all data entered in the form has been saved successfully. The save function does not validate any entered data. On screens that display an expandable/collapsible field set, you must click the ‘Save’ button displayed within the expandable/collapsible field set to save the information entered before being able to click the ‘Save’ icon (floppy disk) located within the action bar or use the ‘Previous’ and ‘Next’

buttons to navigate to another page. Click the ‘Previous’ and ‘Next’ buttons on a form to save the data entered within a form. Click the ‘X’ button in the upper right-hand corner of the form in your browser to close the form without saving.

Exhibit 3-24 Action Bar - Save





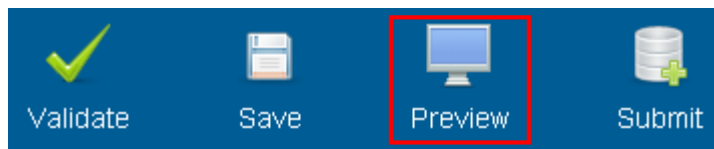
- Preview:** Click the ‘Preview’ icon () at any stage of completing a Section 5 Notices and Supports form to preview the form. After you click the ‘Preview’ icon (), you will be given the option to view a regular version of the PDF (the confidential business information (CBI) version of the form or the non-CBI version if the form contains no CBI) or a sanitized version of the PDF. Choosing either option will generate and display a watermarked PDF of the form in a separate tab of your internet browser. Please note that attachment header sheets no longer generate within the PDF. Refer to **Section 10** for further information on the preview functionality.

Exhibit 3-25 Action Bar - Preview





- Submit:** You can click the ‘Submit’ icon () to submit a Section 5 Notices and Supports form after you and/or an assigned Support have completed all sections of a Section 5 Notices and Supports form. After you click the ‘Submit’ icon () a pop-up message displays to confirm the submission process. The form validates during the submission process and displays any applicable warning or error messages. Refer to **Section 11** for further instructions on validation errors. You can continue with the submission process only after clearing all validation errors. Validation warnings will not prevent you from submitting a form. Upon successful submission of the form, the application generates and sends an email indicating the successful submission of the form to the submitter’s email address. Refer to **Section 14** for more information on submitting a Section 5 Notices and Supports form.

Exhibit 3-26 Action Bar - Submit



- Help Links:** You can click the ‘Help’ links, located at the bottom of each screen, at any stage of completing a Section 5 Notices and Supports form.
 - If you click the ‘CDX Homepage’ link, the application takes you to the CDX Homepage.

- If you click the ‘MyCDX Homepage’ link, the application takes you to the CDX Login screen.
- If you click the ‘EPA Homepage’ link, the application takes you to the EPA Homepage.
- If you click the ‘Terms and Conditions’ link, the application takes you to the CDX Terms and Conditions screen.
- If you click the ‘Privacy Notice’ link, the application takes you to the CDX Privacy and Security Notice screen.

Exhibit 3-27 shows a screen capture of the action bar ‘Help Links’:

Exhibit 3-27 Action Bar - Help Links

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

3.10 Search Substance Registry Services (SRS)

The ‘Search SRS’ button displays on various screens within a Section 5 Notices and Supports form to identify chemicals that may be stored in SRS.

Search SRS: Click the ‘Search SRS’ button to generate the ‘Search Substance Registry Services’ pop-up window. You can search for the reported chemical(s) by either the ‘Chemical Abstracts Service Registry Number (CASRN)’ or ‘CA Index Name or Other Synonym.’ The application also offers the option of entering user-specified chemical information by clicking the ‘Create New Chemical’ button. Click the ‘Create New Chemical’ button to generate the ‘Chemical Not Found In Substance Registry Services’ pop-up window and enter chemical information by filling in the ‘Chemical Name’ and ‘CASRN’ (if desired) field under the manual entry field set.

The system allows you to enter each chemical by clicking the ‘OK’ button located at the bottom of the ‘Search SRS’ pop-up window. Once you enter all known chemical information and click the ‘OK’ button, the chemical information saves and populates into the chemical description table. The ‘Actions’ column of the chemical table allows you to delete chemicals that have been added.

The Section 5 Notices and Supports application contains functionality to prevent a user from adding duplicate chemicals within a multi-component submission. The application checks chemicals in the following order:

- If both chemicals have CASRNs, they will be compared.
- If only one chemical has a CASRN, they will not be compared and are considered different.
- If neither chemicals have a CASRN, their chemical names will be compared.

An error message generates within the expandable/collapsible field set if a user attempts to add a duplicate chemical within a multi-component submission.

- **CASRN:** Enter the chemical abstracts service registry number of the chemical; this field accommodates dashes. Either the ‘CASRN’ or ‘CA Index Name or Other Synonym’ field is required when searching SRS.
- **CA Index Name or Other Synonym:** Enter the chemical abstract ‘(CA) Index Name or Other Synonym’ of the chemical. This field displays the following options: ‘Matches

Exactly,’ ‘Contains,’ and ‘Begins With.’ Either the ‘CASRN’ or ‘CA Index Name or Other Synonym’ field is required when searching SRS.

- **Search SRS:** Click the ‘Search’ button to initiate the database search for the ‘CASRN’ or ‘CA Index Name or Other Synonym’ for the desired chemical.
- **Create New Chemical:** Click the ‘Create New Chemical’ button to generate the ‘Chemical Not Found In Substance Registry Services’ pop-up window.

Exhibit 3-28 shows a screen capture of the ‘Search Substance Registry Services’ window:

Exhibit 3-28 Search Substance Registry Services Pop-Up Window

The screenshot shows a web application window titled "SEARCH SUBSTANCE REGISTRY SERVICES" from CSPP. The window contains a search form with the following elements:

- Header: CSPP logo and "SEARCH SUBSTANCE REGISTRY SERVICES" title.
- Instructions: "Enter the specific or partial, currently correct Chemical Abstracts (CA) Index name or a Chemical Abstract Services Registry Number (CASRN). Click Search SRS and select the appropriate CA Index name/ CASRN combination from EPA's Substance Registry Services (SRS)."
- Search Prompt: "Please search by CASRN or CA Index Name"
- Form Fields:
 - 1. CASRN: Input field with a dropdown menu set to "Matches exactly".
 - 2. CA Index Name or Other Synonym: Input field with a dropdown menu set to "Matches Exactly".
- Buttons: "Search SRS" (highlighted with a red box) and "Create New Chemical" (highlighted with a red box).

Navigation: Click the ‘Search SRS’ button on the ‘Search Substance Registry Services’ window to initiate the database search for the ‘CASRN’ or ‘CA Index Name or Other Synonym.’ After SRS returns results, select the radio button associated to a chemical, click the ‘OK’ button on the ‘Search SRS’ window, close the ‘Search Substance Registry Services’ window, and navigate back to the screen from which the SRS search was initiated where the chemical information will be populated.

If the chemical is not found in the ‘Search Substance Registry Services’ window, click the ‘Create New Chemical’ button to generate the ‘Chemical Not Found In Substance Registry Services’ pop-up window.

- **CBI:** Check the ‘CBI’ checkbox to claim the entered chemical as confidential. The ‘CBI’ checkbox will not be displayed on the ‘Chemical Not Found In Substance Registry Services’ window for the ‘Class 1 or 2 Chemical Substances,’ ‘Polymer Identification Information,’ or the ‘Monomers and Other Reactants’ screen.
- **Chemical Name:** Enter the chemical name. This is a required field.

- **CASRN:** Enter the CASRN, if available.
- **Maximum Percent:** Enter the maximum percentage for the impurity. This field displays only in the ‘Chemical Not Found In Substance Registry Services’ pop-up window on the ‘Additional Chemical Information’ screen.
- **Cancel:** Click the ‘Cancel’ button to navigate back to the ‘Search Substance Registry Services’ pop-up window.
- **OK:** Click the ‘OK’ button to enter the manually entered chemical information into the fields on the screen from which the SRS search was initiated.

Exhibit 3-29 shows a screen capture of the ‘Chemical Not Found In Substance Registry Services’ pop-up window:

Exhibit 3-29 Chemical Not Found In Substance Registry Services Pop-Up Window



Navigation: Click the ‘OK’ button to save the specified chemical information and navigate back to the screen from which the SRS search was initiated where the chemical information will be populated. Click the ‘Cancel’ button to navigate back to the ‘Search Substance Registry Services’ pop-up window. Click the ‘X’ located in the upper right-hand corner to close the pop-up window and navigate back to the screen from which the SRS search was initiated.

3.11 Add Facility

The ‘Add Facility’ button displays on the ‘Submitter Operation Information’ screen and the ‘Industrial Sites Controlled By Others’ screen within a PMN form. This button also displays on the ‘Site Information’ screen within a NOC form and the ‘Submitter Site Identification’ screen within a Bona Fide Notice. The ‘Add Facility’ button is used to generate the ‘Add Facility’ pop-up window and select the applicable sites for which you will be reporting. The ‘Add Facility’ drop-down menu contains the sites that all AO users within the same organization are registered for within CDX registration; additional facilities can be added within CDX to populate this drop-down menu.

If you are not registered to any facilities within CDX registration, or you have finished identifying all possible sites, a message displays within a pop-up window notifying you to add additional sites within your CDX registration profile to add additional sites to a form.

Click the ‘Add Facility’ button to generate the ‘Add Facility’ pop-up window which displays the following fields: ‘Select a site from the drop-down menu below,’ ‘CBI,’ ‘Alias,’ ‘EPA Registry ID,’ ‘Facility Name,’ ‘Facility Address,’ ‘City,’ ‘State,’ and ‘Postal Code.’ Each individual site may be claimed as CBI.

- **Select a site from the drop-down menu below:** Select a single or multiple sites from the drop-down menu that you will be reporting on.
- **CBI:** Check the ‘CBI’ checkbox to claim the facility information as confidential.
- **Alias:** Enter the site alias. This is a required field if a Joint Submission or Letter of Support is pending for the form.
- **EPA Registry ID:** Displays the EPA registry ID of the site selected from the drop-down menu.
- **Facility Name:** Displays the name of the site selected from the drop-down menu.
- **Facility Address:** Displays the address of the site selected from the drop-down menu.
- **City:** Displays the city of the site selected from the drop-down menu.
- **State:** Displays the state of the site selected from the drop-down menu.
- **Postal Code:** Displays the postal code of the site selected from the drop-down menu.
- **Add Facility:** Click the button to add the selected site to the main page from which you are initiating the search.
- **Cancel:** Click the button to cancel the process of adding a site.

Exhibit 3-30 shows a screen capture of the ‘Add Facility’ pop-up window if there are no additional sites contained within the ‘Select a site from the drop-down menu.’

Exhibit 3-30 Add Facility Message Pop-Up Window

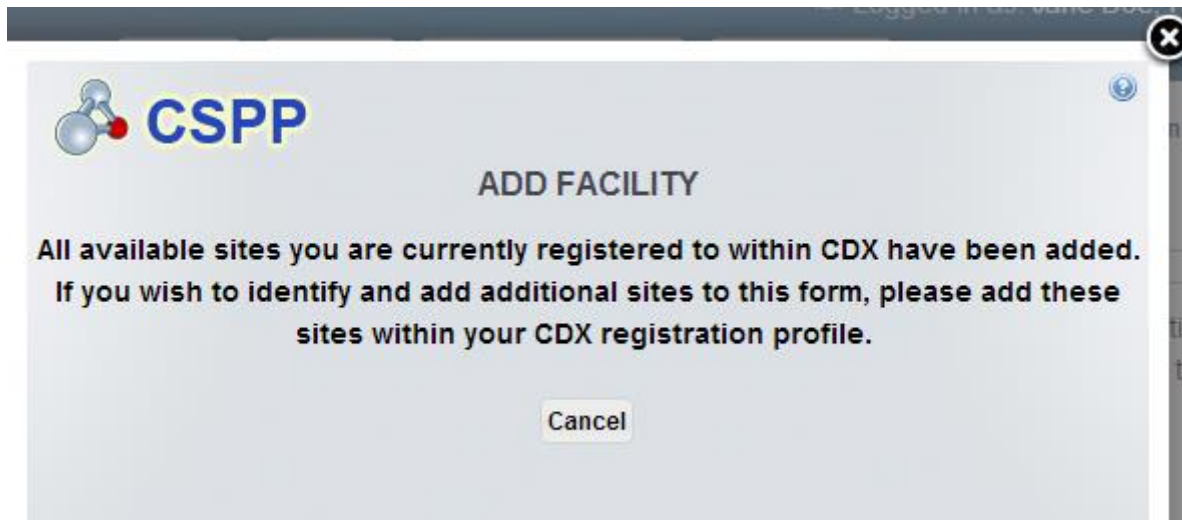
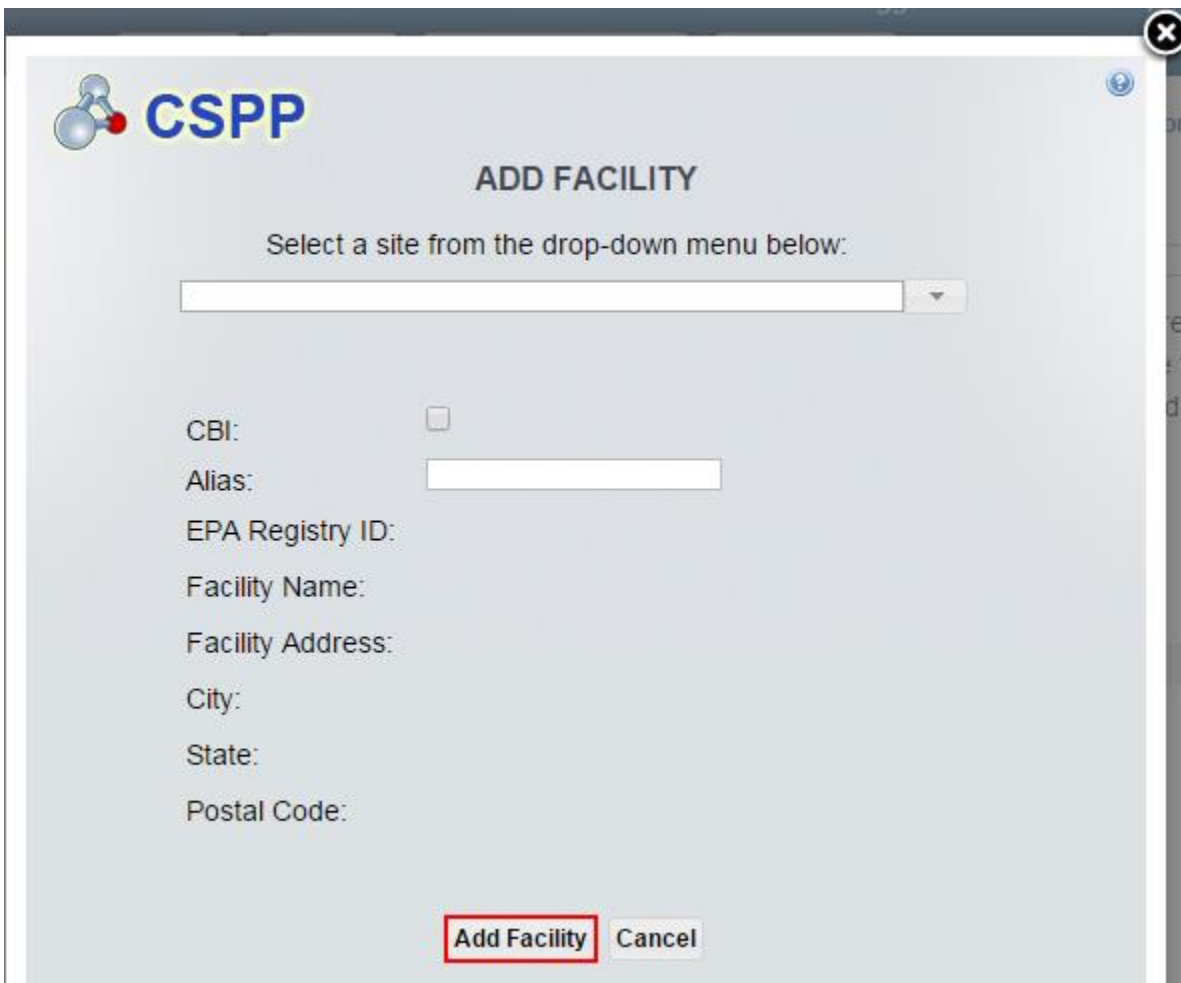


Exhibit 3-31 shows a screen capture of the ‘Add Facility’ pop-up window:

Exhibit 3-31 Add Facility Pop-Up Window



The screenshot shows a pop-up window titled "ADD FACILITY" with the CSPP logo in the top left. The window contains the following elements:

- A dropdown menu with the text "Select a site from the drop-down menu below:" above it.
- A checkbox labeled "CBI:".
- A text input field labeled "Alias:".
- A text input field labeled "EPA Registry ID:".
- A text input field labeled "Facility Name:".
- A text input field labeled "Facility Address:".
- A text input field labeled "City:".
- A text input field labeled "State:".
- A text input field labeled "Postal Code:".
- Two buttons at the bottom: "Add Facility" (highlighted with a red box) and "Cancel".

Navigation: Click the ‘Add Facility’ button to add the selected site to the screen from which you initiated the site identification process.

4 Create Premanufacture Notice (PMN) Form

Anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose is required by Section 5 of TSCA to provide EPA with notice before initiating the activity, known as a PMN form. A PMN must be submitted at least ninety (90) days prior to the manufacture or import of the chemical.

4.1 Create PMN Form

To create a new PMN form, navigate to the ‘Section 5 Notices and Supports Forms’ screen and select ‘Premanufacture Notice (PMN)’ from the ‘Form Type’ drop-down menu. Refer to **Section 3.4** for additional details regarding the ‘Section 5 Notices and Supports Forms’ screen.

Refer to **Section 3.5** for additional details regarding the create passphrase process.

4.1.1 General Form Information

You can navigate to the ‘General Form Information’ screen by clicking the ‘Start New Form’ button and creating a new passphrase, or by accessing a Section 5 Notices and Supports form that is in progress and entering the passphrase associated with the selected form.

The ‘General Form Information’ screen provides fields to input identifying information for a form. You will have the option to assign a ‘Form Alias’ to identify the form. A unique form alias is helpful when a user or company has multiple forms and/or when you must differentiate between forms to the help desk. Upon navigating to the ‘General Form Information’ screen, the system auto-generates a default alias comprised of a form type, date stamp, and time stamp in the following format: <Form Type-YYYYMMDD-HH:MM:SS Time Zone>.

The application contains the following functionality and may generate additional screens for a PMN form based on the type of notice selected from the ‘Type of Notice’ drop-down menu on the ‘General Form Information’ screen:

- If you select ‘SNUN’ from the ‘Type of Notice’ drop-down menu, it is recommended that a cover letter be provided. Otherwise, a warning message will display during validation of the form.
- If you are filing a Mock Submission, click the ‘Next’ button to navigate to the ‘Agent Information’ screen.
- If you are filing a LVE Modification or LoREX Modification, click the ‘Next’ button to navigate to the ‘Fees Certification’ screen.
- If ‘Low Volume Exemption (LVE) @ 40 CFR 723.50(c)(1)’ or ‘LVE Modification’ is selected from the ‘Type of Notice’ drop-down menu, a ‘LVE Certification’ screen generates and displays during the submission process. The ‘LVE Modification’ form type requires a TS Number, a fee certification selection, identification of a technical contact, and selection of a ‘Manufacture’ or ‘Import’ option.
- If ‘Low Release/Low Exposure Exemption (LOREX) @ 40 CFR 723.50(c)(2)’ or ‘LOREX Modification’ is selected from the ‘Type of Notice’ drop-down menu, a ‘LOREX Certification’ screen generates and displays during the submission process. The ‘LOREX Modification’ form type requires a TS Number, a fee certification selection, identification of a technical contact, and selection of a ‘Manufacture’ or ‘Import’ option.

- The ‘TMEA’ form type requires a TS Number, a fee certification selection, identification of a technical contact, and selection of a ‘Manufacture’ or ‘Import’ option.

The ‘PMN Identification’ section provides a field for you to enter information regarding other communications with EPA by entering a ‘TS Number.’ The TS number is determined by a company and is used to identify the form for both payments and connecting related submissions when additional communications (Letters of Support, Joint Submissions, and corrections) are sent before a PMN/LVE case number has been assigned. The TS number can be any six (6) character alphanumeric combination. The TS number should include two (2), three (3), or four (4) letters. Company names, recognizable words, and numerical series are not recommended. The ‘TS Number’ field is required. A unique identification number for the form will generate later if a Letter of Support or Joint Submission is being filed.

The ‘Test Data’ section provides checkboxes to identify data that is included in the notice selected from the ‘Type of Notice’ drop-down menu. The following values will display as checkboxes: ‘Environmental fate data,’ ‘Health effects data,’ ‘Environmental effects data,’ ‘Physical/Chemical properties,’ ‘Risk assessments,’ ‘Structure/Activity relationships,’ ‘Test data not in the possession or control of the submitter,’ and ‘Other data.’

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you if the data is related to the health and environmental effects on the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. You should clearly identify whether test data is on the substance or on an analog. In addition, the chemical composition of the tested material should be characterized. Data should be submitted according to the requirements of §720.50 of the Premanufacture Notification Rule (40 Code of Federal Regulations (CFR) Part 720).

The ‘Identify whether any of the below options apply’ section provides checkboxes for you to indicate how interactions with other companies occur within the form. If the company is filing a Joint Submission, a ‘Joint Submission’ folder generates within the navigation tree for you to enter information concerning the Joint Submission. A unique identification number will be generated and sent to the joint submitter by the primary submitter and will link the two forms together. You will also be able to indicate that a Letter of Support submitted by a Secondary AO is expected with the original PMN form.

- **Form Alias:** Enter the form alias. Upon navigating to the screen, the application displays an auto-generated editable form alias in the following format: <Form Type-YYYYMMDD-HH:MM:SS Time Zone>. This is a required field and is non-editable when amending a PMN submission.
- **Type of Notice:** Select a value to indicate the type of notice for the PMN form. Valid values include: ‘Premanufacture Notice (PMN),’ ‘Significant New Use Notice (SNUN),’ ‘Test Marketing Exemption Application (TMEA),’ ‘Low Volume Exemption (LVE) @ 40 CFR 723.50 (c)(1),’ ‘Low Release/Low Exposure Exemption (LOREX) @ 40 CFR 723.50(c)(2),’ ‘LVE Modification,’ ‘LOREX Modification,’ and ‘Mock Submission.’ Select ‘PMN’ if the application is for a standard, fine-product new chemical substance for placement on the

TSCA inventory. Select ‘Significant New Use Notice’ for any notice that is marked in accordance with a Significant New Use Rule (SNUR). Select ‘TMEA’ for any notice submitted in accordance with the criteria listed in 40 CFR §720.38. A ‘Mock Submission’ is an enforcement case where the chemical was manufactured/imported in the past and is not currently being manufactured/imported by the company. This is a required field and is non-editable when amending a PMN submission.

- **TS Number:** Enter the TS number related to the PMN form; this field accepts any six (6) character alphanumeric combination. The financial institution that receives payment for EPA when it notifies the Agency that the fee has been received uses it. The TS number should include two (2), three (3), or four (4) letters. Company names, recognizable words, and numerical series are not recommended. TS numbers should be unique to the submission and should not be reused in subsequent submissions. This is a required field and is non-editable when amending a PMN submission.
- **Environmental fate data:** Check the ‘Environmental fate data’ checkbox to indicate that the form contains environmental fate data.
- **Health effects data:** Check the ‘Health effects data’ checkbox to indicate that the form contains health effects data.
- **Environmental effects data:** Check the ‘Environmental effects data’ checkbox to indicate that the form contains environmental effects data.
- **Physical/Chemical properties:** Check the ‘Physical/Chemical properties’ checkbox to indicate that the form contains physical/chemical properties data.
- **Test data not in the possession or control of the submitter:** Check the ‘Test data not in the possession or control of the submitter’ checkbox to indicate that the form contains test data not in the possession or control of the submitter.
- **Risk assessments:** Check the ‘Risk assessments’ checkbox to indicate that the form contains risk assessments data.
- **Structure/Activity relationships:** Check the ‘Structure/Activity relationships’ checkbox to indicate that the form contains structure-activity relationships (SAR) data.
- **Other data:** Check the ‘Other data’ checkbox to indicate that the form contains other types of data.
- **Check here if you are filing a joint PMN:** Check the ‘Check here if you are filing a joint PMN’ checkbox to indicate that the form is pending a joint PMN form. A ‘Joint Submission’ folder generates within the navigation tree upon clicking the ‘Save’ icon located at the bottom of the screen within the action bar or by clicking the ‘Next’ button on the ‘General Form Information’ screen. This field is non-editable when creating a PMN amendment.
- **Check here if you have a Letter of Support pending:** Check the ‘Check here if you have a Letter of Support pending’ checkbox to indicate that the form is pending a Letter of Support. A ‘Letter of Support’ folder displays within the navigation tree upon clicking the ‘Save’ icon located at the bottom of the screen within the action bar or by clicking the ‘Next’ button on the ‘General Form Information’ screen. This field is non-editable when amending a PMN submission.

Exhibit 4-1 shows a screen capture of the ‘General Form Information’ screen (Scroll 1):

Exhibit 4-1 General Form Information Screen (PMN) (Scroll 1)

Premanufacture Notice
Primary Authorized Official

Primary PMN-20180830-12:08:59 EDT

Premanufacture Notice (Primary PMN-20180830-12:08:59 EDT) > General Form Information

GENERAL FORM INFORMATION

This form must be submitted using a United States company or subsidiary with a United States address.

The form alias is a required 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:

Type of Notice

Select the **Type of Notice** for the type of form you wish to file.

PMN Identification

Please enter the TS Number (if applicable) that references the specific form.

TS Number:

Test Data

Select the **Test Data** that will be included in this notice.

Environmental fate data:	<input type="checkbox"/>	Risk assessments:	<input type="checkbox"/>
Health effects data:	<input type="checkbox"/>	Structure/Activity relationships:	<input type="checkbox"/>
Environmental effects data:	<input type="checkbox"/>	Other data:	<input type="checkbox"/>
Physical/Chemical properties:	<input type="checkbox"/>		
Test data not in the possession or control of the submitter:	<input type="checkbox"/>		

Identify whether any of the below options apply.

Check here if you are filing a joint PMN:

Upload XML **Validate** **Save** **Preview** **Submit**

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

Exhibit 4-2 shows a screen capture of the ‘General Form Information’ screen (Scroll 2):

Exhibit 4-2 General Form Information Screen (PMN) (Scroll 2)

The screenshot displays the 'General Form Information' screen for a Primary Manufacture Notice (PMN). The user is logged in as Jane Doe, a Primary Authorized Official. The page is divided into several sections:

- Form Alias:** A text field containing 'Primary PMN-20180830-12:08:59 ED'.
- Type of Notice:** A dropdown menu for selecting the type of form to file.
- PMN Identification:** A section for entering the TS Number (if applicable).
- Test Data:** A section for selecting test data to include in the notice, with checkboxes for:
 - Environmental fate data
 - Health effects data
 - Environmental effects data
 - Physical/Chemical properties
 - Test data not in the possession or control of the submitter
 - Risk assessments
 - Structure/Activity relationships
 - Other data

At the bottom of the main content area, there is a 'Next' button highlighted in red. Below the main content is an action bar with buttons for 'Upload XML', 'Validate', 'Save', 'Preview', and 'Submit'. The footer contains links to CDX, MyCDX, EPA, Terms and Conditions, Privacy Notice, and CDX Helpdesk.

Navigation: If you are filing a ‘PMN,’ ‘SNUN,’ ‘LoREX,’ ‘LVE,’ ‘LoREX Modification,’ ‘LVE Modification,’ or ‘TMEA,’ click the ‘Next’ button to navigate to the ‘Fees Certification’ screen. You can also access this screen by clicking the ‘Fees Certification’ link within the navigation tree for an in progress form. If you are filing a ‘Mock Submission,’ click the ‘Next’ button to navigate to the ‘Agent Information’ screen. You can also access this screen by clicking the ‘Agent Information’ link within the navigation tree for an in progress form. The ‘Save’ icon in the action bar or the ‘Next’ button must be clicked before the links within the navigation tree generate and are available to a user.

4.1.2 Fees Certification

The ‘Fees Certification’ screen presents radio buttons to indicate the applicable fee certification statement.

You can access the ‘Fees Certification’ screen by selecting:

- Premanufacture Notice (PMN),
- Significant New Use Notice (SNUN),
- Low Release/Low Exposure Exemption (LOREX) @ 40 CFR 723.50(C)(2),
- LoREX Modification,
- Low Volume Exemption (LVE) @ 40 CFR 723.50(c)(1),
- LVE Modification,
- or Test Marketing Exemption Application (TMEA)

from the ‘Type of Notice’ drop-down menu and by clicking the ‘Next’ button from the ‘General Form Information’ screen. You can also access this screen by clicking the ‘Fees Certification’ link within the navigation tree for an in progress form. If (a) joint submitter(s) is/are identified, the joint submitter may be responsible for paying part of the fee. If more than one joint submitter is identified, the last joint submitter that completes the joint form is responsible for paying the remaining fee balance.

The purpose of the ‘Fees Certification’ screen is to inform EPA of the fee amount that a primary submitter (and potential secondary submitters) pays on behalf of the reporting organization based on the business size. For TMEAs, a user that reports as a graduate of the Sustainable Futures program is exempt from fees. The certification statement selected on the ‘Fees Certification’ screen is non-editable when amending a PMN submission.

The ‘User Fees Certification’ screen used prior to the new Fees rule will still appear in amendments to submissions made prior to the new rule’s effective date – October 1, 2018.

Exhibit 4-3 shows a screen capture of the ‘User Fees Certification’ screen prior to the implementation of the new Fees rule (PMN or SNUN):

Exhibit 4-3 User Fees Certification Screen (PMN or SNUN)

Exhibit 4-4 shows the fee structure implemented for the PMN form type:

Exhibit 4-4 PMN Fee Structure

Form Subtype	Business Size	Fee Amount
PMN, Consolidated PMN, SNUN	Average	• \$16,000
	Small	• \$2,800
LoREX, LoREX Modification, LVE, LVE Modification, TMEA	Average	• \$4,700
	Small	• \$940
TMEA	Sustainable Futures Graduate	• N/A – Exempt From Fees

If a user selects the PMN or SNUN form subtype, the following certification statements display:

- **The Company named in Part I, Section A will remit the fee of \$16,000.00 as specified in 40 CFR 700.45(c):** Select this radio button to indicate that the primary submitter will submit a fee of \$16,000. One of the certification statements must be selected.
- **The Company named in Part I, Section A 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):** Select this radio button to indicate that the primary submitter will submit a fee of \$2,800. One of the certification statements must be selected.
- **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):** Select this radio button to indicate that a fee of \$16,000 will be paid between the primary and joint submitter(s). This displays if a joint/LOS submission is pending. One of the certification statements must be selected.

Exhibit 4-5 shows a screen capture of the 'Fees Certification' screen (PMN or SNUN, no Joint/LOS):

Exhibit 4-5 Fees Certification Screen (PMN or SNUN, No Joint/LOS)

The screenshot shows the 'FEES CERTIFICATION' screen in the CDX system. The user is logged in as Jane Doe, Primary Authorized Official. The page title is 'FEES CERTIFICATION'. The main content area contains the following text:

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, Section A will remit the fee of \$16,000.00 as specified in 40 CFR 700.45(c).
- The Company named in Part I, Section A 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 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.](https://www.epa.gov/sites/production/files/2018-09/documents/2018-09-27_prepubcopy_tsc-fees-finalrule.pdf)

Navigation buttons: Previous, Next (highlighted with a red box).

Bottom bar: Upload XML, Validate, Save, Preview, Submit.

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

Exhibit 4-6 shows a screen capture of the 'Fees Certification' screen (PMN, SNUN, pending Joint/LOS):

Exhibit 4-6 Fees Certification Screen (PMN, SNUN, Pending Joint/LOS)

If a LoREX, LoREX Modification, LVE, LVE Modification, or TMEA form subtype is selected, the following certification statements display:

- **The Company named in Part I, Section A will remit the fee of \$4,700.00 as specified in 40 CFR 700.45(c):** Select this radio button to indicate that the primary submitter will submit a fee of \$4,700. One of the certification statements must be selected.
- **The Company named in Part I, Section A 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):** Select this radio button to indicate that the primary submitter will submit a fee of \$940. One of the certification statements must be selected.
- **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):** Select this radio button to indicate that a fee of \$4,700 will be paid between the

primary and/or joint submitter(s). This displays if a joint/LOS submission is pending. One of the certification statements must be selected.

- The company named in Part I, Section A 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:** Select this radio button to indicate that the reporting company has graduated from EPA's Sustainable Futures Program and is therefore not responsible for paying fees. This displays if the form subtype is 'TMEA.' One of the certification statements must be selected.

Exhibit 4-7 shows a screen capture of the 'Fees Certification' screen (TMEA, pending Joint/LOS):

Exhibit 4-7 Fees Certification Screen (TMEA, Pending Joint/LOS)

Navigation: Click the 'Next' button to navigate to the 'Agent Information' screen. You can also access this screen by clicking the 'Agent Information' link within the navigation tree.

4.1.3 Small Business Concern Definition

Click the ‘View the updated definition of a small business concern’ link to generate the ‘Small Business Concern Definition’ window. The window displays a table of the North American Industry Classification System (NAICS) codes, NAICS descriptions, and applicable small business concern size in number of employees.

If there are codes that are not listed within the NAICS table, a small business definition applies to 500 or fewer employees that a company “owns or controls.”

Exhibit 4-8 shows a screen capture of the ‘Small Business Concern Definition’ window (Scroll 1):

Exhibit 4-8 Small Business Concern Definition Window (Scroll 1)



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

Exhibit 4-9 shows a screen capture of the ‘Small Business Concern Definition’ window (Scroll 2):

Exhibit 4-9 Small Business Concern Definition Window (Scroll 1)

325320	Pesticide and Other Agricultural Chemical Manufacturing	1000 or fewer
325411	Medicinal and Botanical Manufacturing	1000 or fewer
325510	Paint and Coating Manufacturing	1000 or fewer
325611	Soap and Other Detergent 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 Manufacturing	1250 or fewer
325412	Pharmaceutical Preparation Manufacturing	1250 or fewer
325413	InVitro Diagnostic Substance Manufacturing	1250 or fewer
325414	Biological Product (except Diagnostic) Manufacturing	1250 or fewer
325620	Toilet Preparation Manufacturing	1250 or fewer
424690	Other Chemical and Allied Products Merchant Wholesalers	150 or fewer
324110	Petroleum Refineries	1500 or fewer
325992	Photographic Film, Paper, Plate and Chemical Manufacturing	1500 or fewer
424710	Petroleum Bulk Stations and Terminals	200 or fewer
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	200 or fewer

Exhibit 4-10 shows a screen capture of the ‘Small Business Concern Definition’ window (Scroll 3):

Exhibit 4-10 Small Business Concern Definition Window (Scroll 3)

325413	In Vitro Diagnostic Substance Manufacturing	1250 or fewer
325414	Biological Product (except Diagnostic) Manufacturing	1250 or fewer
325620	Toilet Preparation Manufacturing	1250 or fewer
424690	Other Chemical and Allied Products Merchant Wholesalers	150 or fewer
324110	Petroleum Refineries	1500 or fewer
325992	Photographic Film, Paper, Plate and Chemical Manufacturing	1500 or fewer
424710	Petroleum Bulk Stations and Terminals	200 or fewer
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	200 or fewer
325314	Fertilizer (Mixing Only) Manufacturing	500 or fewer
325520	Adhesive Manufacturing	500 or fewer
325910	Printing Ink Manufacturing	500 or fewer
325991	Custom Compounding of Purchased Resins	500 or fewer
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	500 or fewer
325312	Phosphatic Fertilizer Manufacturing	750 or fewer
325612	Polish and Other Sanitation Good Manufacturing	750 or fewer
325613	Surface Active Agent Manufacturing	750 or fewer
325920	Explosives Manufacturing	750 or fewer

Navigation: Click the ‘X’ icon in the upper right-hand corner to close the ‘Small Business Concern Definition’ window and navigate back to the ‘Fees Certification’ screen.

4.1.4 Agent Information

You can access the ‘Agent Information’ screen by clicking the ‘Next’ button from the ‘General Form Information’ screen if you are filing a ‘Mock Submission.’ You can also access this screen by clicking the ‘Next’ button from the ‘Fees Certification’ screen if you are filing a ‘PMN,’ ‘SNUN,’ ‘TMEA,’ ‘LVE,’ ‘LVE Modification,’ ‘LoREX Modification,’ or ‘LoREX.’ You can also navigate to this screen by clicking the ‘Agent Information’ link within the navigation tree.

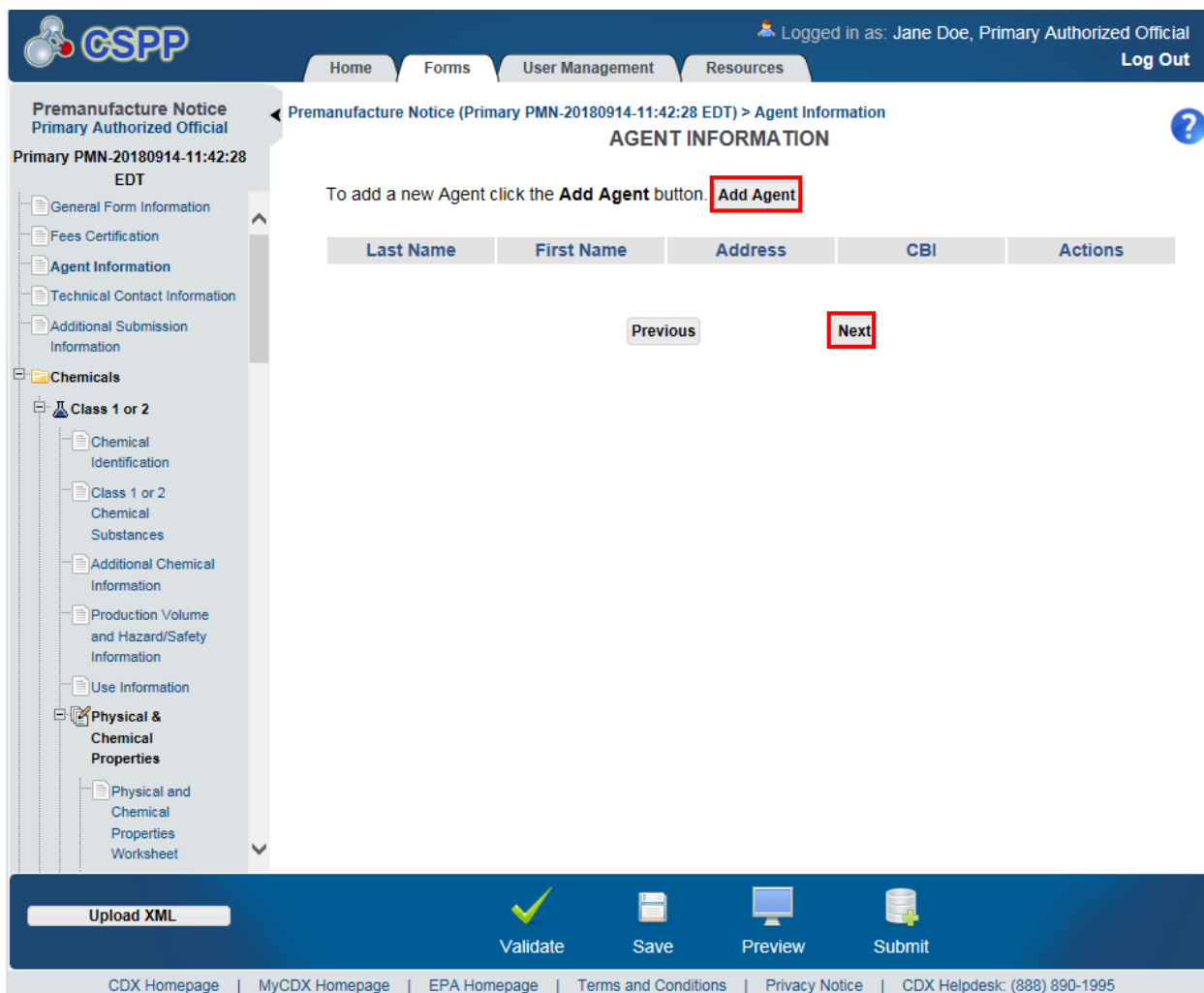
The ‘Agent Information’ screen provides fields for you to enter information regarding all parties involved in representing the PMN form. The agent should be a person who can answer questions

about the form. The ‘Agent Information’ screen displays an ‘Add Agent’ button that generates the ‘Add Agent’ pop-up window for you to input the contact information on behalf of whom the submission is being made. You will be able to enter multiple agents; if the agent is the same individual who is filling out the form, click the ‘Copy CDX Registration’ button to retrieve user information entered during CDX registration. The system provides a checkbox for you to claim entered contact information as confidential by checking the ‘Check here to claim this information as CBI’ checkbox. Each agent will have an individual CBI claim. You will be able to enter contact information for each agent, and click the ‘OK’ button, which will populate the agent table located on the ‘Agent Information’ screen. Click the ‘Delete’ icon (✖) located under the ‘Actions’ column to delete agents. To edit agent information, click the agent name link within the ‘Last Name’ column, which will generate the ‘Add Agent’ pop-up window with the previously entered agent information.

- **Add Agent:** Click the ‘Add Agent’ button to generate the ‘Add Agent’ pop-up window to enter information for multiple agents.
- **Last Name:** Displays the last name of the reported agent. Click the ‘Last Name’ link to generate the ‘Add Agent’ pop-up window and edit the agent information.
- **First Name:** Displays the first name of the reported agent.
- **Address:** Displays the mailing address of the reported agent.
- **CBI:** Indicates the CBI status of the agent information by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete specific agents; a warning message displays to confirm deletion of the agent information.

Exhibit 4-11 shows a screen capture of the ‘Agent Information’ screen:

Exhibit 4-11 Agent Information Screen (PMN)



Navigation: Click the ‘Add Agent’ button to begin the process of adding agent information. Click the ‘Next’ button to navigate to the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Technical Contact Information’ link within the navigation tree.

4.1.4.1 Add Agent

Click the ‘Add Agent’ button to generate the ‘Add Agent’ pop-up window. Enter agent information into the fields displayed on the ‘Add Agent’ pop-up window. Click the ‘Cancel’ button to close the ‘Add Agent’ pop-up window. Click the ‘OK’ button after entering agent information to populate the information on the main ‘Agent Information’ screen.

The identification of an agent is optional.

- **Copy CDX Registration:** Click the ‘Copy CDX Registration’ button to display a prompt confirming the import of CDX registration information and allow the system to populate the agent information fields with your contact information provided during CDX registration.

- **Check here to claim this information as CBI:** Check the ‘Check here to claim this information as CBI’ checkbox to claim agent information as confidential. If the ‘CBI’ checkbox is checked before clicking the ‘Copy CDX Registration’ button, the ‘CBI’ checkbox will become unchecked upon navigating back to the pop-up window after copying CDX registration information. Check the ‘CBI’ checkbox after importing CDX registration information to claim agent information as confidential.
- **First Name:** Enter the agent’s first name. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field only if agent information will be added to the form.
- **Last Name:** Enter the agent’s last name. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field only if agent information will be added to the form.
- **Position:** Enter the agent’s job title.
- **Company Name:** Enter the agent’s company name. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field only if agent information will be added to the form.
- **Phone Number:** Enter the agent’s daytime phone number: U.S. or international. This field does not allow dashes. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field only if agent information will be added to the form.
- **Phone Extension:** Enter the agent’s daytime phone number extension. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information.
- **Email Address:** Enter the agent’s email address. The email address must follow the standard email address format: John.Doe@abc.com. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information.
- **Mailing Address 1:** Enter the first line of the agent’s mailing address. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field only if agent information will be added to the form.
- **Mailing Address 2:** Enter the second line of the agent’s mailing address. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information.
- **City:** Enter the city of the agent’s mailing address. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field only if agent information will be added to the form.
- **State:** Select the state of the agent’s mailing address from the drop-down menu. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field only if agent information will be added to the form and if the ‘Country’ field is set to ‘United States.’ This field is disabled if a non-US country is selected from the ‘Country’ drop-down menu.
- **Postal Code:** Enter the postal code of the agent’s mailing address. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field only if agent information will be added to the form and if the ‘Country’ field is set to ‘United States.’

- **Country:** Select the country of the agent’s mailing address from the drop-down menu. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This field is automatically set to ‘United States’ if a value is selected from the ‘State’ drop-down menu. This is a required field only if agent information will be added to the form.

Exhibit 4-12 shows a screen capture of the ‘Add Agent’ pop-up window:

Exhibit 4-12 Add Agent Pop-Up Window (PMN)

CSPP

ADD AGENT

Please enter the information for the agents who will be responsible for supporting the information on 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**

Navigation: Click the ‘Cancel’ button or the ‘X’ icon in the upper right-hand corner to close the ‘Add Agent’ window and navigate back to the ‘Agent Information’ screen. Click the ‘OK’ button to populate the entered agent information and navigate back to the ‘Agent Information’ screen.

4.1.5 Technical Contact Information

You can access the ‘Technical Contact Information’ screen by clicking the ‘Next’ button from the ‘Agent Information’ screen. You can also access this screen by clicking the ‘Technical Contact Information’ link within the navigation tree.

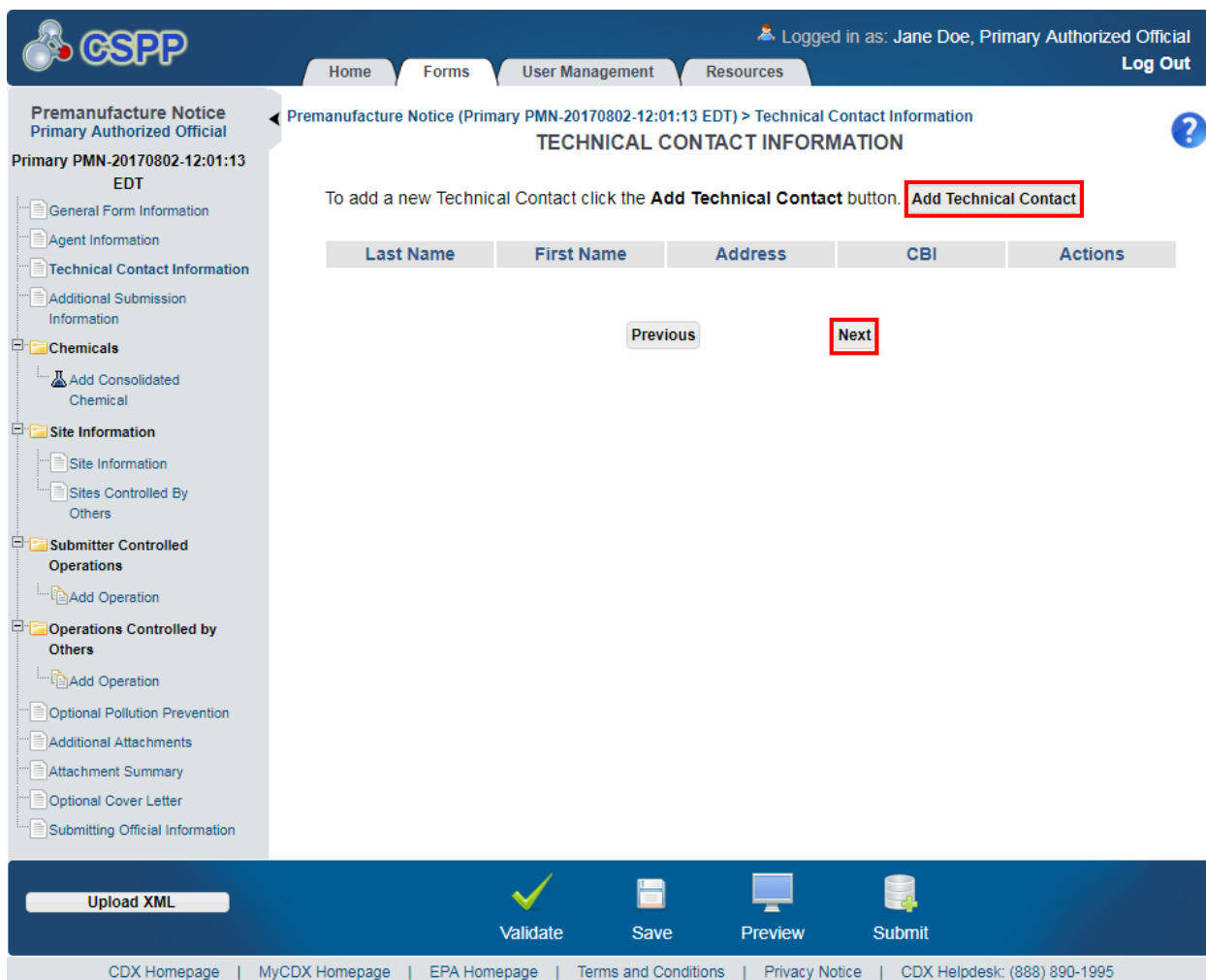
The technical contact should be able to answer, or obtain answers to, questions related to the chemical submitted to EPA within the PMN form. The technical contact does not have to physically work at the site reported on the form, but must be readily available by phone or email. It is required to identify at least one technical contact.

The system provides functionality to enter multiple technical contacts. If the contact is the same person who is filling out the form, the system presents a ‘Copy CDX Registration’ button for you to retrieve your user information from CDX. You will enter the contact information for each technical contact within the ‘Add Technical Contact’ window and click the ‘OK’ button at the bottom of the window, which will populate the technical contacts table located on the ‘Technical Contact Information’ screen. Click the ‘Delete’ icon (✖) located under the ‘Actions’ column to delete a technical contact. Click the technical contact name within the ‘Last Name’ column to edit technical contact information.

- **Add Technical Contact:** Click the ‘Add Technical Contact’ button to generate the ‘Add Technical Contact’ pop-up window, which provides fields for you to enter technical contact information.
- **Last Name:** Displays the last name of the reported technical contact. Click the ‘Last Name’ link to generate the ‘Add Technical Contact’ pop-up window that contains previously identified technical contact information to edit the technical contact information.
- **First Name:** Displays the first name of the reported technical contact.
- **Address:** Displays the address of the reported technical contact.
- **CBI:** Indicates the CBI status of the technical contact information by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete specific technical contacts. A pop-up generates to confirm the deletion of the technical contact information.

Exhibit 4-13 shows a screen capture of the ‘Technical Contact Information’ screen:

Exhibit 4-13 Technical Contact Information Screen (PMN)



Navigation: Click the ‘Add Technical Contact’ button to begin the process of adding technical contact information. Click the ‘Next’ button to navigate to the ‘Additional Submission Information’ screen. You can also access this screen by clicking the ‘Additional Submission Information’ link within the navigation tree.

4.1.5.1 Add Technical Contact

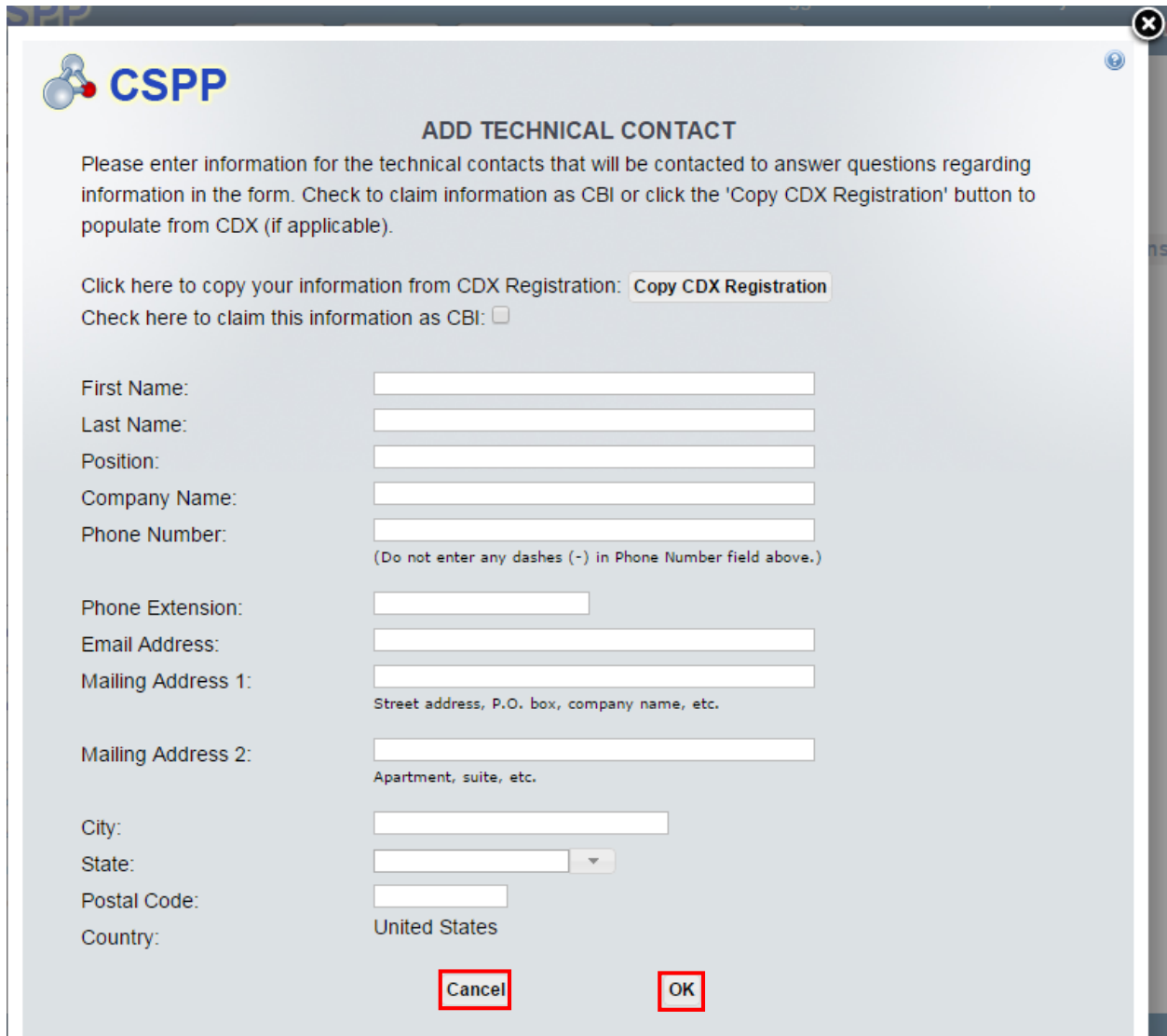
Click the ‘Add Technical Contact’ button to generate the ‘Add Technical Contact’ pop-up window. Enter technical contact information into the fields displayed on the ‘Add Technical Contact’ pop-up window. Click the ‘Cancel’ button to stop populating technical contact information. Click the ‘OK’ button to populate the entered technical contact information on the main ‘Technical Contact Information’ screen.

- **Copy CDX Registration:** Click the ‘Copy CDX Registration’ button to populate the fields with your contact information provided during CDX registration. A prompt will display confirming the import of CDX registration information.

- **Check here to claim this information as CBI:** Check the ‘Check here to claim this information as CBI’ checkbox to claim the technical contact information as confidential. If the ‘CBI’ checkbox is checked before clicking the ‘Copy CDX Registration’ button, the ‘CBI’ checkbox will become unchecked upon navigating back to the pop-up window after copying CDX registration information. Check the ‘CBI’ checkbox after importing CDX registration information to claim a technical contact as confidential.
- **First Name:** Enter the technical contact’s first name. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field.
- **Last Name:** Enter the technical contact’s last name. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field.
- **Position:** Enter the technical contact’s job title.
- **Company Name:** Enter the technical contact’s company name. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field.
- **Phone Number:** Enter the technical contact’s daytime phone number. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field.
- **Phone Extension:** Enter the technical contact’s phone number extension. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information.
- **Email Address:** Enter the technical contact’s email address. The email address must follow the standard email address format: John.Doe@abc.com. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information.
- **Mailing Address 1:** Enter the first line of the technical contact’s mailing address. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field.
- **Mailing Address 2:** Enter the second line of the technical contact’s mailing address. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information.
- **City:** Enter the technical contact’s U.S. city of the mailing address. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field.
- **State:** Select the state of the technical contact’s mailing address from the drop-down menu. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field.
- **Postal Code:** Enter the postal code of the technical contact’s mailing address. Click the ‘Copy CDX Registration’ button to populate the fields with CDX registration information. This is a required field.
- **Country:** Displays ‘United States.’

Exhibit 4-14 shows a screen capture of the ‘Add Technical Contact’ pop-up window:

Exhibit 4-14 Add Technical Contact Pop-Up Window (PMN)



Navigation: Click the ‘Cancel’ button or ‘X’ icon at the upper right-hand corner of the window to return to the ‘Technical Contact Information’ screen without saving the technical contact information. Click the ‘OK’ button to save and populate the entered technical contact information and navigate back to the ‘Technical Contact Information’ screen.

4.1.6 Additional Submission Information

You can access the ‘Additional Submission Information’ screen by clicking the ‘Next’ button from the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Additional Submission Information’ link within the navigation tree.

The ‘Additional Submission Information’ screen gathers information concerning the PMN form that references generic information allowing EPA to set a base point for the project.


The 'Prenotice Communication Number' is a number given to a user during past communication with EPA. The 'Prenotice Communication Number' is required if you are filing a consolidated PMN. EPA must approve all consolidated PMN forms prior to submission. The system will require that you either enter a number into the text field or check the 'None' checkbox. You may declare the entered identification number(s) confidential by checking the 'CBI' checkbox.

EPA uses the 'Previously Submitted Notice Number' to link past, current, and future forms. This number allows EPA to associate previous renditions of the current submission in the PMN process. The system will require that you either enter a case number into the text field or check the 'None' checkbox. You may declare the entered identification number(s) confidential by checking the 'CBI' checkbox.

The 'Bona Fide Intent Notice Number' is listed to show the company previously contacted EPA to determine whether the chemical in question was previously listed on the TSCA inventory. The system will require that you either enter a number into the text field or check the 'None' checkbox. You may declare the entered identification number(s) confidential by checking the 'CBI' checkbox.

On this screen, a company must also declare whether the newly registered chemical will be manufactured or imported. You will have the option to select 'Manufacture' and/or 'Import' and depending on whether the company only intends to do one of the available options, the system provides 'Binding' checkboxes to indicate a binding option. If the 'Manufacture' checkbox is checked, the screens within the 'Submitter Controlled Operations' folder automatically generates upon clicking the 'Save' button located in the bottom action bar.

The binding option demonstrates that you intend to execute the selected option and would be legally bound to that situation if EPA chooses to regulate that chemical. The purpose of the binding option is to enable EPA (if necessary) to efficiently negotiate with a PMN submitter the development of §5(e) consent orders and promulgate SNUR for those new chemical substances that the Agency determines may present an unreasonable risk if certain control actions are not implemented. This option is intended to reduce delays that can slow the development of consent orders. At one time, SNUR were limited to environmental release activities and certain industrial, commercial, or consumer activities, but now they can include other important activities, such as protection in the workplace and hazard communications. Control measures instituted by the submitter to reduce exposures and/or releases of the substance may have a direct bearing on the Agency's conclusions regarding risk. Therefore, you may wish to indicate your willingness to be bound to certain submitted information on the form, which relates to the issue of potential risk such as use, production volume, protective equipment, engineering controls, and/or process description. By indicating your willingness to make these commitments, you would be indicating an interest in future negotiations if EPA deems them necessary.

- **Prenotice Communication Number – None:** Check the 'None' checkbox for the 'Prenotice Communication Number' to indicate that there is no Prenotice Communication Number. Check the 'None' checkbox to remove the 'Prenotice Communication #' fields and associated actions. Un-check the 'None' checkbox to re-generate a 'Prenotice Communication Number' field and enter a value.
- **Prenotice Communication Number:** Enter the Prenotice Communication Number to associate with a previous contact with EPA. Click the 'Save' icon () to save an individual

entry. Click the 'Form' icon (📄) that displays after saving to edit an individual entry. Click the 'Delete' icon (✖) to delete individual entries. Click the 'Add' icon (+) to generate blank text fields to provide additional entries. This field is required if a form is a consolidated submission, regardless of whether the 'None' checkbox is checked.

- **Prenotice Communication Number – CBI:** Check the 'CBI' checkbox to claim all identified Prenotice Communication Numbers as confidential.
- **Previously Submitted Notice Number – None:** Check the 'None' checkbox for the 'Previously Submitted Notice Number' to indicate that there is no previously submitted notice number. Check the 'None' checkbox to remove the 'Previously Submitted Notice Number' fields and associated actions. Un-check the 'None' checkbox to re-generate a 'Previously Submitted Notice Number' field and enter a value.
- **Previously Submitted Notice Number:** Enter the previously submitted notice number to associate with a previous contact with EPA. Enter this number in a case number format (a PMN, SNUN, LVE, LVE Modification, LoREX, LoREX Modification, or TMEA case number format); this value accepts alphanumeric characters and dashes. Click the 'Save' icon (💾) to save an individual entry. Click the 'Form' icon (📄) that displays after saving to edit an individual entry. Click the 'Delete' icon (✖) to delete individual entries. Click the 'Add' icon (+) to generate blank text fields to provide additional entries. This field is required, or the 'None' checkbox must be checked.
- **Previously Submitted Notice Number – CBI:** Check the 'CBI' checkbox to claim all identified previously submitted notice numbers as confidential.
- **Bona Fide Intent Notice Number – None:** Check the 'None' checkbox for the 'Bona Fide Intent Notice Number' to indicate that there is no bona fide intent notice number. Check the 'None' checkbox to remove the 'Bona Fide Intent Notice Number' fields and associated actions. Un-check the 'None' checkbox to re-generate a 'Bona Fide Intent Notice Number' field and enter a value.
- **Bona Fide Intent Notice Number:** Enter the bona fide intent notice number to associate with a previous contact with EPA. Click the 'Save' icon (💾) to save an individual entry. Click the 'Form' icon (📄) that displays after saving to edit an individual entry. Click the 'Delete' icon (✖) to delete individual entries. Click the 'Add' icon (+) to generate blank text fields to provide additional entries. This field is required, or the 'None' checkbox must be checked.
- **Bona Fide Intent Notice Number – CBI:** Check the 'CBI' checkbox to claim all identified bona fide intent notice numbers as confidential.
- **Manufacture:** Check the 'Manufacture' checkbox to claim the intent to manufacture. The screens within the 'Submitter Controlled Operations' folder automatically generate when the 'Manufacture' checkbox is checked.
- **Binding:** Check the 'Binding' checkbox to claim intent to manufacture information as binding.
- **Import:** Check the 'Import' checkbox to claim the intent to import.
- **Binding:** Check the 'Binding' checkbox to claim intent to import information as binding.

Exhibit 4-15 shows a screen capture of the ‘Additional Submission Information’ screen:



Exhibit 4-15 Additional Submission Information Screen (PMN)

Navigation: Click the ‘Next’ button to navigate to the ‘Chemical Identification’ screen. You may also access this screen by clicking the ‘Add Consolidated Chemical’ link within the navigation tree.

4.1.7 Chemical Identification

You can access the ‘Chemical Identification’ screen by clicking the ‘Next’ button from the ‘Additional Submission Information’ screen. You may also click the ‘Add Consolidated Chemical’ link within the navigation tree to access the ‘Chemical Identification’ screen.

The ‘Chemical Identification’ screen identifies the type of chemical the submitter will be entering into the application. You will be able to file a PMN form for a class 1 or 2 chemical substance or a polymer. Based on your selection, the appropriate screens for the respective

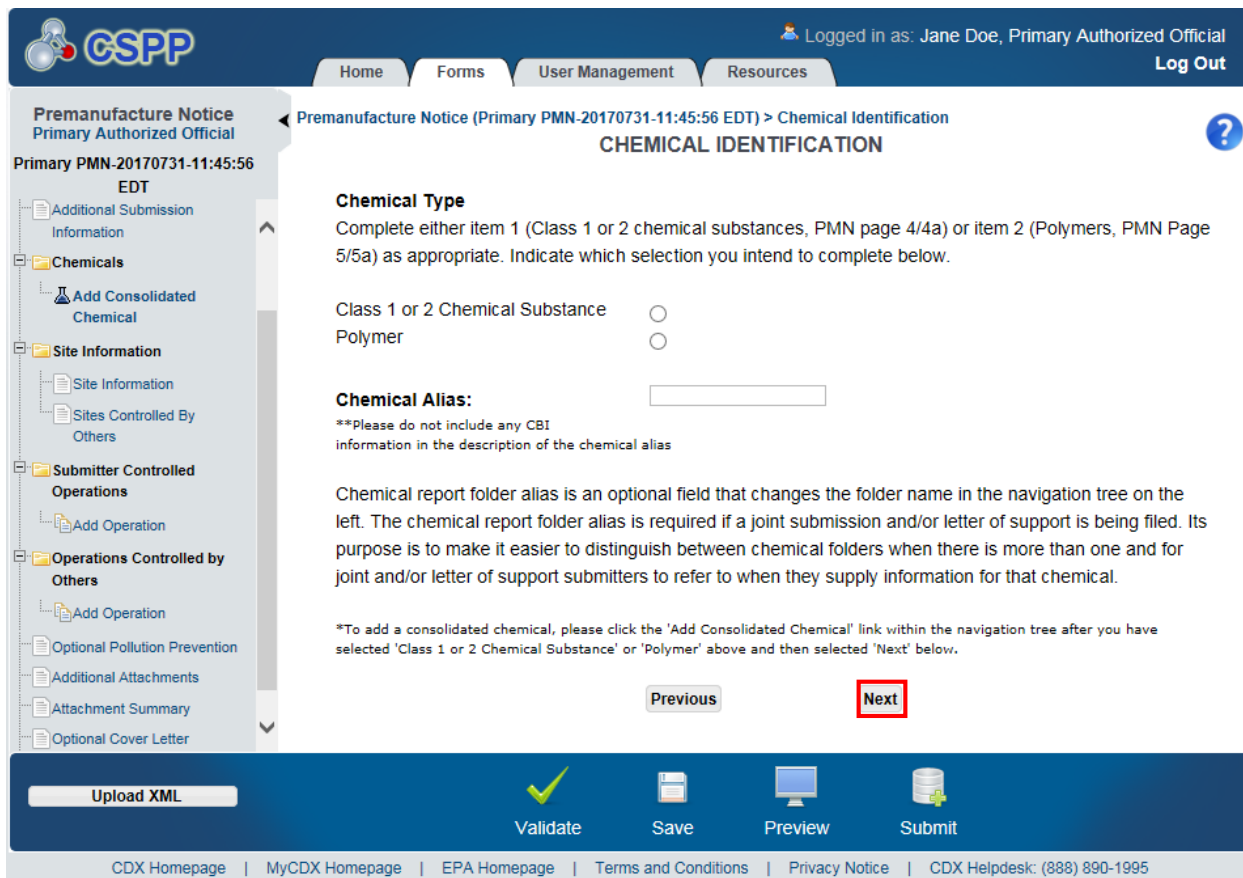
chemical will appear. If you select the ‘Class 1 or 2 Chemical Substance’ radio button, click the ‘Save’ icon () within the bottom action bar, or click the ‘Next’ button to generate the ‘Class 1 or 2 Chemical Substances’ screen within the navigation tree. If you identify the chemical as a polymer by selecting the ‘Polymer’ radio button, click the ‘Save’ icon () within the bottom action bar, or click the ‘Next’ button to generate the ‘Polymer Identification Information’ screen and the ‘Monomers and Other Reactants’ screen within the navigation tree.

This screen provides a field to identify an alias for the chemical substance, and allows you to identify chemicals in a consolidated chemical submission. The chemical alias is required if a Joint Submission or Letter of Support is being filed and renames the chemical folder within the navigation tree.

- **Class 1 or 2 Chemical Substance:** Select the ‘Class 1 or 2 Chemical Substance’ radio button to indicate that the chemical is a class 1 or 2 substance. If you select the ‘Polymer’ radio button after initially selecting the ‘Class 1 or 2 Chemical Substance’ radio button, the application generates a confirmation message warning you that you will lose all data for this chemical if the chemical type changes. Selecting either the ‘Class 1 or 2 Chemical Substance’ or ‘Polymer’ radio button is required.
- **Polymer:** Select the ‘Polymer’ radio button to indicate that the chemical is a polymer. If you select the ‘Class 1 or 2 Chemical Substance’ radio button after initially selecting the ‘Polymer’ radio button, the application generates a confirmation message warning you that you will lose all data for this chemical if the chemical type changes. Selecting either the ‘Class 1 or 2 Chemical Substance’ or ‘Polymer’ radio button is required.
- **Chemical Alias:** Enter the chemical alias to associate with a chemical. This field will auto-generate a chemical alias in the navigation tree upon leaving the screen if this field is left blank. This field is required if the form is pending a Joint Submission or a Letter of Support.

Exhibit 4-16 shows a screen capture of the ‘Chemical Identification’ screen:

Exhibit 4-16 Chemical Identification Screen (PMN)



Navigation: If you selected the ‘Class 1 or 2 Chemical Substance’ radio button, click the ‘Next’ button to navigate to the ‘Class 1 or 2 Chemical Substances’ screen. You can also access this screen by clicking the ‘Class 1 or 2 Chemical Substances’ link within the navigation tree.

If you selected the ‘Polymer’ radio button, click the ‘Next’ button to navigate to the ‘Polymer Identification Information’ screen. You can also navigate to this screen by clicking the ‘Polymer Identification Information’ link within the navigation tree.

4.1.8 Class 1 or 2 Chemical Substances

You can access the ‘Class 1 or 2 Chemical Substances’ screen if you selected the ‘Class 1 or 2 Chemical Substance’ radio button on the ‘Chemical Identification’ screen and clicked the ‘Next’ button. You can also access this screen by clicking the ‘Class 1 or 2 Chemical Substances’ link within the navigation tree for an in progress form.

The ‘Class 1 or 2 Chemical Substances’ screen provides fields for you to enter information describing the chemical for which the PMN is to be filed. This screen will outline the unique chemical properties that show the name, composition, and structure of the chemical. The system provides fields for you to identify several key aspects concerning a chemical’s identity.

For a single component submission, create the field set by clicking the ‘Add New Chemical’ button. Upon clicking the ‘Add New Chemical’ button, the application generates an

expandable/collapsible field set containing numerous fields for you to enter information pertaining to that particular chemical.

For a multi-component submission, create another field set by clicking the ‘Add New Chemical’ button. Multi-component chemical submissions occur when two or more chemicals are always generated together in a single pot and are never isolated. Upon clicking the ‘Add New Chemical’ button, the application generates a field set containing numerous fields for you to enter information pertaining to that particular chemical. Enter additional chemical components, each with unique identifying information, by clicking the ‘Add New Chemical’ button for each additional chemical that is part of the multi-component mixture. All multi-component chemicals will reside in one chemical folder in the navigation tree. Duplicate chemicals are not allowed within a multi-component submission.

For a consolidated submission, create and identify chemicals in separate chemical folders by clicking the ‘Add Consolidated Chemical’ link within the navigation tree.

If you select the ‘Class 1’ radio button on the ‘Class 1 or 2 Chemical Substances’ screen, click the ‘Next’ button to navigate to the ‘Additional Chemical Information’ screen. If you select the ‘Class 2’ radio button on the ‘Class 1 or 2 Chemical Substances’ screen, click the ‘Next’ button to navigate to the ‘Class 2 Substances’ screen.

For a class 1 substance chemical structure diagram, provide a complete and correct chemical structure diagram. A class 1 structural diagram clearly and completely indicates the identity of the atoms and the nature and location of the bonds joining the atoms. Provide ionic charges and known stereo chemical details. Carbon atoms in ring systems do not need to be explicitly shown.

For a class 2 substance chemical structure diagram:

- 1) List the immediate precursor substances with their respective CASRN.
- 2) Describe the nature of the reaction or process.
- 3) Indicate the range of composition and the typical composition (where appropriate).
- 4) Provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.

Provide partial, complete, or representative structural diagrams to the extent possible. The diagram should indicate the characteristic or variable compositional structural components of the substance. If you are unsure of the exact structure, provide the best information you have and indicate that it is your best estimate of the chemical structure.

- **Add New Chemical:** Click the button to generate the class 1 or 2 chemical substances expandable/collapsible field set.
- **Cancel:** Click the ‘Cancel’ link located in the upper right-hand corner of the expandable/collapsible field set to prevent edits from saving and to remove a field set. The ‘Cancel’ link displays when the expandable/collapsible field set is open for editing. A confirmation message displays to confirm the action.
- **Edit:** Click the ‘Edit’ link located in the upper right-hand corner of the expandable/collapsible field set to modify the information entered in the fields. The ‘Edit’

link displays when the expandable/collapsible field set has been saved and the data is not currently editable.

- **Delete:** Click the ‘Delete’ icon (✖) located in the upper right-hand corner of the expandable/collapsible field set to delete the field set. A confirmation message displays to confirm the deletion.
- **Expand All:** Click the ‘Expand All’ link located at the upper right-hand corner of the expandable/collapsible field sets to expand a series of field sets.
- **Collapse All:** Click the ‘Collapse All’ link located at the upper right-hand corner of the expandable/collapsible field sets to collapse a series of field sets.
- **B.1.a. Class of Substance:** In section B.1.a., select the ‘Class 1’ or ‘Class 2’ radio button to identify whether a ‘Class 1’ or ‘Class 2’ chemical substance is being reported. Selecting the ‘Class 2’ chemical substance radio button indicates that some portions of the structure may not be known and a ‘Class 2 Substances’ screen will appear within the navigation tree after clicking the ‘Next’ button for you to enter information concerning how the chemical was created. If multiple ‘Class 2’ chemical components are added, only one ‘Class 2 Substances’ screen will generate that applies to all the components. Check the ‘CBI’ checkbox to claim the chemical substance class as confidential. Either the ‘Class 1’ or ‘Class 2’ radio button must be selected.
- **Class 1:** Select the ‘Class 1’ radio button to identify the chemical as a ‘Class 1’ substance. A ‘Class 1’ substance is a single molecular entity that can be represented by a single, definite structural diagram. Either the ‘Class 1’ or the ‘Class 2’ radio button in the ‘B.1.a. Class of Substance’ section is required.
- **Class 2:** Select the ‘Class 2’ radio button to identify the chemical as a ‘Class 2’ substance. A ‘Class 2’ substance is a substance whose composition cannot be represented by a single, definite chemical structural diagram. Class 2 substances include substances of unknown, variable, or uncertain composition, complex mixtures or reaction products, or well-defined substances without specific structures. Either the ‘Class 1’ or the ‘Class 2’ radio button in the ‘B.1.a. Class of Substance’ section is required.
- **CBI:** Check the ‘CBI’ checkbox to claim the ‘Class of Substance’ as confidential.
- **Search SRS:** Click the ‘Search SRS’ button to generate the ‘Search Substance Registry Services’ pop-up window. Refer to **Section 3.10** for additional details regarding the search SRS functionality.
- **CASRN:** Displays the CASRN of the chemical identified on the ‘Search Substance Registry Services’ pop-up window, if applicable.
- **Chemical Name:** Displays the chemical name of the chemical identified on the ‘Search Substance Registry Services’ pop-up window. For class 1 substances, a ‘Chemical Abstracts (CA) Index Name’ must be provided. For class 2 substances either a ‘CA Index Name’ or ‘CA Preferred Name’ must be provided, whichever is appropriate based on current CA nomenclature rules and conventions. This is a required field.
- **CBI:** Check the ‘CBI’ checkbox to claim the ‘Chemical Name’ field as confidential and generate the ‘Generic Chemical Name’ text field.

- **B.6. Generic Chemical Name:** Enter the generic name to associate with a chemical. This field only displays when ‘CASRN’ and ‘Chemical Name’ are marked as ‘CBI.’ This is a required field if there is no pending Letter of Support or Joint Submission for the form.
- **Method 1 (CAS Inventory Expert Service):** Select the ‘Method 1 (CAS Inventory Expert Service)’ radio button to identify the ID method as the CAS Inventory Expert Service (IES) method and generate the ‘IES Order #’ field. A copy of the identification report obtained from the CAS Inventory Expert Services must be submitted as an attachment to this notice; an IES report is required. For a consolidated submission, each chemical must be ‘Method 1’ except when the submission is pending a Letter of Support for that chemical. In the case of an LVE/LOREX modification form type, this ‘Method 1’ requirement is not applicable. A single response option in the ‘B.1.c. ID Method’ section is required if there is no pending Letter of Support or Joint Submission for the form.
- **Method 2 (Other Method):** Select the ‘Method 2 (Other Method)’ radio button to identify the ID method as ‘Other Method.’ An alternative method of providing a name, such as a Scientific and Technical Information Network (STN) database report or a CAS Client Services report, qualifies as ‘Method 2.’ The chemical can be ‘Method 2’ if the consolidated submission is pending a Letter of Support. A single response option in the ‘B.1.c. ID Method’ section is required if there is no pending Letter of Support or Joint Submission for the form.
- **IES Order #:** Enter the IES order number of the report. This field only displays when the ‘Method 1 (CAS Inventory Expert Service)’ radio button is selected. This is a required field if the ‘Method 1 (CAS Inventory Expert Service)’ radio button is selected and if there is no pending Letter of Support or Joint Submission for the form.
- **B.1.d. Molecular Formula:** Enter the molecular formula associated with a chemical. The molecular formula must give the correct identity and number of atoms of each element contained in the PMN molecule or a description if the substance is a class 2 material. The system will not allow subscripts and superscripts to be used. This is a required field if there is no pending Letter of Support or Joint Submission for the form.
- **CBI:** Check the ‘CBI’ checkbox to claim the ‘Molecular Formula’ data as confidential.
- **Attachments:** Select the section of the page the file is associated with that you intend to attach from the drop-down menu. This drop-down menu contains the following values: ‘Chemical Structure Diagram’ and ‘ID Method.’ This is a required field to upload an attachment.
- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window. Refer to **Section 3.6** for further details regarding the attach document functionality.
- **Section:** Displays the section associated with a document.
- **File Name:** Displays the file name and file extension of the file that is uploaded on the ‘Attach Documents’ pop-up window.
- **Description:** Displays the description associated with a document.
- **Pages:** Displays the number of pages a document contains.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’

- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire document row permanently from the system; a warning message displays to confirm the deletion of the document.
- **Save:** Click the button to save the information entered within the expandable/collapsible field set. You must click this button instead of the ‘Save’ icon (💾) located within the bottom action bar to successfully save the entered information within the field set before being able to navigate away from the screen using the ‘Previous’ and ‘Next’ buttons. Refer to **Section 3.9** for more information regarding the save functionality in an expandable/collapsible field set.

Exhibit 4-17 shows a screen capture of the ‘Class 1 or 2 Chemical Substances’ screen (Scroll 1):

Exhibit 4-17 Class 1 or 2 Chemical Substances Screen (PMN) (Scroll 1)

Exhibit 4-18 shows a screen capture of the ‘Class 1 or 2 Chemical Substances’ screen (Scroll 2):

Exhibit 4-18 Class 1 or 2 Chemical Substances Screen (PMN) (Scroll 2)

The screenshot displays the GSPP (Global Submission Processing Portal) interface. The user is logged in as Jane Doe, a Primary Authorized Official. The main navigation menu includes Home, Forms, User Management, and Resources. The left sidebar shows a navigation tree for 'Premanufacture Notice Primary Authorized Official' with a primary PMN number of 20141201-11:36:29 EST. The 'Chemicals' section is expanded, showing 'Chemical 5863' and 'Class 1 or 2 Chemical Substances'. The main content area contains the following sections:

- B.1.c. ID Method:** Radio buttons for 'Method 1 (CAS Inventory Expert Service)' (selected) and 'Method 2 (Other Method)'. An input field for 'IES Order #' is present.
- B.1.d. Molecular Formula:** An input field and a 'CBI' checkbox.
- B.1.e. Chemical Structure Diagram:** A section for attaching a chemical structure diagram.
- Attach Document:** A dropdown menu to choose a section for document attachment, followed by an 'Attach Document' button.
- Table:** A table with columns: Section, File Name, Description, Pages, CBI, and Actions.
- Buttons:** 'Save' and 'Add New Chemical' buttons.

At the bottom of the main content area, there are 'Previous' and 'Next' buttons. The 'Next' button is highlighted with a red box. The footer contains navigation links: CDX Homepage, MyCDX Homepage, EPA Homepage, Terms and Conditions, Privacy Notice, and CDX Helpdesk: (888) 890-1995.

Navigation: If you select the ‘Class 1’ radio button, click the ‘Next’ button to navigate to the ‘Additional Chemical Information’ screen. You can also access this screen by clicking the ‘Additional Chemical Information’ link within the navigation tree. If you select the ‘Class 2’ radio button, click the ‘Next’ button to navigate to the ‘Class 2 Substances’ screen. You can also access this screen by clicking the ‘Class 2 Substances’ link within the navigation tree for an in progress form.

4.1.9 Class 2 Substances

You can access the ‘Class 2 Substances’ screen by clicking the ‘Next’ button from the ‘Class 1 or 2 Chemical Substances’ screen when you select the ‘Class 2’ radio button for the ‘Class of Substance’ field. You can also access this screen by clicking the ‘Class 2 Substances’ link within the navigation tree for an in progress form.

The ‘Class 2 Substances’ screen captures information regarding a class 2 chemical substance. A class 2 chemical substance is a substance that may not have a defined chemical structure that has been identified. This screen provides fields to identify specific elements in the creation of the chemical using the following fields: ‘Precursor Substances,’ ‘Nature of Reaction,’ and ‘Range of Composition.’

Enter precursor substances by searching SRS or using manual entry when the substance is not in SRS. The selected substances will display in a table listing the ‘Chemical Name’ and ‘CASRN.’

The system provides fields to capture ‘Nature of Reaction’ and ‘Range of Composition’ in text boxes. The ‘Nature of Reaction’ and ‘Range of Composition’ text boxes can be claimed as CBI.

- **B.1.e.1. Precursor Substances:** This table captures the chemicals identified as immediate precursor substances, along with the respective CASRNs, if applicable.
- **CBI:** Check the ‘CBI’ checkbox to claim the precursor substances information as confidential.
- **Search SRS:** Click the ‘Search SRS’ button to generate the ‘Search Substance Registry Services’ pop-up window. Refer to **Section 3.10** for additional details regarding the search SRS functionality.
- **Chemical Name:** Displays the chemical name associated with a precursor substance. Click the chemical name link to generate the ‘Search SRS’ pop-up window to make edits.
- **CASRN:** Displays the CASRN, if applicable, associated with a precursor substance.
- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire chemical row permanently from the system; a warning message displays to confirm the deletion of the chemical.
- **B.1.e.2. Nature of Reaction:** Enter the nature of the reaction or process description.
- **CBI:** Check the ‘CBI’ checkbox to claim the nature of reaction information as confidential.
- **B.1.e.3. Range of Composition:** Enter the range of composition and the typical composition description. Provide the range of composition in weight percent for each specific component or class of components that you intend to manufacture for commercial purposes.
- **CBI:** Check the ‘CBI’ checkbox to claim the range of composition information as confidential.
- **Attachments:** Select the section of the page the document you intend to attach is associated with from the drop-down menu. This drop-down menu contains the following values: ‘B.1.e.1. Precursor Substances,’ ‘B.1.e.2. Nature of Reaction,’ and ‘B.1.e.3. Range of Composition.’ This is a required field.
- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window and initiate the document upload process. Refer to **Section 3.6** for further details regarding the attach document functionality.
- **Section:** Displays the section associated with a document.
- **File Name:** Displays the file name and file extension of a file that is uploaded on the ‘Attach Documents’ window.
- **Description:** Displays the description associated with a document.

- **Pages:** Displays the number of pages a document contains.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire document row permanently from the system; a warning message displays to confirm the deletion.

Exhibit 4-19 shows a screen capture of the ‘Class 2 Substances’ screen (Scroll 1):

Exhibit 4-19 Class 2 Substances Screen (PMN) (Scroll 1)

Premanufacture Notice
Primary Authorized Official
Primary PMN-20141201-11:36:29 EST

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

Premanufacture Notice (Primary PMN-20141201-11:36:29 EST) > Class 2 Substances

CLASS 2 SUBSTANCES

Class 2 Substance Details

In the fields below for a class 2 substance (1) List the immediate precursor substances with their respective CAS Registry Numbers (if applicable). (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate).

B.1.e.1. Precursor Substances CBI:

Search SRS Click the ‘Search SRS’ button to search EPA’s Substance Registry Services (SRS) for a precursor substance or to manually enter the Chemical Name and CASRN (if applicable) if it is not found in SRS.

Chemical Name	CASRN	Action

B.1.e.2. Nature of Reaction CBI:

B.1.e.3. Range of Composition CBI:

Upload XML | Validate | Save | Preview | Submit

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Exhibit 4-20 shows a screen capture of the ‘Class 2 Substances’ screen (Scroll 2):

Exhibit 4-20 Class 2 Substances Screen (PMN) (Scroll 2)

Navigation: Click the ‘Next’ button to navigate to the ‘Additional Chemical Information’ screen. You can also access this screen by clicking the ‘Additional Chemical Information’ link within the navigation tree.

4.1.10 Additional Chemical Information

You can navigate to the ‘Additional Chemical Information’ screen by selecting the ‘Class 1’ radio button on the ‘Class 1 or 2 Chemical Substances’ screen and clicking the ‘Next’ button, by clicking the ‘Next’ button on the ‘Class 2 Substances’ screen, or clicking the ‘Next’ button from the ‘Monomers and Other Reactants’ screen. You can also access this screen by clicking the ‘Additional Chemical Information’ link within the navigation tree.

The ‘Additional Chemical Information’ screen captures information regarding the chemicals produced as byproducts and impurities when a chemical is manufactured. This screen also

captures other names for the chemical at hand in the ‘Synonyms’ and ‘Trade Identification’ tables.

An ‘Impurities’ table displays information regarding the impurities that may be reasonably anticipated to be in the respective chemical or polymer as manufactured for commercial purpose. Click the ‘Search SRS’ button to access the ‘Search SRS’ pop-up window and populate the ‘Impurities’ table. You will also be able to enter a chemical using the ‘Chemical Name’ and ‘CASRN’ field (if applicable) on the ‘Chemical Not Found In Substance Registry Services’ pop-up window. If there are unidentified impurities, enter “unidentified.” You also have the option of claiming the chemical as confidential by checking the ‘CBI’ checkbox. A ‘Maximum %’ field is also displayed which captures the maximum percentage for the impurity. Documents may be attached for the ‘Impurities’ section if necessary.

A ‘Byproducts’ table provides fields to capture information regarding the byproducts that may be produced from the manufacture of the respective chemical or polymer. Click the ‘Search SRS’ button to access the ‘Search SRS’ pop-up window and populate the ‘Byproducts’ table. You may associate a CASRN with a byproduct (if applicable) and check the ‘CBI’ checkbox to claim a byproduct as confidential. Documents may be attached for the ‘Byproducts’ section if necessary.

A ‘Synonyms’ table provides fields to capture the synonyms that the respective chemical or polymer may be referred to in the documentation. A maximum of five synonyms can be entered in the table. The search SRS functionality cannot be used to populate the ‘Synonyms’ table. You may attach documents associated with the ‘Synonyms’ section to provide additional synonyms if necessary.


A ‘Trade Identification’ table provides fields to capture information about the trade names by which the respective chemical or polymer may be referred in documentation. The number of trade names that may be added is unlimited. You may attach documents associated with the ‘Trade Identification’ section to provide additional information if necessary.

The ‘Attach Documents’ pop-up window provides fields to upload documents related to the ‘Impurities,’ ‘Byproducts,’ ‘Synonyms,’ and/or ‘Trade Identification’ section(s). Select the section of the page the document is associated with from the ‘Section’ drop-down menu, and click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window and attach a document. The system provides a ‘CBI’ checkbox to claim the uploaded document as confidential. If you claim a document as CBI, the system requires you to upload the sanitized version of the attached document.

If the sanitized version of the document is not provided, the Section 5 Notices and Supports form will fail validation upon navigating away from the ‘Attach Documents’ window. To view or edit previously attached documents, click the appropriate file name of the document within the ‘File Name’ column of the attachments table.

The attachments table displays the section of the page the document is associated with, the file name and file extension of the document, the document description, the number of pages in the document, and if the document was claimed CBI. Click the ‘Delete’ icon (✖) located under the ‘Actions’ column to delete unwanted documents. Click a file name link in the ‘File Name’ column to generate the ‘Attach Documents’ pop-up window to view and/or edit an attached document.

- **B.3. Impurities – Search SRS:** Click the ‘Search SRS’ button to display the ‘Search Substance Registry Services’ pop-up window. Refer to **Section 3.10** for further details regarding the search SRS functionality.
- **Impurity:** Displays the name of the impurity. An impurity is a chemical substance that you did not intend to be present with your PMN substance. List all known impurities that are present, regardless of their weight percent. List the expected maximum percentage of each impurity and indicate its confidentiality status. An impurity may be suggestive of chemical precursors or chemical processes. Click the ‘Impurity’ link to navigate to the ‘Search Substance Registry Services’ pop-up window to edit chemical information for an impurity.
- **CASRN:** Displays the Chemical Abstracts Service Registry Number for the impurity (if applicable).
- **Maximum %:** Displays the maximum percentage for the impurity; decimal values are accepted.
- **CBI:** Indicates the CBI status of the impurity by displaying either a ‘Y’ or an ‘N.’
- **Action:** Click the ‘Delete’ icon (✖) to delete the entire impurity entry permanently from the system; a warning message displays to confirm the deletion.
- **B.7. Byproducts - Search SRS:** Click the ‘Search SRS’ button to generate the ‘Search Substance Registry Services’ pop-up window. Refer to **Section 3.10** for further details regarding the search SRS functionality.
- **Byproduct Name:** Displays the name of the byproduct. Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance. List any byproducts that you reasonably anticipate will result from the manufacture, processing, use and disposal of the new chemical substance at sites under your control. Click the ‘Byproduct Name’ link to generate the ‘Search Substance Registry Services’ pop-up window to view and/or edit byproduct information. Provide the specific chemical name, CAS numbers if they can be determined, and the confidentiality status of the byproducts formed. If no byproducts are formed, enter “None” or leave the section blank.
- **CASRN:** Displays the CASRN for the byproduct (if applicable).
- **CBI:** Indicates the CBI status of the byproduct by displaying either a ‘Y’ or an ‘N.’
- **Action:** Click the ‘Delete’ icon (✖) to delete the entire byproduct entry permanently from the system; a warning message displays to confirm the deletion.
- **B.4. Synonyms - CBI:** Check the ‘CBI’ checkbox to claim the ‘Synonym’ field set as confidential.
- **Synonym:** Enter the synonym of the chemical; there is a maximum of five chemical synonyms that can be added in the ‘Synonyms’ table. Additional synonyms can be provided in an attachment. Synonyms include common chemical names used in scientific or technical literature, and code numbers or code names referenced in the PMN and its attachments. Indicate which synonyms may be proprietary and require CBI protection. Chemical name synonyms must be consistent with the chemical structure and thus not misleading. If you add a blank, editable line in this table and click the ‘Next’ button, no error will display indicating that the blank line should be saved or deleted. If text is entered in a blank field and you click the ‘Next’ button, the application will save the entered value. If you click the ‘Form’ icon

() , edit the entered values and click the 'Next' button without saving the changed value, an error will generate.











- **Actions:** Click the 'Add' icon () to add a new text field to enter additional synonyms. Click the 'Save' icon () to save a chemical synonym. Click the 'Form' icon () that appears after saving to edit a chemical synonym. Click the 'Delete' icon () to delete a previously added chemical synonym. To cancel changes to a field, simply clear the data entered in the field.
- **B.5. Trade Identification – CBI:** Check the 'CBI' checkbox to claim the trade identification section as confidential.
- **Trade Name:** Enter the trade identification name. List any trade name that is used, or will be used, for the neat chemical substance, whether or not they are registered brands/trademarks. The number of trade names that can be added is unlimited. Check the 'CBI' checkbox to indicate the CBI status of trade names. If you add a blank, editable line in this table and click the 'Next' button, no error will display indicating that the blank line should be saved or deleted. If text is entered in a blank field and you click the 'Next' button, the application will save the entered value. If you click the 'Form' icon () , change the entered value(s) and click the 'Next' button without saving the changed value(s), an error message will generate.
- **Actions:** Click the 'Add' icon () to add a new text field to enter additional trade identification names. Click the 'Save' icon () to save a trade identification name. Click the 'Form' icon () to edit a trade identification name. Click the 'Delete' icon () to delete a previously added trade identification name.
- **Attachments:** Select the section of the page with which the document is associated from the drop-down menu. This drop-down menu contains the following values: 'Byproducts Section,' 'Impurities Section,' 'Synonyms Section,' and 'Trade Identification Section.'
- **Attach Document:** Click the 'Attach Document' button to generate the 'Attach Documents' pop-up window. Refer to **Section 3.6** for further details regarding the attach document functionality.
- **Section:** Displays the section of the page with which the document is associated.
- **File Name:** Displays the file name and file extension of the file that is uploaded on the 'Attach Documents' pop-up window.
- **Description:** Displays the description associated with a document.
- **Pages:** Displays the number of pages a document contains.
- **CBI:** Indicates the CBI status of a document by displaying either a 'Y' or an 'N.'
- **Action:** Click the 'Delete' icon () to delete the entire attached document row permanently from the system; a warning message displays to confirm deletion of the document.

Exhibit 4-21 shows a screen capture of the ‘Additional Chemical Information’ screen (Scroll 1):

Exhibit 4-21 Additional Chemical Information Screen (PMN) (Scroll 1)

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

Home Forms User Management Resources

Premanufacture Notice Primary Authorized Official
 Primary PMN-20141201-11:36:29 EST

Premanufacture Notice (Primary PMN-20141201-11:36:29 EST) > Additional Chemical Information

ADDITIONAL CHEMICAL INFORMATION

B.3. Impurities
 (a) - Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purpose. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."
 (b) - Estimate the maximum weight % of each impurity. If there are unidentified impurities, estimate their total weight %.

Click the Search SRS button on the right to search SRS or to manually enter an impurity. **Search SRS**

Impurity	CASRN	Maximum%	CBI	Action
----------	-------	----------	-----	--------

B.7. Byproducts
 Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance. Provide the CAS Registry Number if available.

Click the Search SRS button on the right to search SRS or to manually enter a byproduct. **Search SRS**

Byproduct Name	CASRN	CBI	Action
----------------	-------	-----	--------

B.4. Synonyms CBI:
 Enter any chemical synonyms for the new chemical substance.

Upload XML

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Exhibit 4-22 shows a screen capture of the ‘Additional Chemical Information’ screen (Scroll 2):

Exhibit 4-22 Additional Chemical Information Screen (PMN) (Scroll 2)

The screenshot displays the GSPP (Global Submission Processing Platform) interface for a Premanufacture Notice (PMN). The user is logged in as Jane Doe, a Primary Authorized Official. The navigation tree on the left shows the current path: Home > Forms > User Management > Resources > Chemicals > Chemical 5863 > Additional Chemical Information. The main content area is divided into sections for entering chemical information. Section B.4, 'Synonyms', includes a table with columns for 'Synonym' and 'Actions'. Section B.5, 'Trade Identification', includes a table with columns for 'Trade Name' and 'Actions'. Below these sections is an 'Attachments' section with a dropdown menu and an 'Attach Document' button. At the bottom of the main content area, there are 'Previous' and 'Next' buttons, with the 'Next' button highlighted in a red box. The footer contains navigation links for CDX, MyCDX, EPA, and CDX Helpdesk, along with a footer bar with 'Upload XML', 'Validate', 'Save', 'Preview', and 'Submit' buttons.

Navigation: Click the ‘Next’ button to navigate to the ‘Production Volume and Hazard/Safety Information’ screen. You can also access this screen by clicking the ‘Production Volume and Hazard/Safety Information’ link within the navigation tree.

4.1.11 Polymer Identification Information

You can access the ‘Polymer Identification Information’ screen by clicking the ‘Next’ button from the ‘Chemical Identification’ screen if you select the ‘Polymer’ radio button. You can also access this screen by clicking the ‘Polymer Identification Information’ link within the navigation tree after selecting the ‘Polymer’ radio button on the ‘Chemical Identification’ screen.

The ‘Polymer Identification Information’ screen captures information describing the polymer(s) for which the PMN will be filed. This screen outlines the unique chemical properties that show the name, composition, and structure of the polymer. The system will provide fields for you to identify several key aspects concerning a polymer’s identity.

To reference a monomer cleared with an LVE, comments should be included in an attachment (for example, on a reaction scheme).

Click the ‘Add New Chemical’ button to create a chemical field set. Upon clicking the ‘Add New Chemical’ button, an expandable/collapsible field set generates that contains numerous fields that pertain to the particular polymer. You are able to enter multiple chemical substances, each with unique information, by clicking the ‘Add New Chemical’ button for each chemical you wish to identify.

For a single component submission, create the field set by clicking the ‘Add New Chemical’ button. Upon clicking the ‘Add New Chemical’ button, the application generates a field set containing numerous fields that captures information pertaining to that particular chemical.

For a multi-component submission, click the ‘Add New Chemical’ button to create a field set. Multi-component chemical submissions occur when two or more chemicals always generate together in a single pot and are never isolated. Upon clicking the ‘Add New Chemical’ button, the application generates a field set that provides numerous fields to enter information pertaining to that particular chemical. Enter additional chemical substances, each with unique identifying information, by clicking the ‘Add New Chemical’ button for each additional chemical that is part of the multi-component mixture. All multi-component chemicals will reside in one chemical folder in the navigation tree.

For a consolidated submission, create separate chemical folders by clicking the ‘Add Consolidated Chemical’ link within the navigation tree. A form may contain a maximum of six (6) separate chemical folders.

- **Add New Chemical:** Click the ‘Add New Chemical’ button to generate a polymer identification information expandable/collapsible field set.
- **Cancel:** Click the ‘Cancel’ link located in the upper right-hand corner of the expandable/collapsible field set to prevent edits from saving and to remove a field set. The ‘Cancel’ link displays when the expandable/collapsible field set is open for editing. A confirmation message displays to confirm the action.
- **Edit:** Click the ‘Edit’ link located in the upper right-hand corner of the expandable/collapsible field set to modify the information entered in the fields. The ‘Edit’ link displays when the expandable/collapsible field set has been saved and the data is not currently editable.
- **Delete:** Click the ‘Delete’ icon (✖) located in the upper right-hand corner of the expandable/collapsible field set to delete the field set; a confirmation message displays to confirm the deletion.
- **Expand All:** Click the ‘Expand All’ link located at the upper right-hand corner of the expandable/collapsible field sets to expand a series of field sets.
- **Collapse All:** Click the ‘Collapse All’ link located at the upper right-hand corner of the expandable/collapsible field sets to collapse a series of field sets.
- **Search SRS:** Click the button to generate the ‘Search SRS’ pop-up window. Refer to **Section 3.10** for additional details regarding the search SRS functionality.

- **CASRN:** Displays the CASRN of the chemical identified on the ‘Search SRS’ pop-up window, if applicable.
- **Chemical Name:** Displays the name of the chemical that has been identified on the ‘Search SRS’ pop-up window.
- **CBI:** Check the ‘CBI’ checkbox to identify the chemical as confidential.
- **Generic chemical name:** Enter the generic name to associate with a chemical. This field displays when ‘Chemical Name’ and ‘CASRN’ are claimed CBI. This is a required field if there is no pending Letter of Support or Joint Submission for the form.
- **Method 1 (CAS Inventory Expert Service):** Select the ‘Method 1 (CAS Inventory Expert Service)’ radio button to identify the ID method as the ‘CAS Inventory Expert Service’ method. Submit a copy of the identification report obtained from the CAS Inventory Expert Services as an attachment to this notice. For a consolidated submission, each chemical must be ‘Method 1’ except when the submission is pending a Letter of Support for that chemical. Select the ‘Method 1 (CAS Inventory Expert Service)’ radio button to generate the ‘IES Order #’ field. A single response option in the ‘ID Method’ section is required if there is no pending Letter of Support or Joint Submission for the form.
- **IES Order #:** Select the ‘Method 1 (CAS Inventory Expert Service)’ radio button to generate this field. Enter the IES order number. This is a required field if the ‘Method 1 (CAS Inventory Expert Service)’ radio button is selected.
- **Method 2 (Other Method):** Select the ‘Method 2 (Other Method)’ radio button to identify the ID method as ‘Other Method.’ An alternative method of providing a name, such as a STN database report or a CAS Client Services report, qualifies as ‘Method 2.’ If the chemical is pending a Letter of Support, the method can only be ‘Method 2.’ A single response option in the ‘ID Method’ section is required if there is no pending Letter of Support or Joint Submission for the form.
- **Attachments:** Select the section of the page with which the document is associated from the drop-down menu. This drop-down menu contains the following values: ‘Chemical Structure Diagram’ and ‘ID Method.’ It is required that a document be attached for the ID Method if there is no pending Letter of Support or Joint Submission for the form.
- **Attach Document:** Click the button to generate the ‘Attach Documents’ pop-up window. Refer to **Section 3.6** for additional details regarding the attach document functionality.
- **Section:** Displays the section of the page with which the file is associated.
- **File Name:** Displays the file name and file extension of a document that is uploaded on the ‘Attach Documents’ pop-up window.
- **Description:** Displays the description of a document.
- **Pages:** Displays the number of pages in a document.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire attached document row permanently from the system. A warning message displays to confirm the deletion.

- **Save:** Click the button to save the information entered within the expandable/collapsible field set. You must click this button instead of the ‘Save’ icon (📄) located within the bottom action bar to successfully save the entered information within the field set before being able to navigate away from the screen using the ‘Previous’ and ‘Next’ buttons. Refer to **Section 3.9** for more information regarding the save functionality in an expandable/collapsible field set.

Exhibit 4-23 shows a screen capture of the ‘Polymer Identification Information’ screen (Scroll 1):

Exhibit 4-23 Polymer Identification Information Screen (PMN) (Scroll 1)

The screenshot displays the 'Polymer Identification Information' screen for a Premanufacture Notice (PMN-20140527-12:59:24 EDT). The interface includes a top navigation bar with 'Home', 'Forms', 'User Management', and 'Resources' tabs, and a 'Log Out' button. The user is logged in as 'Jane Doe, Primary Authorized Official'. The left sidebar shows a tree view of the PMN structure, with 'Polymer Identification Information' highlighted. The main content area contains a 'Search SRS' button and a text box for searching EPA's Substance Registry Services (SRS). Below this are input fields for 'CASRN', 'Chemical Name', 'CBI', and 'Generic chemical name'. The 'ID Method' section has two radio buttons: 'Method 1 (CAS Inventory Expert Service)' (selected) and 'Method 2 (Other Method)'. There are also fields for 'IES Order #', 'Chemical Structure Diagram', and 'Attach Document'. The bottom of the screen features an action bar with 'Upload XML', 'Validate', 'Save', 'Preview', and 'Submit' buttons.

Exhibit 4-24 shows a screen capture of the ‘Polymer Identification Information’ screen (Scroll 2):

Exhibit 4-24 Polymer Identification Information Screen (PMN) (Scroll 2)

Navigation: Click the ‘Next’ button to navigate to the ‘Monomers and Other Reactants’ screen. You can also access this screen by clicking the ‘Monomers and Other Reactants’ link within the navigation tree.

4.1.12 Monomers and Other Reactants

You can navigate to the ‘Monomers and Other Reactants’ screen by clicking the ‘Next’ button from the ‘Polymer Identification Information’ screen. You can also access this screen by clicking the ‘Monomers and Other Reactants’ link within the navigation tree.

The ‘Monomers and Other Reactants’ screen is used to identify the chemical measurements and monomers that make up a polymer. The screen is divided into two sections to identify different elements describing a polymer, ‘Polymer Weight Information’ and ‘Monomers and Other Reactants.’

In the ‘Monomers and Other Reactants’ section, enter the typical weight percent of each monomer or other reactant in the polymer. Enter the maximum weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes. The maximum residual should be less than the typical composition. Do not use parts per million (ppm) units (1 ppm = 0.0001 wt%).

To reference a monomer cleared with an LVE, include an attachment detailing any specifics.

- **CBI:** Check the ‘CBI’ checkbox to claim the ‘Polymer Weight Information’ section as confidential.
- **Method of Measurement:** Only a single response option can be selected for ‘Method of Measurement.’ valid values include ‘GPC’ and ‘Other (Specify).’ Gel-permeation chromatography (GPC) is a well-established method for establishing the number average molecular weight (M_n) and weight fractions below 500 and 1,000 Daltons. It may not be useful for all polymer evaluations; however, solubility problems and misleading calibration standards can lead to questionable GPC data. Correction estimates can be documented and presented in cases where only a soluble fraction of the polymer can be analyzed. This is a required field if there is no pending Letter of Support or Joint Submission for the form.
- **Specify other method of measurement:** Enter the method of measurement when you select the ‘Other (Specify)’ radio button as the method of measurement. This is a required field when the ‘Other (Specify)’ radio button is selected.
- **(i) lowest number avg. molecular weight:** Enter the lowest number average molecular weight; the entered value must be a positive numerical value and can contain decimal values. This is a required field if there is no pending Letter of Support or Joint Submission.
- **(ii) max. weight % below 500 molecular weight:** Enter the maximum weight percentage below 500 molecular weight. The value entered must be a positive numerical value greater than or equal to zero (0), but less than or equal to one hundred (100) and can contain decimal values. This value must be less than or equal to the value specified in the ‘(iii) max. weight % below 1000 molecular weight’ field. This is a required field if there are no pending Joint Submissions or Letters of Support.
- **(iii) max. weight % below 1000 molecular weight:** Enter the maximum weight percentage below 1,000 molecular weight. The value entered must be a positive numerical value greater than or equal to zero (0) but less than or equal to one hundred (100) and can contain decimal values. This value must be greater than or equal to the value specified in the ‘(ii) max. weight % below 500 molecular weight’ field. This is a required field if there are no pending Joint Submissions or Letters of Support.
- **Add Monomer:** Click the ‘Add Monomer’ button to generate the monomer expandable/collapsible field set.
- **Cancel:** Click the ‘Cancel’ link located in the upper right-hand corner of the expandable/collapsible field set to prevent edits from saving and to remove a field set. The ‘Cancel’ link displays when the expandable/collapsible field set is open for editing. A confirmation message displays to confirm the action.
- **Edit:** Click the ‘Edit’ link located in the upper right-hand corner of the expandable/collapsible field set to modify the information entered in the fields. The ‘Edit’

link displays when the expandable/collapsible field set has been saved and the data is not currently editable.

- **Delete:** Click the ‘Delete’ icon (✖) located in the upper right-hand corner of the expandable/collapsible field set to delete the field set. A confirmation message displays to confirm the deletion.
- **Expand All:** Click the ‘Expand All’ link located at the upper right-hand corner of the expandable/collapsible field sets to expand a series of field sets.
- **Collapse All:** Click the ‘Collapse All’ link located at the upper right-hand corner of the expandable/collapsible field sets to collapse a series of field sets.
- **Search SRS:** Click the ‘Search SRS’ button to generate the ‘Search Substance Registry Services’ pop-up window. Refer to **Section 3.10** for additional details regarding the search SRS functionality.
- **Monomer or Other Reactant:** Displays the monomer or other reactant name; this field populates based on information entered on the ‘Search SRS’ pop-up window. This is a required field.
- **Include in Identity:** Check the ‘Include in Identity’ checkbox to claim the value for ‘Monomer or Other Reactant’ as part of the monomer identification. This checkbox is most applicable for monomers that are less than or equal to 2% since the monomer is not considered to be included in the identity unless this checkbox is checked. This checkbox appears when a value of ‘2’ or less is entered into the ‘Typical Composition’ text field.
- **CBI:** Check the ‘CBI’ checkbox to claim the monomer or other reactant name and CASRN as confidential.
- **CAS Registry Number:** Displays the CASRN for the specified monomer; this field populates based on information entered on the ‘Search SRS’ pop-up window.
- **Chemical Name:** Displays the name of the chemical identified on the ‘Search SRS’ pop-up window.
- **Typical Composition:** Enter the typical composition value that a monomer contributes to a polymer; the value entered must be a positive numerical value greater than zero (0) and less than or equal to one hundred (100) and can contain decimal values. If the value entered is less than or equal to ‘2’ a warning will be displayed in the global ‘Validate’ function or during the submission process indicating that the typical composition is a value that is less than or equal to 2 percent and asking you whether it should be included in the chemical identity. This is a required field, and the value must be greater than zero (0).
- **CBI:** Check the ‘CBI’ checkbox to claim the ‘Typical Composition’ and ‘Include In Identity’ fields as confidential.
- **Maximum Residual:** Enter the maximum residual value. Indicate the maximum weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes. Enter a percent value less than or equal to the maximum weight; do not use ppm units (1 ppm = 0.0001 wt%). The value entered must be a positive numerical value that is less than or equal to the typical composition value. This is a required field.



- **CBI:** Check the ‘CBI’ checkbox to claim the ‘Maximum Residual’ field as confidential.
- **Save:** Click the button to save the information entered within the expandable/collapsible field set. You must click this button instead of the ‘Save’ icon () located within the bottom action bar to successfully save the entered information within the field set before being able to navigate away from the screen using the ‘Previous’ and ‘Next’ buttons. Refer to **Section 3.9** for more information regarding the save functionality in an expandable/collapsible field set.
- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window. Refer to **Section 3.6** for additional details regarding the attach document functionality.
- **File Name:** Displays the file name and file extension of the document that is uploaded on the ‘Attach Documents’ pop-up window. Click the file name link to navigate to the ‘Attach Documents’ pop-up window to make any edits.
- **Description:** Displays the description associated with a document.
- **Pages:** Displays the number of pages a document contains.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon () to delete the entire attached document row permanently from the system. A warning message displays to confirm the deletion of the document.

Exhibit 4-25 shows a screen capture of the ‘Monomers and Other Reactants’ screen (Scroll 1):

Exhibit 4-25 Monomers and Other Reactants Screen (PMN) (Scroll 1)

CDX GSPP | Logged in as: Jane Doe, Primary Authorized Official | [Home](#) | [Forms](#) | [User Management](#) | [Resources](#) | [Log Out](#)

Premanufacture Notice (Primary PMN-20141201-11:36:29 EST) > Monomers and Other Reactants

MONOMERS AND OTHER REACTANTS

B.2.a. Polymer Weight Information CBI:

Indicate the method of measurement in which the polymer weight was recorded.

Method of Measurement: GPC Other(Specify)

Specify other method of measurement:

Indicate the number-average weight of the lowest molecular weight composition of the polymer you intend to manufacture. Indicate maximum weight percent of low molecular weight species (not including residual monomers, reactants, or solvents) below 500 and below 1,000 absolute molecular weight of that composition.

(i) lowest number avg. molecular weight:

(ii) max. weight % below 500 molecular weight: %

(iii) max. weight % below 1000 molecular weight: %

B.2.b. Monomers and Other Reactants

Enter a percent value less than or equal to the maximum weight, do not use ppm units. (1 ppm = 0.0001 wt%).

Select the Add Monomer button to add monomers that make up the polymer composition.

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

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Exhibit 4-26 shows a screen capture of the ‘Monomers and Other Reactants’ screen (Scroll 2):

Exhibit 4-26 Monomers and Other Reactants Screen (PMN) (Scroll 2)

Navigation: Click the ‘Next’ button to navigate to the ‘Additional Chemical Information’ screen. You can also access this screen by clicking the ‘Additional Chemical Information’ link within the navigation tree.

4.1.13 Production Volume and Hazard/Safety Information

You can navigate to the ‘Production Volume and Hazard/Safety Information’ screen by clicking the ‘Next’ button from the ‘Additional Chemical Information’ screen. You can also access this screen by clicking the ‘Production Volume and Hazard/Safety Information’ link within the navigation tree.

The ‘Production Volume and Hazard/Safety Information’ screen collects different information regarding a chemical’s production and hazard elements.

Production Volume: The ‘Production Volume’ section captures information about production for the respective chemical or polymer for the ‘Maximum first 12-month production’ and the ‘Maximum 12-month production.’ The ‘Maximum first 12-month production’ value should be less than or equal to the ‘Maximum 12-month production’ value. The maximum volume may not exceed 100,000,000,000,000 kg/year for either field. The entered values will automatically display decimal points upon navigating away from the page. Decimals are allowed up to the milligram (.000001). Estimates should be on a 100% new chemical substance basis. Your production volumes should be estimated as accurately as possible, but you are not bound to your estimates unless you check the ‘Binding’ checkbox and are creating an LVE or LVE modification submission. Include amounts you intend to produce for export. Provide an estimate of the first 12 months of production and the maximum production volume for any consecutive 12-month period during the first three (3) years of commercial manufacture. You may upload an attachment to enter additional production information.

Hazard Information: The ‘Hazard Information’ section captures information regarding hazards that the company chooses to disclose. For EPA to take respirator use into account when evaluating risks posed by a new chemical, the MSDS (material safety data sheet) for the substance must specify a respirator that is appropriate for the types of anticipated exposures. For the same reason, all respirators must be certified by the National Institute for Occupational Safety and Health (NIOSH), and be referenced in the MSDS as “NIOSH certified” respirators.

If any type of risk assessment is prescribed to determine personal protective equipment (PPE) requirements, such risk assessment must be performed by a qualified Industrial Hygienist (IH) or other authorized occupational safety and health specialist.

Engineering controls are the preferred methods for managing workplace exposures to hazards. If these controls are inadequate or lacking, personal protective equipment must be used.

For EPA to take glove use into account when evaluating risks posed by a new chemical, the MSDS for the substance must specify gloves that are impervious to the substances of concern, as well as suitable for the type of tasks.

Close-fitting goggles or a full-face piece facemask are preferred for vapor, mist, or fume exposures, or wherever workplace contaminants can readily bypass loose-fitting equipment.

The information is collected in a file attachment. The system will display instructional text for you to identify which forms should be uploaded.

Provide the MSDS for the PMN substance or intermediate or product mixture (that contains it) as an attachment to the PMN. Also, include hazard warning statements or labels, if relevant. The personal protection requirements of the MSDS become integral requirements of an LVE notice.

- **CBI:** Check the ‘CBI’ checkbox to claim the production volume information as confidential.
- **Binding:** Check the ‘Binding’ checkbox to claim the production volume information as binding. This checkbox is enabled for LVE or LVE modifications only.
- **Maximum first 12-month production:** Provide an estimate of the first 12 months of production. The entered value must be a numerical value and must be greater than zero but less than 100,000,000,000,000 kg/year. This field accepts decimals to the milligram and is a required field if you do not have a pending Joint Submission and/or Letter of Support.

- **Maximum 12-month production:** Enter the data associated with the production volume. Provide an estimate of the maximum production volume for any consecutive 12-month period during the first three (3) years of commercial manufacture. The entered value must be a numerical value and must be greater than zero but less than 100,000,000,000,000 kg/year. This value must be greater than or equal to the ‘Maximum first 12-month production’ value. This field accepts decimals to the milligram and is a required field if you do not have a pending Joint Submission and/or Letter of Support.
- **Binding:** Check the ‘Binding’ checkbox to claim the hazard information as binding.
- **Attachments:** Select the section of the page with which the attached document is associated. This drop-down menu contains the following value: ‘Production Information Section’ and ‘Hazard Information Section.’
- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window. Refer to **Section 3.6** for additional details regarding the attach document functionality.
- **Section:** Displays the section with which the document is associated.
- **File Name:** Displays the file name and file extension of the file that is uploaded on the ‘Attach Documents’ pop-up window. Click the file name link to navigate to the ‘Attach Documents’ pop-up window to make any edits.
- **Description:** Displays the description associated with a document.
- **Pages:** Displays the number of pages a document contains.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire attached document row permanently from the system. A warning message displays to confirm the deletion.

Exhibit 4-27 shows a screen capture of the ‘Production Volume and Hazard/Safety Information’ screen:

Exhibit 4-27 Production Volume and Hazard/Safety Information Screen (PMN)

The screenshot displays the GSPP interface for a Premanufacture Notice (PMN). The user is logged in as Jane Doe, a Primary Authorized Official. The current screen is titled 'PRODUCTION VOLUME AND HAZARD/SAFETY INFORMATION' for PMN-20140527-12:59:24 EDT. The left navigation pane shows a tree structure with 'Production Volume and Hazard/Safety Information' highlighted. The main content area contains instructions for providing production volume information, a section for 'C.1. Production Volume' with input fields for 'Maximum first 12-month production' and 'Maximum 12-month production', and a section for '3. Hazard Information' with an 'Attach Document' button. At the bottom, there are buttons for 'Previous' and 'Next', and a footer with navigation links and contact information.

Navigation: Click the ‘Next’ button to navigate to the ‘Use Information’ screen. You can also access this screen by clicking the ‘Use Information’ link within the navigation tree.

4.1.14 Use Information

You can navigate to the ‘Use Information’ screen by clicking the ‘Next’ button from the ‘Production Volume and Hazard/Safety Information’ screen. You can also access this screen by clicking the ‘Use Information’ link within the navigation tree.

The ‘Use Information’ screen captures data about how the new chemical substance is intended to be used by function and application. Function refers to the chemical purpose for which the substance is designed and is often based on the physical and chemical properties of the substance. Application refers to how the substance is used in particular processes or products. An example of a function and application would be as a dispersive dye for finishing polyester fibers.

When you navigate to the screen, the screen contains instructional text and an ‘Add Use’ button. When you click the ‘Add Use’ button, an expandable/collapsible field set opens and displays the ‘Use Information’ fields. Upon saving the entry, the expandable/collapsible field set collapses and displays the ‘Category of Use’ and ‘Production %’ values.

You will first enter a description for the ‘Category of Use’ field. Each use will center on the ‘Category of Use’ and the different variables surrounding it. The category of use information should be specific enough to allow EPA reviewers to anticipate potential exposure patterns for the new substance (e.g. merely indicating “Dye” is not sufficient – is it photographic dye, a reactive dye for nylon fibers, or a dye to be incorporated in a polymer making film?). LVE notices limit you to your stated category of use(s), so make sure your description fully encompasses all intended uses for any LVE. When you claim the ‘Category of Use’ as CBI, you are required to enter a ‘Generic Use Description.’ The generic use description will be available publicly.

The table captures the different elements of use that the PMN form captures. The ‘Production %’ and ‘% in Formulation’ values will be captured to indicate how the product will be used and at what percent in that use. Each use must capture the percent of the production and percent in formulation for each category of use. The ‘Production %’ must equal up to 100% for all uses if there is no pending Letter of Support or Joint Submission for the form, and the field can be declared CBI. The ‘% in Formulation’ value can equal up to 100%, and the field can be declared CBI.

The ‘% of substance expected’ per use is captured for the following categories: ‘Site Limited,’ ‘Consumer,’ ‘Industrial,’ and ‘Commercial.’ The ‘% of substance expected’ value must total 100%. The ‘% of substance expected’ values can be claimed as CBI or listed as binding. These use types are used to determine the risks that the chemical will place on society.

- **Add Use:** Click the ‘Add Use’ button to add a new use information expandable/collapsible field set.
- **Cancel:** Click the ‘Cancel’ link located in the upper right-hand corner of the expandable/collapsible field set to prevent edits from saving and to remove a field set. The ‘Cancel’ link displays when the expandable/collapsible field set is open for editing. A confirmation message displays to confirm the action.
- **Edit:** Click the ‘Edit’ link located in the upper right-hand corner of the expandable/collapsible field set to modify the information entered in the fields. The ‘Edit’ link displays when the expandable/collapsible field set has been saved and the data is not currently editable.
- **Delete:** Click the ‘Delete’ icon (✖) located in the upper right-hand corner of the expandable/collapsible field set to delete the field set. A confirmation message displays to confirm the deletion.
- **Expand All:** Click the ‘Expand All’ link located at the upper right-hand corner of the expandable/collapsible field sets to expand a series of field sets.
- **Collapse All:** Click the ‘Collapse All’ link located at the upper right-hand corner of the expandable/collapsible field sets to collapse a series of field sets.

- **Category of Use:** Enter the category of use for the specific chemical substance by function and application. This is a required field.
- **CBI:** Check the ‘CBI’ checkbox to claim the category of use information as confidential and generate the ‘Generic Use Description’ field. Claiming the ‘Category of Use’ field as CBI and then un-checking the ‘CBI’ checkbox generates a confirmation message that all attached documents will be deleted.
- **Binding:** Check the ‘Binding’ checkbox to claim the category of use information as binding.
- **C.2.b. Generic Use Description:** Enter the generic use description of the chemical. This field displays when the ‘Category of Use’ field is claimed CBI. If you claim any category of use description as confidential, enter a generic description of that category. This field is required when the ‘Category of Use’ field is claimed CBI.
- **Total Production for this Use %:** Enter an estimate of the percent of total production for the first three years devoted to each category of use for the specific chemical. The entered value must be a value greater than zero (0) but less than or equal to one hundred (100). The ‘Production %’ must equal up to 100% for all uses if there is no pending Letter of Support or Joint Submission for the form. This field allows for decimal values. This is a required field.
- **CBI:** Check the ‘CBI’ checkbox to claim the ‘Total Production for this Use’ information as confidential.
- **In Formulation %:** Estimate the percent of the new substance as formulated in mixture, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use. The entered value must be a value greater than zero (0) but less than or equal to one hundred (100) and can include decimal values. This is a required field.
- **CBI:** Check the ‘CBI’ checkbox to claim the ‘Percentage in Formulation’ information as confidential.
- **CBI:** Check the ‘CBI’ checkbox to claim the percentage of substance expected per use information as confidential.
- **Binding:** Check the ‘Binding’ checkbox to claim the percentage of substance expected per use information as binding.
- **Site Limited %:** Enter the site limited percentage of substance expected per use for the submitted substance. Blank fields are recognized as zeroes. This field allows for decimal values. Break down the use(s) by percentage for the indicated end user categories. For example, site-limited means the substance will only be used on the adjacent property unit where manufactured and will not intentionally be removed from the site except for waste disposal.
- **Consumer %:** Enter the consumer percentage of substance expected per use for the submitted substance. Blank fields are recognized as zeroes. This field allows for decimal values. Break down the use(s) by percentage for the indicated end user categories. Consumer use means that private individuals will use the chemical substance or products containing the substance for personal use or enjoyment.
- **Industrial %:** Enter the industrial percentage of substance expected per use for the submitted substance. Blank fields are recognized as zeroes. This field allows for decimal

values. Break down the use(s) by percentage for the indicated end user categories. Industrial use means that the chemical substance or product containing the substance will be used at the locations of other manufacturers or processors.

- **Commercial %:** Enter the commercial percentage of substance expected per use for the submitted substance. Blank fields are recognized as zeroes. This field allows for decimal values. Break down the use(s) by percentage for the indicated end user categories. Indicate percentage of product volume expected for the listed “use” sectors. Commercial use refers to the chemical substance or product containing the chemical substance being used by a company to provide a consumer service.
- **If you have provided a “consumer” use, provide details:** Enter consumer use details. Provide a detailed description of the use(s) of this chemical substance in consumer products. In addition, include estimates of the concentration of the new chemical substance as expected in consumer products and describe the chemical reactions by which this substance loses its identity in the consumer product. This is a required field if the ‘Consumer % of substance expected per use’ field is populated and is a value greater than zero (0).
- **CBI:** Check the ‘CBI’ checkbox to claim the ‘If you have provided a ‘consumer’ use, provide details’ information as confidential.
- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window. Refer to **Section 3.6** for additional details regarding the attach document functionality.
- **File Name:** Displays the file name and file extension of the file uploaded on the ‘Attach Documents’ pop-up window. Click the ‘File Name’ link to navigate to the ‘Attach Documents’ pop-up window to make any edits.
- **Description:** Displays the description associated with a document.
- **Pages:** Displays the number of pages a document contains.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire attached document row permanently from the system. A warning message displays to confirm deletion of the document.
- **Save:** Click the button to save the information entered within the expandable/collapsible field set. You must click this button instead of the ‘Save’ icon (💾) located within the bottom action bar to successfully save the entered information within the field set before being able to navigate away from the screen using the ‘Previous’ and ‘Next’ buttons. Refer to **Section 3.9** for more information regarding the save functionality in an expandable/collapsible field set.
- **Production Total:** Displays the total production percentage for all uses. This value must be equal to 100, unless a Joint Submission or Letter of Support is pending, in which case the total value requirement is not immediately applicable.

Exhibit 4-28 shows a screen capture of the 'Use Information' screen (Scroll 1):

Exhibit 4-28 Use Information Screen (PMN) (Scroll 1)

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

Home Forms User Management Resources

Premanufacture Notice Primary Authorized Official
Premanufacture Notice (Primary PMN-20140527-12:59:24 EDT) > Use Information
USE INFORMATION
Expand All | Collapse All

Primary PMN-20140527-12:59:24 EDT

General Form Information
User Fees Certification
Agent Information
Technical Contact Information
Additional Submission Information

Chemicals

Class 2 Chemical Substance

Chemical Identification
Class 1 or 2 Chemical Substances
Additional Chemical Information
Production Volume and Hazard/Safety Information
Use Information

Physical & Chemical Properties

Physical and Chemical Properties Worksheet
Physical and Chemical

If a use is claimed as confidential, the Generic Use Description (public version of the CBI use) field must be completed. As you add use information, it will appear below. Click the 'CBI' checkbox for 'Category of Use' to hide details. (Click on it again to show those details).

Category of Use: CBI: Binding:
(by function and application i.e. a dispersive dye for finishing polyester fibers)

C.2.b. Generic Use Description:

Total Production % CBI:
for this Use:

In Formulation: % CBI:

% of substance expected per use: CBI: Binding:

Upload XML

Validate Save Preview Submit

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

Exhibit 4-29 shows a screen capture of the ‘Use Information’ screen (Scroll 2):

Exhibit 4-29 Use Information Screen (PMN) (Scroll 2)

Navigation: Click the ‘Next’ button to navigate to the ‘Physical and Chemical Properties Worksheet’ screen. You can also access this screen by clicking the ‘Physical and Chemical Properties Worksheet’ link within the navigation tree.

4.1.15 Physical and Chemical Properties Worksheet

You can navigate to the ‘Physical and Chemical Properties Worksheet’ screen by clicking the ‘Next’ button from the ‘Use Information’ screen. You can also access this screen by clicking the ‘Physical and Chemical Properties Worksheet’ link within the navigation tree.

The ‘Physical and Chemical Properties Worksheet’ screen is used to capture optional information about a chemical’s properties. EPA uses the chemical properties to determine additional safety data about a chemical; the properties are used to determine potential risks and exposures of the chemicals.

The properties for a chemical are captured in an expandable/collapsible field set format. The following categories may apply to a chemical: ‘Physical state of neat substance,’ ‘Vapor Pressure @ temperature,’ ‘Density/relative density,’ ‘Solubility @ temperature ___ solvent ___,’ ‘Solubility in water @ temperature ___,’ ‘Melting temperature,’ ‘Boiling/sublimation temperature @ ___,’ ‘Spectra,’ ‘Dissociation constant,’ ‘Particle size distribution,’ ‘Octanol/water partition coefficient,’ ‘Henry’s Law constant,’ ‘Volatilization from water,’ ‘Volatilization from soil,’ ‘pH @ concentration [concentration],’ ‘Flammability,’ ‘Explosibility,’ and ‘Adsorption/coefficient.’ All of the properties will capture the relevant values for a chemical. Each property may be claimed individually as CBI.

To enter physical/chemical property information, select a physical/chemical property from the drop-down menu and click the ‘Add Property’ button. The expandable/collapsible field set expands and displays all fields that should be entered for that property. You are then able to enter all relevant information regarding that property. Value fields are able to accept ‘<’ or ‘>’ symbols. When all information is entered, click the ‘Save’ button. Each property may only be entered once per chemical.

You may also enter an option for ‘Other.’ The ‘Other’ option will allow you to enter a user-specified property and any relevant values. The property will capture the relevant values for the chemical and the property measurement can be identified as ‘Measured’ or ‘Estimate.’ The ‘Other’ option may be claimed individually as CBI. You may enter multiple properties as ‘Other.’

You may upload attachments for the chemical properties on the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ screen.

EPA’s risk assessment process does utilize physiochemical properties, as some of the attributes listed here can relate directly to chemical risks. Among the most useful parameters of a new substance to EPA are the boiling point, the melting point, vapor pressure, the Octanol/water partition coefficient, water solubility, Henry’s Law Constant, hydrolysis, spectral data, mass spectrometry (MS), proton and C13 Nuclear Magnetic Resonance (NMR), Infrared (IR), and Ultraviolet (UV) absorption, and the soil/sediment absorption coefficient. In the absence of this data, EPA will estimate to the extent possible physiochemical data to aid in their risk evaluations.

Indicate whether the value you provide is based on an actual test measurement (‘Measured’) or is based on an estimate (‘Estimate’). Note that EPA staffers indicate that data qualifiers such as ‘negligible’ or ‘soluble’ are not useful descriptions.

You are not required to generate the listed test data if you do not have it.

Physical/chemical properties data may be so unique that they could in the future link the PMN substance to a commercial product or may tend to identify unique classes of chemical substance, and therefore some data elements may represent confidential business information. Review the CBI status of each entry carefully, and avoid making unsupportable claims.

- **Add Property:** Click the ‘Add Property’ button to add and open a new ‘Property’ expandable/collapsible field set for a selected property.
- **Cancel:** Click the ‘Cancel’ link located in the upper right-hand corner of an expandable/collapsible field set to prevent edits from saving and to remove a field set. The

'Cancel' link displays when an expandable/collapsible field set is open for editing. A confirmation message displays to confirm the action.

- **Edit:** Click the 'Edit' link located in the upper right-hand corner of an expandable/collapsible field set to modify the information entered in the fields. The 'Edit' link displays when the expandable/collapsible field set has been saved and the data is not currently editable.
- **Delete:** Click the 'Delete' icon (✖) located in the upper right-hand corner of an expandable/collapsible field set to delete the field set. A confirmation message displays to confirm the deletion.
- **Expand All:** Click the 'Expand All' link located at the upper right-hand corner of the expandable/collapsible field sets to expand a series of field sets.
- **Collapse All:** Click the 'Collapse All' link located at the upper right-hand corner of the expandable/collapsible field sets to collapse a series of field sets.
- **Adsorption/Coefficient - Value:** Enter the adsorption/coefficient value of the chemical substance. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Adsorption/coefficient' property is selected.
- **Adsorption/Coefficient - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Adsorption/coefficient' property is selected.
- **Adsorption/Coefficient – CBI:** Check the 'CBI' checkbox to claim the adsorption/coefficient property as confidential.
- **Boiling/sublimation temperature @ – Value:** Enter the boiling/sublimation temperature in °C of the chemical substance. This is a required field if the 'Boiling/sublimation temperature @' property is selected.
- **Boiling/sublimation temperature @ [pressure] torr:** Enter the value of the pressure in torr for which the boiling/sublimation of the chemical substance was determined. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Boiling/sublimation temperature @' property is selected.
- **Boiling/sublimation temperature @ - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Boiling/sublimation temperature @' property is selected.
- **Boiling/sublimation temperature @ - CBI:** Check the 'CBI' checkbox to claim the 'Boiling/sublimation temperature @' property as confidential.
- **Density/relative density - Value:** Enter the density/relative density value of the chemical substance in g/cm³. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Density/relative density' property is selected.
- **Density/relative density - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Density/relative density' property is selected.
- **Density/relative density - CBI:** Check the 'CBI' checkbox to claim the 'Density/relative density' property as confidential.

- **Dissociation constant - Value:** Enter the dissociation constant value of the chemical substance. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Dissociation constant' property is selected.
- **Dissociation constant - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Dissociation constant' property is selected.
- **Dissociation constant - CBI:** Check the 'CBI' checkbox to claim the 'Dissociation constant' property as confidential.
- **Explosibility - Value:** Enter the explosibility value of the chemical substance. This field allows text or numbers to be entered and is also able to accept '<' or '>' symbols. This is a required field if the 'Explosibility' property is selected.
- **Explosibility - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Explosibility' property is selected.
- **Explosibility - CBI:** Check the 'CBI' checkbox to claim the 'Explosibility' property as confidential.
- **Flammability - Value:** Enter the flammability value of the chemical substance. This field allows text and is also able to accept '<' or '>' symbols. This is a required field if the 'Flammability' property is selected.
- **Flammability - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Flammability' property is selected.
- **Flammability - CBI:** Check the 'CBI' checkbox to claim the 'Flammability' property as confidential.
- **Henry's Law constant - Value:** Enter the Henry's law constant value of the chemical substance in atm-m³/mole. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Henry's Law constant' property is selected.
- **Henry's Law constant - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Henry's Law constant' property is selected.
- **Henry's Law - CBI:** Check the 'CBI' checkbox to claim the 'Henry's Law constant' property as confidential.
- **Melting Temperature - Value:** Enter the melting temperature of the chemical substance in °C. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Melting Temperature' property is selected.
- **Melting Temperature - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Melting Temperature' property is selected.
- **Melting Temperature - CBI:** Check the 'CBI' checkbox to claim the 'Melting Temperature' property as confidential.

- **Octanol/water partition coefficient - Value:** Enter the Octanol/water partition coefficient value of the chemical substance. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Octanol/water partition coefficient' property is selected.
- **Octanol/water partition coefficient - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Octanol/water partition coefficient' property is selected.
- **Octanol/water partition coefficient - CBI:** Check the 'CBI' checkbox to claim the 'Octanol/water partition coefficient' property as confidential.
- **Particle size distribution - Value:** Enter the particle size distribution value of the chemical substance. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Particle size distribution' property is selected.
- **Particle size distribution - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Particle size distribution' property is selected.
- **Particle size distribution - CBI:** Check the 'CBI' checkbox to claim the 'Particle size distribution' property as confidential.
- **Physical state of neat substance - Value:** Select the physical state of a neat substance of chemicals, which can be either a 'Solid,' 'Liquid,' or 'Gas.' This is a required field if the 'Physical state of neat substance' property is selected.
- **Physical state of neat substance - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Physical state of neat substance' property is selected.
- **Physical state of neat substance - CBI:** Check the 'CBI' checkbox to claim the 'Physical state of neat substance' property as confidential.
- **pH @ concentration [concentration]:** Enter the concentration at which the pH was measured. This field allows for text. This is a required field if the 'pH @ concentration [concentration]' property is selected.
- **pH @ concentration [concentration] - Value:** Enter the pH value. This field allows text and is also able to accept '<' or '>' symbols. This is a required field if the 'pH @ concentration [concentration]' property is selected.
- **pH @ concentration [concentration] - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'pH @ concentration [concentration]' property is selected.
- **pH @ concentration [concentration] - CBI:** Check the 'CBI' checkbox to claim the 'pH @ concentration [concentration]' property as confidential.
- **Solubility @ temperature solvent:** Enter the temperature value in °C for which the solubility was measured. This field allows text and is also able to accept '<' or '>' symbols. This is a required field if the 'Solubility @ temperature solvent' property is selected.

- **Solubility @ temperature solvent - Solvent:** Enter the solvent that will be used for the chemical substance. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Solubility @ temperature solvent' property is selected.
- **Solubility @ temperature solvent - Value:** Enter the solubility of the chemical substance in g/L.
- **Solubility @ temperature solvent - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Solubility @ temperature solvent' property is selected.
- **Solubility @ temperature solvent - CBI:** Check the 'CBI' checkbox to claim the 'Solubility @ temperature solvent' property as confidential.
- **Solubility in Water @ temperature:** Enter the temperature value in °C of the chemical for which the solubility in water was measured. This is a required field if the 'Solubility in Water @ temperature' property is selected.
- **Solubility in Water @ temperature - Value:** Enter the solubility in water of the chemical substance in g/L. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Solubility in Water @ temperature' property is selected.
- **Solubility in Water @ temperature - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Solubility in Water @ temperature' property is selected.
- **Solubility in Water @ temperature - CBI:** Check the 'CBI' checkbox to claim the 'Solubility in Water @ temperature' property as confidential.
- **Spectra - Value:** Enter the spectra value of the chemical substance. Value fields are able to accept '<' or '>' symbols. This is a required field if the spectra property is selected.
- **Spectra - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Spectra' property is selected.
- **Spectra - CBI:** Check the 'CBI' checkbox to claim the 'Spectra' property as confidential.
- **Vapor Pressure @ temperature:** Enter the temperature value in °C of the chemical for which the vapor pressure was measured. This is a required field if the 'Vapor Pressure @ temperature' property is selected.
- **Vapor Pressure @ temperature - Value:** Enter the value of the Vapor Pressure in torr units of the chemical substance. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Vapor Pressure @ temperature' property is selected.
- **Vapor Pressure @ temperature - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Vapor Pressure @ temperature' property is selected.
- **Vapor Pressure @ temperature - CBI:** Check the 'CBI' checkbox to claim the 'Vapor Pressure @ temperature' property as confidential.

- **Volatilization from water - Value:** Enter the volatilization from water value of the chemical substance. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Volatilization from water' property is selected.
- **Volatilization from water - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Volatilization from water' property is selected.
- **Volatilization from water - CBI:** Check the 'CBI' checkbox to claim the 'Volatilization from water' property as confidential.
- **Volatilization from soil - Value:** Enter the volatilization from soil value. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Volatilization from soil' property is selected.
- **Volatilization from soil - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Volatilization from soil' property is selected.
- **Volatilization from soil - CBI:** Check the 'CBI' checkbox to claim the 'Volatilization from soil' property as confidential.
- **Other:** Enter any 'Other' property that you may specify.
- **Other - Value:** Enter an 'Other' property value. Value fields are able to accept '<' or '>' symbols. This is a required field if the 'Other' property was selected.
- **Other - Measured or Estimate:** Indicate whether the property value is 'Measured' or based on an 'Estimate' by selecting the appropriate value from the drop-down menu. This is a required field if the 'Other' property is selected.
- **Other - CBI:** Check the 'CBI' checkbox to claim the property as confidential.

Exhibit 4-30 shows a screen capture of the ‘Physical and Chemical Properties Worksheet’ screen (Scroll 1):

Exhibit 4-30 Physical and Chemical Properties Worksheet Screen (PMN) (Scroll 1)

Premanufacture Notice (Primary PMN-20140313-10:33:26 EDT) > Physical and Chemical Properties Worksheet

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

To assist EPA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notice. Identify the property measured, the value of the property, the units in which the property is measured (as necessary), and whether or not the property is claimed as confidential. The physical state of the neat substance should be provided. These measured properties should be for the neat (100% pure) chemical substance. Properties that are measured for mixtures or formulations should be so noted (% PMN substance in). You should submit this worksheet as a supplement to your submission of test data. This worksheet is not a substitute for submission of test data.

Property	Edit	
▶ Adsorption/ Coefficient	Edit	✖
▶ Boiling/sublimation temperature @ 1 torr pressure	Edit	✖
▶ Density/ relative density	Edit	✖
▶ Dissociation constant	Edit	✖
▶ Explodability	Edit	✖
▶ Flammability	Edit	✖
▶ Henry's Law constant	Edit	✖
▶ Melting Temperature	Edit	✖
▶ Octanol/ water partition coefficient	Edit	✖
▶ Particle size distribution	Edit	✖
▶ Physical state of neat substance	Edit	✖
▶ pH @ concentration 10	Edit	✖
▶ Solubility @temperature 15°C solvent	Edit	✖
▶ Solubility in Water @ temperature 15°C	Edit	✖
▶ Spectra	Edit	✖
▶ Vapor Pressure @ temperature 15°C	Edit	✖
▶ Volatilization from water	Edit	✖

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Exhibit 4-31 shows a screen capture of the ‘Physical and Chemical Properties Worksheet’ screen (Scroll 2):

Exhibit 4-31 Physical and Chemical Properties Worksheet Screen (PMN) (Scroll 2)

substance. Properties that are measured for mixtures or formulations should be so noted (% PMN substance in). You should submit this worksheet as a supplement to your submission of test data. This worksheet is not a substitute for submission of test data.

Expand All | Collapse All

▶ Adsorption/ Coefficient	Edit	✗
▶ Boiling/sublimation temperature @ 1 torr pressure	Edit	✗
▶ Density/ relative density	Edit	✗
▶ Dissociation constant	Edit	✗
▶ Explodability	Edit	✗
▶ Flammability	Edit	✗
▶ Henry's Law constant	Edit	✗
▶ Melting Temperature	Edit	✗
▶ Octanol/ water partition coefficient	Edit	✗
▶ Particle size distribution	Edit	✗
▶ Physical state of neat substance	Edit	✗
▶ pH @ concentration 10	Edit	✗
▶ Solubility @temperature 15°C solvent	Edit	✗
▶ Solubility in Water @ temperature 15°C	Edit	✗
▶ Spectra	Edit	✗
▶ Vapor Pressure @ temperature 15°C	Edit	✗
▶ Volatilization from water	Edit	✗
▶ Volatilization from soil	Edit	✗

Previous **Next**

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Navigation: Click the ‘Next’ button to navigate to the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ screen. You can also access this screen by clicking the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ link within the navigation tree.

4.1.16 Physical and Chemical Properties Worksheet – Continued (Optional)

You can navigate to the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ screen by clicking the ‘Next’ button from the ‘Physical and Chemical Properties Worksheet’

screen. You can also access this screen by clicking the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ link within the navigation tree.

The ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ screen is used to capture all the studies and attachments that refer to the chemical properties captured on the ‘Physical and Chemical Properties Worksheet’ screen. When you first access the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ screen, instructional text, an ‘Attach Document’ button, and an attachments table displays.

When you attach a document, the properties that were selected on the ‘Physical and Chemical Properties Worksheet’ screen will be listed with checkboxes in the ‘Attach Documents’ pop-up window for you to select which properties an attachment is associated with. Check the properties that are relevant to the document, and then select a type and subtype value for the document. You will be able to attach a document, enter a description of the document, and list the number of pages.

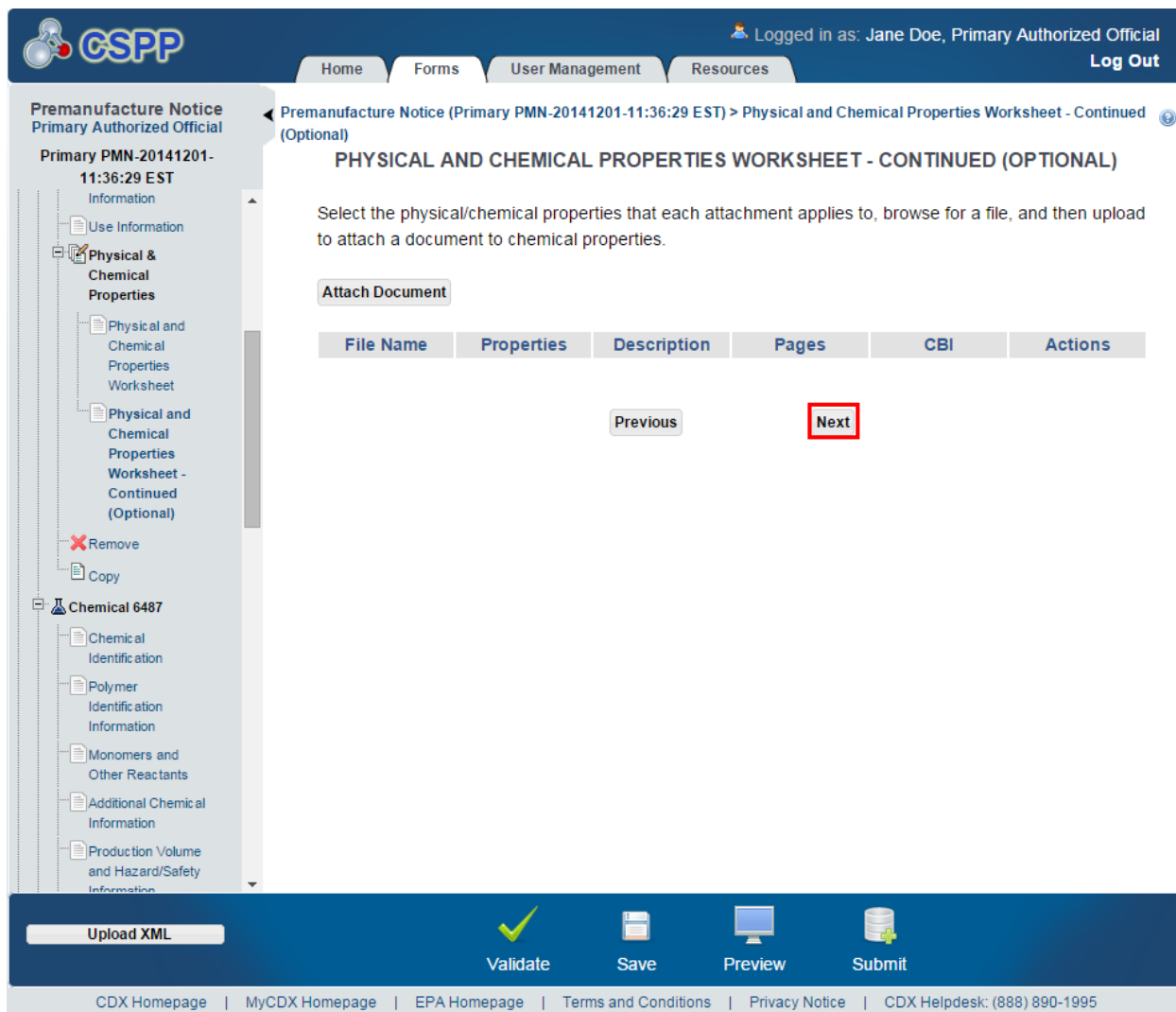
The system provides functionality to claim an uploaded document as CBI. If a document is claimed as CBI, the system requires you to upload the sanitized version of the attached document. To view, open, or edit previously attached documents, click the appropriate file name of the document within the ‘File Name’ column of the attachment table.

The attachment table displays the ‘File Name,’ ‘Properties,’ ‘Description,’ ‘Pages,’ ‘CBI,’ and ‘Actions’ columns. Click the ‘Delete’ icon (✖) located under the ‘Actions’ column to delete unwanted documents.

- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window. Refer to **Section 3.6** for additional details regarding the attach document functionality.
- **File Name:** Displays the file name and file extension of the original file that is uploaded on the ‘Attach Documents’ pop-up window. Click the ‘File Name’ link to navigate to the ‘Attach Documents’ pop-up window to make any edits.
- **Properties:** Displays the chemical properties associated with a document.
- **Description:** Displays the description associated with a document.
- **Pages:** Displays the number of pages a document contains.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire attached document row permanently from the system. A warning message displays to confirm the deletion.

Exhibit 4-32 shows a screen capture of the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ screen:

Exhibit 4-32 Physical and Chemical Properties Worksheet - Continued (Optional) Screen



Navigation: Click the ‘Next’ button to navigate to the ‘Site Information’ screen if you have not identified another chemical. You can also access this screen by clicking the ‘Site Information’ link within the navigation tree. If you would like to add a consolidated chemical, click the ‘Add Consolidated Chemical’ link within the navigation tree.

4.1.17 Physical and Chemical Properties Worksheet – Continued (Optional) Attach Documents

You can navigate to the ‘Attach Documents’ window by clicking the ‘Attach Document’ button on the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ screen.

When attaching a document, the properties selected on the ‘Physical and Chemical Properties Worksheet’ screen will display with checkboxes to allow the properties to which the attachment

refers to be selected. Select the type and subtype for the attachment and the properties relevant to the document, attach the document, and enter the number of pages.

The system allows the uploaded document to be claimed as CBI. If a document is claimed as CBI, the system requires the sanitized version of the attached document to be uploaded. To access or edit previously attached documents, click the appropriate file name of the document within the 'File Name' column of the attachment table.

- **Type:** Select the document type from the drop-down menu.
- **Subtype:** Select the document subtype from the drop-down menu.
- **Chemical Properties:** Displays the physical and/or chemical properties identified on the 'Physical and Chemical Properties Worksheet' screen that can be potentially associated with a document. Check the appropriate chemical properties that are associated with a document that is being attached. These checkboxes are enabled only if 'Physical Chemical Property' is selected from the 'Type' drop-down menu.
- **Attachment:** Displays the 'Browse' button to search for and identify documents on your local hard drive to be attached that can be associated with the physical/chemical properties identified on the 'Physical and Chemical Properties Worksheet' screen.
- **Description:** Enter the description associated with a document.
- **Pages:** Enter the number of pages a document contains.
- **CBI:** Check the 'CBI' checkbox to claim the document as confidential.
- **Sanitized Attachment:** Click the 'Browse' button to generate the 'File Upload' window to search for a particular file on your hard drive. For any attached document claimed as CBI, you are required to attach a sanitized version of the document.

Exhibit 4-33 shows a screen capture of the ‘Attach Documents’ pop-up window from the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ screen (Scroll 1):

Exhibit 4-33 Physical and Chemical Properties Worksheet - Continued (Optional) Attach Documents Pop-Up Window (PMN) (Scroll 1)

ATTACH DOCUMENTS

Type and Subtype
Select the type and subtype of the attachment

Type: Physical Chemical Property

Chemical Properties

- Adsorption/ Coefficient
- Boiling/ sublimation temperature @
- Density/ relative density
- Dissociation constant
- Explodability
- Flammability
- Henry's Law constant
- Melting Temperature
- Octanol/ water partition coefficient
- Particle size distribution
- Physical state of neat substance
- pH @ concentration [concentration]
- Solubility @temperature solvent
- Solubility in Water @temperature
- Spectra
- Vapor Pressure @temperature
- Volatilization from water
- Volatilization from soil
- Other Property

Attachment
Select the file to attach

File: Browse

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

Exhibit 4-34 shows a screen capture of the ‘Attach Documents’ pop-up window on the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ screen (Scroll 2):

Exhibit 4-34 Physical and Chemical Properties Worksheet - Continued (Optional) Attach Documents Pop-Up Window (PMN) (Scroll 2)

Boiling/ sublimation temperature @

Density/ relative density

Dissociation constant

Explodability

Flammability

Henry's Law constant

Melting Temperature

Octanol/ water partition coefficient

Particle size distribution

Physical state of neat substance

pH @ concentration [concentration]

Solubility @temperature solvent

Solubility in Water @temperature

Spectra

Vapor Pressure @temperature

Volatilization from water

Volatilization from soil

Other Property

Attachment File: Browse

Select the file to attach

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 File: Browse

Select the sanitized file to attach

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

Cancel **OK**

Navigation: Click the ‘Cancel’ button or ‘X’ icon located in the upper right-hand corner to stop the process of adding document information. Click the ‘OK’ button to save the entered information and navigate back to the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ screen.

4.1.18 Site Information

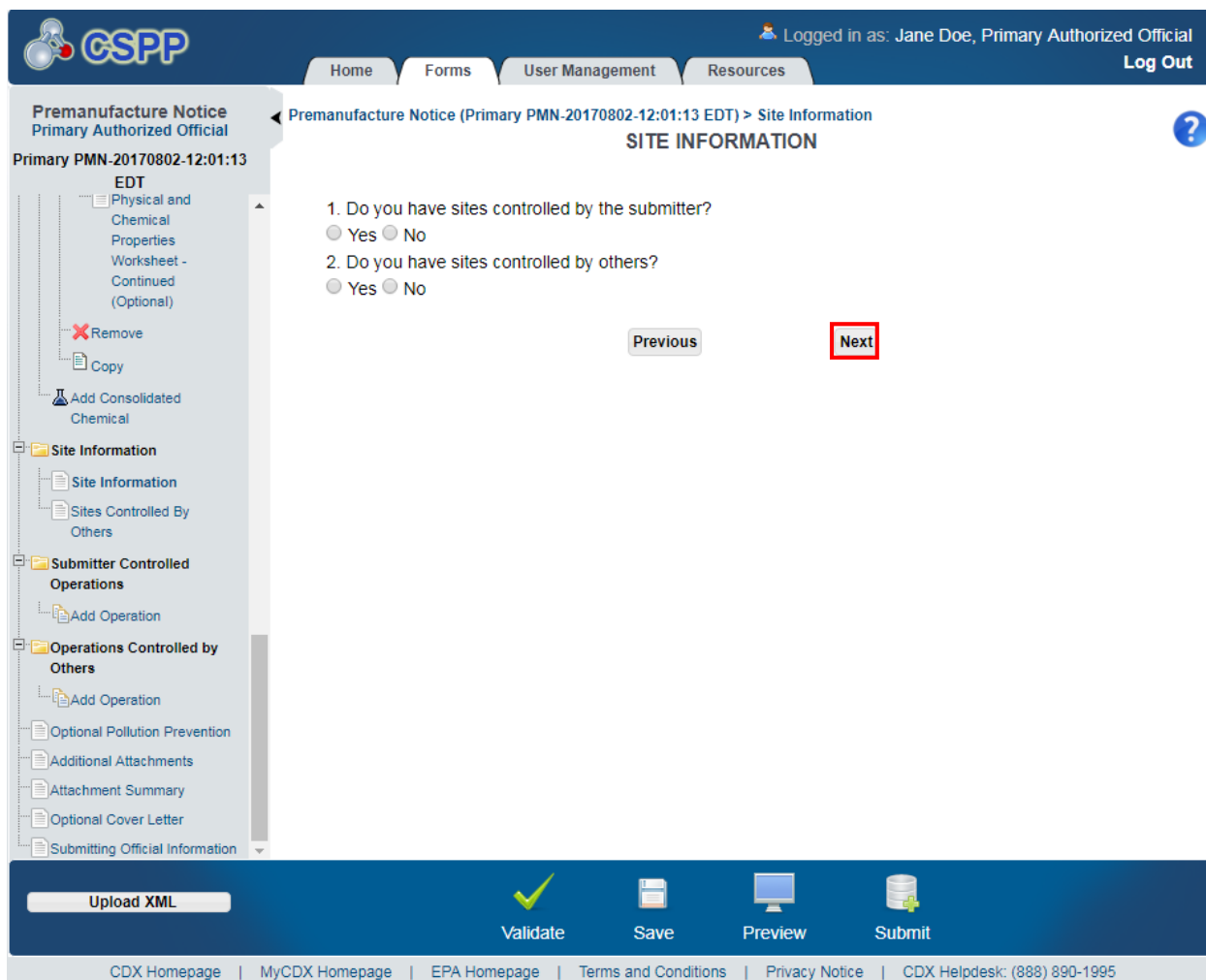
You can navigate to the ‘Site Information’ screen by clicking the ‘Next’ button from the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ screen. You can also access this screen by clicking the ‘Site Information’ link within the navigation tree.

The ‘Site Information’ screen captures information about the identification of submitter-controlled sites and sites controlled by others. If a user indicates there are submitter-controlled sites, the ‘Submitter Operation Information,’ ‘Occupational Exposures,’ and ‘Environmental Releases’ screens are automatically generated within the ‘Submitter Controlled Operations’ folder of the navigation tree. If a user indicates there are sites controlled by others, the ‘Industrial Sites Controlled By Others,’ ‘Exposures/Releases,’ and ‘Byproduct Information’ screens automatically generate within the ‘Operations Controlled By Others’ folder within the navigation tree upon clicking the ‘Next’ button. Toll manufacturing sites are considered sites controlled by the submitter.

- **Do you have sites controlled by the submitter?:** Select the ‘Yes’ radio button to indicate that you have submitter controlled sites to identify; this response automatically generates the screens within the ‘Submitter Controlled Operations’ folder in the PMN navigation tree upon clicking the ‘Next’ button. Select the ‘No’ radio button if you do not have any submitter-controlled sites to identify. An error message displays if a submitter-controlled site displays within the navigation tree and the ‘No’ radio button is selected.
- **Do you have sites controlled by others?:** Select the ‘Yes’ radio button to indicate that you have sites controlled by others to identify; this response automatically generates the screens within the ‘Operations Controlled by Others’ folder in the PMN navigation tree upon clicking the ‘Next’ button. Select the ‘No’ radio button if you do not have any sites controlled by others to identify. An error message displays if a site controlled by others displays within the navigation tree and the ‘No’ radio button is selected.

Exhibit 4-35 shows a screen capture of the ‘Site Information’ screen:

Exhibit 4-35 Site Information Screen (PMN)



Navigation: Click the ‘Next’ button to navigate to the ‘Sites Controlled By Others’ screen. You can also access this screen by clicking the ‘Sites Controlled By Others’ link within the navigation tree.

4.1.19 Sites Controlled By Others

You can navigate to the ‘Sites Controlled By Others’ screen by clicking the ‘Next’ button from the ‘Site Information’ screen. You can also access this screen by clicking the ‘Sites Controlled By Others’ link within the navigation tree.

The ‘Sites Controlled By Others’ screen captures information about known and/or unknown sites not controlled by the submitter. Complete the ‘Operations Controlled By Others’ section within the navigation tree for typical processing or use operations involving the new chemical substance at sites not controlled by the submitter. Importers do not have to complete this section for operations outside the U.S.; however, you must report any processing or use activities after import. Complete a separate ‘Operations Controlled By Others’ section for each type of processing, or use operation involving the new chemical substance. If the same operation is

performed at more than one site, describe the typical operation common to these sites. The screen first captures whether there is any data for other controlled sites. If there is no data for sites controlled by others, the screen will not update and the option of selecting the 'Next' button is available. If there is data for sites controlled by others, an additional question will appear. The screen then captures whether site-specific data for the chemical is known for 'Sites Controlled By Others.' If you indicate that there is site-specific data by selecting the 'Yes' radio button, the screen will generate a text field to enter the '# of unknown sites' and a 'CBI' checkbox to claim the number of unknown sites as confidential. If there is no site-specific data, the screen displays a text box to capture the number of unknown sites.

- **Do you have any sites controlled by others for which you have information to report?:** If you select 'Yes' the screen will display the question 'Do you have site-specific information?' If you select 'No' only the listed navigation options will display. If an operation controlled by others displays within the navigation tree, the 'Yes' radio button must be selected for this question.
- **Do you have site-specific information?:** If you select 'Yes' the screen generates fields to capture specific site information. If you select 'No,' a confirmation message displays indicating that any other sites you have will be deleted.
- **# of unknown sites:** Enter the number of unknown sites; zero (0) is an acceptable value. This is a required field.
- **CBI:** Check the 'CBI' checkbox to claim the number of unknown sites as confidential.

Exhibit 4-36 shows a screen capture of the ‘Sites Controlled By Others’ screen:

Exhibit 4-36 Sites Controlled By Others Screen (PMN)

Navigation: Click the ‘Next’ button to navigate to the ‘Submitter Operation Information’ screen. You can also click the ‘Add Operation’ link under the ‘Submitter Controlled Operations’ folder within the navigation tree to generate the submitter controlled operation screens or click the ‘Submitter Operation Information’ link under the ‘Submitter Controlled Operations’ folder within the navigation tree.

4.1.20 Submitter Operation Information

You can navigate to the ‘Submitter Operation Information’ screen by clicking the ‘Next’ button from the ‘Sites Controlled By Others’ screen. You can also access this screen by clicking the ‘Submitter Operation Information’ link under the ‘Submitter Controlled Operations’ folder within the navigation tree. You can add additional sites by clicking the ‘Add Operation’ link within the navigation tree under the ‘Submitter Controlled Operations’ folder.

The ‘Submitter Operation Information’ screen captures information about an operation that occurs at a particular site or group of sites. You are asked a series of questions and based on the

responses, a series of fields displays regarding a specific operation. The guided approach is designed to eliminate errors and ensure the completion of all relevant sections for a site. You will be able to enter an operation alias to identify the operation. Importers are not required to complete this section for operations outside the U.S.; however, any industrial processing or use operation that takes place after import must be described. It should be noted that Toll manufacturing sites are considered to be sites controlled by the submitter.

You will first be asked to select the site(s) and chemical(s) for the operation and will then select the applicable operation type checkboxes.

If you select an option other than 'Use' for the operation type, you will be asked whether the chemical is manufactured or processed as a 'batch' or 'continuous' process. Based on the property selected, fill in the relevant information. If you select the 'Use' operation type, then there will be no further options on this screen. The follow-up screens are used to capture specific information about the operation type process.

The system provides a text box for describing the process description. Additional process information may also be included in an attachment. In the process description, include the following information: (1) Diagram the major unit operation steps and chemical conversions. Include interim storage and specify transport containers (e.g., 5-gallon pails, 55-gallon drum, rail car, tank truck, etc.). (2) Provide the identity, approximate weight (by kilograms (kg) kg/day or kg/batch on a new chemical substance basis), and entry point of all starting materials, feedstocks (including reactants, solvents, catalysts, etc.), products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch). (3) Identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance. If releasing to two media at the same step, assign a second release number for the second medium.

You may claim the process description or attachment as CBI. If an attached document is claimed as CBI, the system requires a sanitized version of the attached document to be uploaded. To access or edit previously attached documents, click the file name of the document within the 'File Name' column of the document table.

The document table displays the file name and file extension of the document, the document description, the number of pages in the document, and whether a sanitized copy of the document was attached. Click the 'Delete' icon (✖) under the 'Actions' column to delete unwanted documents.

- **Operation Alias:** Enter the operation alias. This field makes it easier to distinguish between operations in the navigation tree when there is more than one operation. This is a required field if the form is pending a Joint Submission or a Letter of Support.
- **Add Facility:** Click the button to generate the 'Add Facility' pop-up window and select a site from the drop-down menu to add to the 'Submitter Operation Information' screen. Refer to **Section 3.11** for additional details regarding the add facility functionality.
- **Site Name:** Displays the site name.
- **Address:** Displays the site address.
- **City:** Displays the site city.

- **State:** Displays the site state.
- **Postal Code:** Displays the site postal code.
- **CBI:** Indicates the CBI status of the site by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete a site from the table. A warning message displays to confirm the deletion of the site.
- **Select the chemical(s) that this submission pertains to:** Displays all consolidated chemicals in a PMN submission with associated checkbox(es).
- **CBI:** Check the ‘CBI’ checkbox to claim the operation type as confidential.
- **Manufacturing:** Check the ‘Manufacturing’ checkbox to indicate that manufacturing is taking place at the site. Checking the ‘Manufacturing’ checkbox generates the ‘Is it batch or continuous’ radio buttons.
- **Processing:** Check the ‘Processing’ checkbox to indicate that processing is taking place at the site. Checking the ‘Processing’ checkbox generates the ‘Is it batch or continuous’ radio buttons.
- **Use:** Check the ‘Use’ checkbox to indicate that chemical use is taking place at the site.
- **CBI:** Check the ‘CBI’ checkbox to claim the amount and duration information as confidential.
- **Is it batch or continuous?:** Select the ‘Batch’ radio button to indicate that the chemical is produced in a batch process. Select the ‘Continuous’ radio button to indicate that the chemical is produced on a continuous basis. Either the ‘Batch’ or ‘Continuous’ radio button is required to be selected.
- **Max kg/batch:** Enter the maximum number of kilograms produced per batch. This field only displays when you select the ‘Batch’ radio button and is a required field. This field accepts decimal values.
- **Hours/batch:** Enter the hours of manufacturing or processing time needed per batch. This field only displays when you select the ‘Batch’ radio button and is a required field. This field accepts decimal values.
- **Batches/year:** Enter the number of batches produced per year. This field only displays when you select the ‘Batch’ radio button and is a required field. This field accepts decimal values.
- **Max kg/day:** Enter the maximum number of kg of a chemical produced per day. This field only displays when you select the ‘Continuous’ radio button and is a required field. This field accepts decimal values.
- **Hours/day:** Enter the number of hours per day that the chemical is processed or manufactured; this value cannot exceed 24. This field only displays when you select the ‘Continuous’ radio button and is a required field. This field accepts decimal values.
- **Days/year:** Enter the number of days per year that the chemical is processed or manufactured; this value cannot exceed 365. This field only displays when you select the ‘Continuous’ radio button, and is a required field. This field accepts decimal values.
- **CBI:** Check the ‘CBI’ checkbox to claim the process description as confidential.

- **Binding:** Check the ‘Binding’ checkbox to claim the process description as binding.
- **Process Description:** Enter the process description. In the ‘Process Description’ text box, or an attachment, address the following items: (1) Diagram the major unit operation steps and chemical conversions. Include interim storage and transport containers (specify – e.g., 5-gallon pails, 55-gallon drum, rail car, tank truck, etc.). (2) Provide the identity, the approximate weight (by kg/day or kg/batch on a 100% new chemical substance basis), and entry point of all starting materials and feedstocks (including reactants, solvents, catalysts, etc.), and of all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch). (3) Identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance. If releasing to two media at the same step, assign a second release number for the second medium. Either this field is required or a document must be attached.
- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window. Refer to **Section 3.6** for additional details regarding the attach document functionality.
- **File Name:** Displays the file name and file extension of the file that is uploaded on the ‘Attach Documents’ pop-up window.
- **Description:** Displays the description associated with a document.
- **Pages:** Displays the number of pages a document contains.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire attached document row permanently from the system. A warning message displays to confirm the deletion.

Exhibit 4-37 shows a screen capture of the ‘Submitter Operation Information’ screen (Scroll 1):

Exhibit 4-37 Submitter Operation Information Screen (PMN) (Scroll 1)

Premanufacture Notice
Primary Authorized Official

Primary PMN-20141201-11:36:29 EST

Premanufacture Notice (Primary PMN-20141201-11:36:29 EST) > Submitter Operation Information

SUBMITTER OPERATION INFORMATION

Operation Alias:

The operation alias is a text field that changes the folder name in the navigation tree on the left. Its purpose is to make it easier to distinguish between operations when there is more than one. The operation alias is only required if a letter of support and/or joint submission is pending; otherwise, this field is optional.

Please select the site to report operations on:

Add Facility

Site Name	Address	City	State	Postal Code	CBI	Actions

Select the chemical(s) that this submission pertains to:

Chemical 1
 Chemical 2

A.1.b Operation Type CBI:

Please select the type of operations present at this site.
 Manufacturing:
 Processing:
 Use:

A.1.c. Operation Description

Amount and Duration (Complete 1 or 2 as appropriate): CBI:
 Is it batch or continuous?

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Exhibit 4-38 shows a screen capture of the ‘Submitter Operation Information’ screen (Scroll 2):

Exhibit 4-38 Submitter Operation Information Screen (PMN) (Scroll 2)

Navigation: Click the ‘Next’ button to navigate to the ‘Occupational Exposures’ screen. You can also access this screen by clicking the ‘Occupational Exposures’ link within the navigation tree.

4.1.21 Occupational Exposures

You can navigate to the ‘Occupational Exposures’ screen by clicking the ‘Next’ button from the ‘Submitter Operation Information’ screen. You can also access this screen by clicking the ‘Occupational Exposures’ link within the navigation tree.

Click the ‘Add’ button to generate an expandable/collapsible field set to enter occupational exposure information. The application displays fields for you to enter information for ‘Worker Category (1),’ ‘Worker Activity (1),’ ‘Protective Equipment/Engineering Controls (3),’ ‘Physical Form(s) (5),’ ‘% New Substance (5),’ ‘# Workers Exposed (8),’ ‘Maximum Duration Hours/Day (10),’ and ‘Maximum Duration Days/Year (11).’ EPA is attempting to estimate exposure levels,

the number of workers potentially exposed, and possible routes and duration of exposure to the PMN substance. Work with your plant engineers to develop accurate data; review the CBI status of data you provide.

Information entered into the ‘Maximum Duration Hours/Day (10)’ and ‘Maximum Duration Days/Year (11)’ fields must be a positive whole number or decimal. The system does not allow special characters to be saved in these fields. If further explanation is required regarding duration of exposure, please provide this in an attachment.

- **Add:** Click the ‘Add’ button to generate the ‘Occupational Exposure – Submitter Controlled Sites’ expandable/collapsible field set.
- **Cancel:** Click the ‘Cancel’ link located in the upper right-hand corner of the expandable/collapsible field set to prevent edits from saving and remove the field set. The ‘Cancel’ link displays when the expandable/collapsible field set is open for editing. A confirmation message displays to confirm the action.
- **Edit:** Click the ‘Edit’ link located in the upper right-hand corner of the expandable/collapsible field set to modify the information entered in the fields. The ‘Edit’ link displays when the expandable/collapsible field set has been saved and the data is not currently editable.
- **Delete:** Click the ‘Delete’ icon (✖) located in the upper right-hand corner of the expandable/collapsible field set to delete the field set. A confirmation message displays to confirm the deletion. The ‘Delete’ icon (✖) displays when the user has clicked the ‘Add’ button.
- **Expand All:** Click the ‘Expand All’ link located at the upper right-hand corner of the expandable/collapsible field sets to expand a series of field sets.
- **Collapse All:** Click the ‘Collapse All’ link located at the upper right-hand corner of the expandable/collapsible field sets to collapse a series of field sets.
- **Worker Category (1):** Select the category of work from the drop-down menu in which a worker may be exposed to a chemical substance. This is a required field.
- **CBI:** Check the ‘CBI’ checkbox to claim worker category information as confidential.
- **Worker Activity (1):** Select the worker activity (e.g. bag dumping, tote filling, unloading drums, sampling, cleaning, etc.) in which workers may be exposed to a chemical substance. Please note that if you are populating this field via an XML file created from the ePMN thick client, this drop-down menu will not populate. This is a required field.
- **User Defined Worker Activity:** Enter the worker activity in which workers may be exposed to a chemical substance. This field displays only for certain worker activity values.
- **Protective Equipment/Engineering Controls (3):** Enter the protective equipment/engineering controls used to protect workers. This is a required field.
- **CBI:** Check the ‘CBI’ checkbox to claim the protective equipment/engineering controls, physical form(s), and % new substance information as confidential.
- **Binding:** Check the ‘Binding’ checkbox to claim the protective equipment/engineering controls information as binding.


- **Physical Form(s) (5):** Enter the physical forms(s) of the new chemical substance (e.g., solid, crystal, granule, powder, or dust) at the time of exposure. Be as specific as possible on the physical form (e.g., is the PMN substance isolated as a crystalline or amorphous powder, wet cake, flake solid, granular solid, or a fused solid?). If data on particle size of solids are available, it should be included as an attachment. For wet cakes, a percent moisture estimate may prevent EPA from making an estimate that is too conservative. Please pay particular attention to the information within if this field is populated via XML file. The information contained within the 'Physical Forms and % New Substance' field in the thick client separates into two (2) separate fields, the 'Physical Form(s)' field and '% New Substance' field when these fields are populated via an XML file generated from the ePMN thick client. This is a required field.
- **Binding:** Check the 'Binding' checkbox to claim the physical form(s) information as binding.
- **% New Substance (5):** Enter the percentage of new chemical substance (if part of a mixture) at the time of exposure. A value of zero (0) entered in this field will display an error. Please pay particular attention to the information if this field is populated via XML file. The information contained within the 'Physical Forms and % New Substance' field in the thick client separates into two (2) separate fields, the 'Physical Form(s)' field and '% New Substance' field when these fields are populated via an XML file generated from the ePMN thick client. This is a required field that accepts decimal values.
- **Binding:** Check the 'Binding' checkbox to claim the percentage new substance information as binding.
- **# Workers Exposed (8):** Enter the number of workers exposed. Estimate the maximum number of all workers involved in each activity for all sites combined. This is a required field.
- **CBI:** Check the 'CBI' checkbox to claim the number of workers exposed as confidential.
- **Hours/Day (10):** Enter the maximum duration occupational exposure occurs for the activity for any worker in hours per day; this field allows decimal values. A value of zero (0) entered in this field will display an error. This is a required field.
- **Days/Year (11):** Enter the maximum duration occupational exposure occurs for the activity for any worker in days per year; this field allows decimal values. A value of zero (0) entered in this field will display an error. This is a required field.
- **CBI:** Check the 'CBI' checkbox to claim the maximum duration values as confidential.
- **Save:** Click the button to save the information entered within the expandable/collapsible field set. You must click this button instead of the 'Save' icon () located within the bottom action bar to successfully save the entered information within the field set before being able to navigate away from the screen using the 'Previous' and 'Next' buttons. Refer to **Section 3.9** for more information regarding the save functionality in an expandable/collapsible field set.

Exhibit 4-39 shows a screen capture of the ‘Occupational Exposures’ screen (Scroll 1):

Exhibit 4-39 Occupational Exposures Screen (PMN) (Scroll 1)

The screenshot displays the 'Occupational Exposures' screen within the GSPP (Global Site Profile) system. The top navigation bar includes 'Home', 'Forms', 'User Management', and 'Resources', with a 'Log Out' button on the right. The user is identified as 'Jane Doe, Primary Authorized Official'. The main content area is titled 'Premanufacture Notice (Primary PMN-20141201-11:36:29 EST) > Occupational Exposures' and 'OCCUPATIONAL EXPOSURES'. A sub-section 'A.2 Occupational Exposure - Submitter Controlled Sites' is expanded, showing a form with various input fields and checkboxes. The form includes sections for 'Worker Category (1)', 'Worker Activity (1)', 'Protective Equipment/ Engineering Controls (3)', 'Physical Form(s) (5)', '% New Substance (5)', '# Workers Exposed (8)', 'Maximum Duration', and 'Hours/Day (10)'. A 'Cancel' button is visible in the top right of the form area. The bottom action bar contains an 'Upload XML' button and four icons representing 'Validate', 'Save', 'Preview', and 'Submit'. The footer of the page provides links to 'CDX Homepage', 'MyCDX Homepage', 'EPA Homepage', 'Terms and Conditions', 'Privacy Notice', and 'CDX Helpdesk: (888) 890-1995'.

Exhibit 4-40 shows a screen capture of the ‘Occupational Exposures’ screen (Scroll 2):

Exhibit 4-40 Occupational Exposures Screen (PMN) (Scroll 2)

The screenshot shows the 'Occupational Exposures' screen in the GSPP system. The user is logged in as Jane Doe, Primary Authorized Official. The navigation tree on the left includes sections for 'Premanufacture Notice', 'Site Information', 'Submitter Controlled Operations', and 'Operations Controlled by Others'. The main form area contains the following fields and controls:

- Worker Activity (1):
- Protective Equipment/ Engineering Controls (3):
- Physical Form(s) (5):
- % New Substance (5): %
- # Workers Exposed (8):
- Maximum Duration:
- Hours/Day (10):
- Days/Year (11):

At the bottom of the form area, there is a 'Save' button and a message: 'Click the **Add** button to add an occupational exposure.

Below the form area, there are 'Previous' and 'Next' buttons. The 'Next' button is highlighted with a red box.

The bottom navigation bar includes an 'Upload XML' button, a 'Validate' button (with a green checkmark), a 'Save' button, a 'Preview' button, and a 'Submit' button. The footer contains links to CDX Homepage, MyCDX Homepage, EPA Homepage, Terms and Conditions, Privacy Notice, and CDX Helpdesk: (888) 890-1995.

Navigation: Click the ‘Next’ button to navigate to the ‘Environmental Releases’ screen. You can also access this screen by clicking the ‘Environmental Releases’ link within the navigation tree.

4.1.22 Environmental Releases

You can navigate to the ‘Environmental Releases’ screen by clicking the ‘Next’ button from the ‘Occupational Exposures’ screen. You can also access this screen by clicking the ‘Environmental Releases’ link within the navigation tree.


The ‘Environmental Releases’ screen captures information about the environmental release and disposal status of a particular site. The information on exposure and environmental release is related to the flow diagram/process description on the ‘Submitter Operation Information’ screen. This page is duplicated and populated for each flow diagram supplied in the PMN (manufacturing, each processing description, and any use diagrams). The information provided should focus on the PMN substance. EPA reviewers pay particular attention to human exposure

and environmental release date under their TSCA mandate to protect against unreasonable risks from new chemical substances. In the absence of this information, EPA will make its own estimates of worker exposure and environmental release, which are usually conservative. You should present data that is accurate and as complete as possible.

The page displays an ‘Add’ button to add an expandable/collapsible field set to enter ‘Environmental Release and Disposal – Submitter Controlled Sites’ information. The page displays fields to enter information for ‘Release Number,’ the amount of the new substance released ‘to environment’ and the amount of new substance released ‘to control technology,’ ‘Media of Release,’ ‘Control Technology Description,’ and ‘Release after Control Technology.’

You will be asked to enter information concerning the release to water, such as Publicly Owned Treatment Works (POTW), navigable waterways, and others.

- **Add:** Click the ‘Add’ button to generate the ‘Environmental Release and Disposal – Submitter Controlled Sites’ expandable/collapsible field set.
- **Cancel:** Click the ‘Cancel’ link located in the upper right-hand corner of the expandable/collapsible field set to prevent edits from saving and remove the field set. The ‘Cancel’ link displays when the expandable/collapsible field set is open for editing. A confirmation message displays to confirm the action.
- **Edit:** Click the ‘Edit’ link located in the upper right-hand corner of the expandable/collapsible field set to modify the information entered in the fields. The ‘Edit’ link displays when the expandable/collapsible field set has been saved and the data is not currently editable.
- **Delete:** Click the ‘Delete’ icon (✖) located in the upper right-hand corner of the expandable/collapsible field set to delete the field set. A confirmation message displays to confirm the deletion. The ‘Delete’ icon (✖) displays when the user clicks the ‘Add’ button.
- **Expand All:** Click the ‘Expand All’ link located at the upper right-hand corner of the expandable/collapsible field sets to expand a series of field sets.
- **Collapse All:** Click the ‘Collapse All’ link located at the upper right-hand corner of the expandable/collapsible field sets to collapse a series of field sets.
- **Release Number (1):** Enter the number of each release point identified in the process description on the ‘Submitter Operation Information’ screen. This is a required field.
- **CBI:** Check the ‘CBI’ checkbox to claim the release number information and amount of new substance information as confidential.
- **Amount of new substance released to Environment (2a):** Select the applicable radio button and enter the amount of new substance released to environment. Release estimates should be consistent with the release levels shown on the preceding flow diagram on the ‘Submitter Operation Information’ screen. Include intermittent release estimates from cleaning of equipment and transportation containers, even if cleaned off-site. Either the ‘Amount of new substance released to Environment’ or the ‘Amount of new substance released to Control Technology’ field should be populated.

- **Amount of new substance released to Environment kg/day:** Select the radio button to claim that the amount of new substance released to the environment is measured in kilograms per day.
- **Amount of new substance released to Environment kg/batch:** Select the radio button to claim that the amount of new substance released to the environment is measured in kilograms per batch.
- **Amount of new substance released to Control Technology (2b):** Enter the amount of new substance released to control technology. Release estimates should be consistent with the release levels shown on the preceding flow diagram on the ‘Submitter Operation Information’ screen. Include intermittent release estimates from cleaning of equipment and transportation containers, even if cleaned off-site. Either the ‘Amount of new substance released to environment’ or the ‘Amount of new substance released to Control Technology’ field should be populated.
- **Amount of new substance released to Control Technology kg/day:** Select the radio button to claim that the amount of new substance released to control technology is measured in kilograms per day.
- **Amount of new substance released to Control Technology kg/batch:** Select the radio button to claim that the amount of new substance released to control technology is measured in kilograms per batch.
- **Media of Release (4):** Identify the media of release (i.e., stack air, fugitive air, surface water, on-site or off-site land or incineration, POTW, or other (please specify)) to which the new substance will be released from that release point from the drop-down menu. This is a required field.
- **CBI:** Check the ‘CBI’ checkbox to claim the media of release, control technology description, and release after control technology information as confidential.
- **If Other, specify:** Enter the other media of release when you select ‘Other’ from the ‘Media of Release’ drop-down menu.
- **Control Technology Description (5a):** Enter the control technology description. Describe control technology, if any, and control efficiency used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method and state whether it is approved for disposal of Resource Conservation and Recovery Act (RCRA) hazardous waste. For each site, describe any additional disposal methods that will be used and whether the waste is subject to secondary or tertiary on-site treatment. Indicate if you want this information to bind. Check the ‘CBI’ checkbox if the information is confidential. This is a required field.
- **Binding:** Check the ‘Binding’ checkbox to claim the control technology description as binding.
- **Release after Control Technology (5b):** Enter the release after control technology. Estimate the amount released to the environment after control technology (in kilograms per day). This is a required field.
- **Save:** Click the button to save the information entered within the expandable/collapsible field set. You must click this button instead of the ‘Save’ icon () located within the bottom

action bar to successfully save the entered information within the field set before being able to navigate away from the screen using the 'Previous' and 'Next' buttons. Refer to **Section 3.9** for more information regarding the save functionality in an expandable/collapsible field set.

- **POTW Name:** Enter the POTW (publicly owned treatment works) name.
- **POTW NPDES #:** Enter the POTW National Pollutant Discharge Elimination System (NPDES) number.
- **POTW CBI:** Check the 'CBI' checkbox to claim the POTW as confidential.
- **Navigable Waterway Name:** Enter the navigable waterway name.
- **Navigable Waterway NPDES #:** Enter the navigable waterway NPDES number.
- **Navigable Waterway CBI:** Check the 'CBI' checkbox to claim the navigable waterway as confidential.
- **Other (Specify) Name:** Enter the name of the other destination of release to water.
- **Other (Specify) CBI:** Check the 'CBI' checkbox to claim the other destination of release to water as confidential.

Exhibit 4-41 shows a screen capture of the 'Environmental Releases' screen (Scroll 1):

Exhibit 4-41 Environmental Releases Screen (PMN) (Scroll 1)

The screenshot displays the GSPP (Global Site Profile) interface. At the top, the user is logged in as Jane Doe, a Primary Authorized Official. The main navigation menu includes Home, Forms, User Management, and Resources. The current page is titled 'ENVIRONMENTAL RELEASES' under the 'Premanufacture Notice (Primary PMN-20140527-12:59:24 EDT) > Environmental Releases' section. The left sidebar shows a tree view with categories like 'Site Information', 'Submitter Controlled Operations', and 'Operations Controlled by Others'. The main content area is titled 'A.3. Environmental Release and Disposal - Submitter Controlled Sites' and contains a form with the following fields:

- Release Number (1):
- Amount of new substance released:
 - to Environment (2a): Kg/Day Kg/Batch
 - to Control Technology (2b): Kg/Day Kg/Batch
- Media of Release (4):
- Control Technology Description (5a):
- Release after Control Technology (5b):

Additional form elements include checkboxes for 'CBI' and 'Binding', a 'Cancel' button, and a 'Save' button at the bottom of the form. The bottom toolbar contains an 'Upload XML' button and icons for 'Validate', 'Save', 'Preview', and 'Submit'. The footer includes links to CDX Homepage, MyCDX Homepage, EPA Homepage, Terms and Conditions, Privacy Notice, and CDX Helpdesk: (888) 890-1995.

Exhibit 4-42 shows a screen capture of the ‘Environmental Releases’ screen (Scroll 2):

Exhibit 4-42 Environmental Releases Screen (PMN) (Scroll 2)

The screenshot displays the 'Environmental Releases' screen for a Primary Authorized Official. The interface includes a top navigation bar with 'Home', 'Forms', 'User Management', and 'Resources' tabs. The user is logged in as 'Jane Doe, Primary Authorized Official'. The main content area is divided into a left-hand navigation tree and a central form. The navigation tree shows a hierarchy from 'Premanufacture Notice' down to 'Environmental Releases'. The central form contains several sections: 'Media of Release (4)' with a dropdown menu set to 'Other' and a text input for '(If Other, specify)'; 'Control Technology Description (5a)' with a large text area; 'Release after Control Technology (5b)' with a text input and a 'Save' button; and 'A.3.7. Mark the destinations of release to water' with three rows of fields for 'Name', 'NPDES #', and 'CBI' checkboxes. A 'Next' button is highlighted with a red box, and a 'Previous' button is also visible. At the bottom, there is a blue bar with 'Upload XML', 'Validate', 'Save', 'Preview', and 'Submit' buttons, and a footer with various links and the CDX Helpdesk contact information.

Navigation: Click the ‘Next’ button to navigate to the ‘Industrial Sites Controlled By Others’ screen. You can also access this screen by clicking the ‘Industrial Sites Controlled By Others’ link within the navigation tree. Click the ‘Add Operation’ link under the ‘Operations Controlled By Others’ folder within the navigation tree to generate the screens for an operation controlled by others.

4.1.23 Industrial Sites Controlled By Others

Click the ‘Add Operation’ link under the ‘Operations Controlled By Others’ folder within the navigation tree to generate the screens for an operation controlled by others. You can navigate to this screen by clicking the ‘Next’ button from the ‘Environmental Releases’ screen. You can also access this screen by clicking the ‘Industrial Sites Controlled By Others’ link within the navigation tree under the ‘Operations Controlled by Others’ folder.

The ‘Industrial Sites Controlled By Others’ screen captures information about activities occurring at a particular site or group of sites. You will be able to enter an operation alias to identify the operation. Importers are not required to complete this section for operations outside the U.S.; however, any industrial processing or use operation that takes place after import must be described.

You will first be asked to select the site(s) and chemical(s) for the operation. You will then proceed to the next screen to enter resources concerning the operation. The system provides a field to add an operation process description.

The site(s) and chemical(s) for the operation must be identified. The system then navigates to the next screen to enter resources concerning the operation. The ‘Industrial Sites Controlled By Others’ screen also displays a field to add an operation process description. In the operation description, include the following information: (1) Diagram the major unit operation steps and chemical conversions, including interim storage and specify transport containers (e.g., 5-gallon pails, 55-gallon drums, rail cars, tank trucks, etc.). On the diagram, identify by letter and briefly describe each worker activity. (2) Either in the diagram or in the text field, provide the identity, the approximate weight (by kg/day or kg/batch, on a 100% new chemical substance basis), and entry point of all feedstocks (including reactants, solvents and catalysts, etc.), products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch). (3) Either in the diagram or in the text field, identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance.

- **Operation Alias:** Enter the operation alias. This is a required field if the form is pending a Joint Submission or a Letter of Support.
- **Add Facility:** Click the button to generate the ‘Add Facility’ pop-up window and select a site from the drop-down menu to add to the ‘Industrial Sites Controlled By Others’ screen. Refer to **Section 3.11** for additional details regarding the add facility functionality.
- **Site Name:** Displays the site name.
- **Address:** Displays the site address.
- **City:** Displays the site city.
- **State:** Displays the site state.
- **Postal Code:** Displays the site postal code.
- **CBI:** Indicates the CBI status of the site by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete a site from the table. A warning message confirming deletion of the site displays.
- **Select the chemical(s) that this submission pertains to:** Displays all consolidated chemicals in a PMN form.
- **Operation Description:** Enter the operation process description. Cover the following items:
 - (1) Diagram the major unit operation steps and chemical conversions, including interim storage and transport containers (specify – e.g., 5-gallon pails, 55-gallon drums, rail cars, tank trucks, etc.). On the diagram, identify by letter and briefly describe each worker activity.
 - (2) Either in the diagram or in the text field, provide the identity, the approximate weight (by kg/day or kg/batch, on a 100% new chemical substance basis), entry point of all feedstocks

(including reactants, solvents and catalysts, etc.), all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch). (3) Either in the diagram or in the text field, identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance. Either this field is required or a document must be attached.

- **CBI:** Check the ‘CBI’ checkbox to claim the operation description as confidential.
- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window. Refer to **Section 3.6** for additional details regarding the attach document functionality.
- **File Name:** Displays the file name and file extension of the document that was uploaded on the ‘Attach Documents’ pop-up window.
- **Description:** Displays the description associated with a document.
- **Pages:** Displays the number of pages a document contains.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire attached document row permanently from the system. A warning message displays to confirm deletion of the document.

Exhibit 4-43 shows a screen capture of the ‘Industrial Sites Controlled By Others’ screen (Scroll 1):

Exhibit 4-43 Industrial Sites Controlled By Others Screen (PMN) (Scroll 1)

CDX | Logged in as: Jane Doe, Primary Authorized Official | [Home](#) | [Forms](#) | [User Management](#) | [Resources](#) | [Log Out](#)

Premanufacture Notice
Primary Authorized Official
Primary PMN-20141201-11:36:29 EST

Premanufacture Notice (Primary PMN-20141201-11:36:29 EST) > Industrial Sites Controlled By Others

INDUSTRIAL SITES CONTROLLED BY OTHERS

Operation Alias:

The operation alias is an optional field that changes the folder name in the navigation tree on the left. Its purpose is to make it easier to distinguish between operations when there is more than one. The operation alias is required if a letter of support and/or joint submission is pending.

Please select the site to report operations on:

Add Facility

Site Name	Address	City	State	Postal Code	CBI	Actions

Select the chemical(s) that this submission pertains to:

Chemical 1
 Chemical 2

Operation Description:
B.1.b. Please describe the attached process/operation (optional)
CBI:

Attach Document

Upload XML | **Validate** | **Save** | **Preview** | **Submit**

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

Exhibit 4-44 shows a screen capture of the ‘Industrial Sites Controlled By Others’ screen (Scroll 2):

Exhibit 4-44 Industrial Sites Controlled By Others Screen (PMN) (Scroll 2)

The screenshot displays the GSPP (Global Site Profile) web application. At the top, it shows the user is logged in as Jane Doe, a Primary Authorized Official. The navigation menu includes Home, Forms, User Management, Resources, and Log Out. The left sidebar shows a navigation tree with categories like 'Premanufacture Notice', 'Operations Controlled by Others', and 'Optional Pollution Prevention'. The main content area contains instructions about operation aliases and a form for reporting operations. The form includes a table for adding facilities, a section for selecting chemicals, an operation description field, and an attach document section. At the bottom, there are buttons for 'Validate', 'Save', 'Preview', and 'Submit', with the 'Next' button highlighted in red.

Navigation: Click the ‘Next’ button to navigate to the ‘Exposures/Releases’ screen. You can also access this screen by clicking the ‘Exposures/Releases’ link within the navigation tree.

4.1.24 Exposures/Releases

You can navigate to the ‘Exposures/Releases’ screen by clicking the ‘Next’ button from the ‘Industrial Sites Controlled By Others’ screen. You can also access this screen by clicking the ‘Exposures/Releases’ link within the navigation tree under the ‘Operations Controlled By Others’ folder.

The screen provides buttons to add expandable/collapsible field sets for worker exposure release information and environmental disposal information. The screen displays fields in the worker exposure expandable/collapsible field set to enter information for ‘Letter of Activity (1),’ ‘# Workers Exposed (2),’ ‘Duration of Exposure Hours/Day (4a),’ ‘Duration of Exposure

Days/Year (4b),’ ‘Protective Equipment/Engineering Controls (6),’ ‘Physical Form (6),’ ‘% New Substance (6),’ and ‘% in Formulation (7).’ The screen displays fields in the environmental release expandable/collapsible field set to enter information for ‘Release Number (9),’ the amount of the new substance released directly ‘to environment (10a),’ the amount of new substance released ‘into control technology (10b),’ ‘Media of Release (12),’ and ‘Control Technology (12).’

Information entered into the ‘Duration of Exposure Hours/Day (4a)’ and ‘Duration of Exposure Days/Year (4b)’ fields must be a positive whole number or decimal. The system does not allow special characters to be saved in these fields. If further explanation is required regarding duration of exposure, please provide this in an attachment.

- **Add:** Click the ‘Add’ button to generate the ‘Worker Exposure’ expandable/collapsible field set.
- **Cancel:** Click the ‘Cancel’ link located in the upper right-hand corner of the expandable/collapsible field set to prevent edits from saving and to remove a field set. The ‘Cancel’ link displays when the expandable/collapsible field set is open for editing. A confirmation message displays to confirm the action.
- **Edit:** Click the ‘Edit’ link located in the upper right-hand corner of the expandable/collapsible field set to modify the information entered in the fields. The ‘Edit’ link displays when the expandable/collapsible field set has been saved and the data is not currently editable.
- **Delete:** Click the ‘Delete’ icon (✖) located in the upper right-hand corner of the expandable/collapsible field set to delete the field set. A confirmation message displays to confirm the deletion.
- **Expand All:** Click the ‘Expand All’ link located at the upper right-hand corner of the expandable/collapsible field sets to expand a series of field sets.
- **Collapse All:** Click the ‘Collapse All’ link located at the upper right-hand corner of the expandable/collapsible field sets to collapse a series of field sets.
- **Letter of Activity (1):** Indicate the activities in which workers may be exposed to the specified substance.
- **CBI:** Check the ‘CBI’ checkbox to claim the letter of activity as confidential.
- **# Workers Exposed (2):** Enter an estimate of the number of workers exposed for all sites combined.
- **CBI:** Check the ‘CBI’ checkbox to claim the number of workers exposed as confidential.
- **Duration of Exposure Hours/Day (4a):** Enter an estimate of the typical duration of exposure per worker in hours/day. This field allows decimal values.
- **Duration of Exposure Days/Year (4b):** Enter an estimate of the typical duration of exposure per worker in days/year. This field allows decimal values.
- **CBI:** Check the ‘CBI’ checkbox to claim the duration of exposure hours/day and days/year as confidential.


- **Protective Equipment/Engineering Controls (6):** Enter a description of any protective equipment and engineering controls, if any, used to protect workers. Please pay particular attention to the information within if this field is populated via XML file. The information contained within the ‘Protective Equipment/Engineering Controls/Physical Forms’ field in the thick client separates into two (2) separate fields, the ‘Protective Equipment/Engineering Controls’ and ‘Physical Forms’ field when these fields are populated via an XML file generated from the ePMN thick client.
- **CBI:** Check the ‘CBI’ checkbox to claim the protective equipment/engineering controls, physical form(s), % new substance, and % in formulation information as confidential.
- **Physical Form (6):** Enter a description of physical forms of exposure. Please pay particular attention to the information populated in this field if this field is populated via XML file. The information contained within the ‘Protective Equipment/Engineering Controls/Physical forms’ field in the thick client separates into two (2) separate fields, the ‘Protective Equipment/Engineering Controls’ and ‘Physical Forms’ field when these fields are populated via an XML file generated from the ePMN thick client.
- **% New Substance (6):** Describe percentage of new chemical substance (if in mixture).
- **% in Formulation (7):** Estimate the percent of the new substance as formulated when packaged or used as a final product.
- **Save:** Click the button to save the information entered within the expandable/collapsible field set. You must click this button instead of the ‘Save’ icon () located within the bottom action bar to successfully save the entered information within the field set before being able to navigate away from the screen using the ‘Previous’ and ‘Next’ buttons. Refer to **Section 3.9** for more information regarding the save functionality in an expandable/collapsible field set.

Exhibit 4-45 shows a screen capture of the ‘Exposures/Releases’ screen (Scroll 1):

Exhibit 4-45 Exposures/Releases Screen (PMN) (Scroll 1)

- **Add:** Click the ‘Add’ button to generate the ‘Environmental Disposal’ expandable/collapsible field set.
- **Release Number (9):** Enter the number of each release point from the process diagram previously entered.
- **CBI:** Check the ‘CBI’ checkbox to claim the release number information as confidential.


- **Amt New Substance Released Directly into Environment (10a):** Enter an estimate of the amount of the new substance released directly to the environment in Kg/day or Kg/batch.
- **Amt New Substance Released Directly into Environment – Kg/Day:** Select the ‘Kg/Day’ radio button to indicate that the amount of substance released into environment measures in kilograms per day.
- **Amt New Substance Released Directly into Environment – Kg/Batch:** Select the ‘Kg/Batch’ radio button to indicate that the amount of substance released into environment measures in kilograms per batch.
- **Amt New Substance Released Directly into Control Technology (10b):** Estimate the amount of the new substance released into control technology in Kg/Day or Kg/Batch.
- **Amt New Substance Released Directly into Control Technology – Kg/Day:** Select the ‘Kg/Day’ radio button to indicate that the amount of substance released into control technology measures in kilograms per day.
- **Amt New Substance Released Directly into Control Technology – Kg/Batch:** Select the ‘Kg/Batch’ radio button to indicate that the amount of substance released into control technology measures in kilograms per batch.
- **Media of Release (12):** Select a value from the drop-down menu to capture the media of release. The ‘Media of Release’ drop-down menu contains the following values: ‘Fugitive Air,’ ‘Off-Site Incineration,’ ‘On-site Incineration,’ ‘On-site WWT,’ ‘POTW,’ ‘Stack Air,’ ‘Surface Water,’ and ‘Other,’ that will be used to limit the release of the new substance to the environment. Please pay particular attention to the information within if this field is populated via XML file. The information contained within the ‘Media of Release & Control Technology’ field in the thick client separates into two (2) separate fields, the ‘Media of Release’ drop-down menu and ‘Control Technology’ field when these fields are populated via an XML file generated from the ePMN thick client.
- **(If Other, specify):** Enter the other media of release.
- **CBI:** Check the ‘CBI’ checkbox to claim the media of release and control technology information as confidential.
- **Control Technology (12):** Enter the control technology, if any, which will be used to limit the release of the new substance to the environment. Please pay particular attention to the information within if this field is populated via XML file. The information contained within the ‘Media of Release & Control Technology’ field in the thick client separates into two (2) distinct fields, the ‘Media of Release’ drop-down menu and ‘Control Technology’ field when these fields are populated via an XML file generated from the ePMN thick client.
- **Save:** Click the button to save the information entered within the expandable/collapsible field set. You must click this button instead of the ‘Save’ icon () located within the bottom action bar to successfully save the entered information within the field set before being able to navigate away from the screen using the ‘Previous’ and ‘Next’ buttons. Refer to **Section 3.9** for more information regarding the save functionality in an expandable/collapsible field set.

Exhibit 4-46 shows a screen capture of the ‘Exposures/Releases’ screen (Scroll 2):

Exhibit 4-46 Exposures/Releases Screen (PMN) (Scroll 2)

Navigation: Click the ‘Next’ button to navigate to the ‘Byproduct Information’ screen. You can also access this screen by clicking the ‘Byproduct Information’ link within the navigation tree.

4.1.25 Byproduct Information

You can navigate to the ‘Byproduct Information’ screen by clicking the ‘Next’ button from the ‘Exposures/Releases’ screen. You can also access this screen by clicking the ‘Byproduct Information’ link under the ‘Operations Controlled By Others’ folder within the navigation tree.

The ‘Byproduct Information’ screen captures byproducts resulting from a particular site. The system displays fields to enter byproducts.

- **CBI:** Check the ‘CBI’ checkbox to claim all byproducts as confidential.
- **Byproduct:** Enter byproducts that may result from the operation.
- **Actions:** Click the ‘Save’ icon (📄) to save an entered byproduct. Click the ‘Delete’ icon (✖) to delete a byproduct. Click the ‘Add’ icon (+) to add a byproduct. Click the ‘Form’ icon (📄) to edit a saved byproduct.

Exhibit 4-47 shows a screen capture of the ‘Byproduct Information’ screen:

Exhibit 4-47 Byproduct Information Screen (PMN)

The screenshot shows the 'Byproduct Information' screen within the CDX system. The top navigation bar includes 'Home', 'Forms', 'User Management', and 'Resources'. The user is logged in as 'Jane Doe, Primary Authorized Official'. The main content area is titled 'BYPRODUCT INFORMATION' and contains the instruction: 'Identify byproducts that may result from the operation. Check the CBI checkbox if the information is confidential.' Below this is a section labeled 'B.2.14. Byproducts CBI:' with an unchecked checkbox. A table with two columns, 'Byproduct' and 'Actions', is present. The 'Actions' column contains icons for 'Save' (📄), 'Delete' (✖), and 'Add' (+). At the bottom of the table are 'Previous' and 'Next' buttons, with the 'Next' button highlighted by a red box. The bottom navigation bar features an 'Upload XML' button and icons for 'Validate', 'Save', 'Preview', and 'Submit'. The footer contains links to 'CDX Homepage', 'MyCDX Homepage', 'EPA Homepage', 'Terms and Conditions', 'Privacy Notice', and 'CDX Helpdesk: (888) 890-1995'.

Navigation: Click the ‘Next’ button to navigate to the ‘Optional Pollution Prevention’ screen. You can also access this screen by clicking the ‘Optional Pollution Prevention’ link within the navigation tree.

4.1.26 Optional Pollution Prevention

You can navigate to the ‘Optional Pollution Prevention’ screen by clicking the ‘Next’ button from the ‘Byproduct Information’ screen. You can also access this screen by clicking the ‘Optional Pollution Prevention’ link within the navigation tree.

The ‘Optional Pollution Prevention’ screen provides fields for companies to enter data about their pollution prevention efforts. The company has the option of entering information as a free text field or as an attachment. The company can claim the information as confidential by checking the ‘CBI’ checkbox.

The system allows an uploaded document to be claimed as CBI. If a document is claimed as CBI, the system requires the sanitized version of the attached document to be uploaded. To access or edit previously attached documents, click the appropriate file name of the document within the ‘File Name’ column of the document table.

The attachment table displays the file name and file extension of the document, the document description, the number of pages the document contains, and the CBI status of the document. Click the ‘Delete’ icon (✖) located within the ‘Actions’ column to delete unwanted documents.

You may provide information not reported elsewhere in this form regarding your efforts to reduce or minimize potential risks associated with activities surrounding manufacturing, processing, use, and disposal of the PMN substance on the ‘Optional Pollution Prevention’ screen. Include new information pertinent to pollution prevention, including source reduction, recycling activities and safer processes or products available due to the new chemical substance. Source reduction includes the reduction in the amount or toxicity of chemical wastes by technological modification, process and procedure modification, product reformulation, and/or raw materials substitution. Recycling refers to the reclamation of useful chemical components from wastes that would otherwise be treated or released as air emissions or water discharges, or land disposal. Quantitative or qualitative descriptions of pollution prevention, source reduction and recycling should emphasize potential risk reduction in addition to compliance with existing regulatory requirements. EPA is interested in the information to assess overall net reductions in toxicity or environmental releases and exposures, not the shifting of risks to other media (e.g., air to water) or non-environmental areas (e.g., occupational or consumer exposure). To the extent known, information about the technology being replaced will assist EPA in its relative risk determination. In addition, information on the relative cost or performance characteristics of the PMN substance to potential alternatives may be provided.

Describe the expected net benefits, such as:

- (1) An overall reduction in risk to human health or the environment;
- (2) A reduction in the generation of waste materials through recycling, source reduction or other means;
- (3) A reduction in the use of hazardous starting materials, reagents, or feedstocks;
- (4) A reduction in potential toxicity, human exposure and/or environmental release; or
- (5) The extent to which the new chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment.

EPA strongly encourages submitters to provide pollution prevention data in their notices, as this information assists the Agency in balancing the benefits of a PMN substance against its unique risks.

While Agency staffers frequently receive information on the benefits of the PMN substance with respect to its use(s), data on pollution prevention effects are rarely included. This section should be utilized to indicate to EPA benefits in terms of the raw materials incorporated, the manufacturing process, emission reductions, less toxic waste byproducts, or lower risks upon end use and disposal. You should consider the entire life cycle of the PMN substance in your evaluation.

Also consider opportunities for product stewardship or other risk management controls that could significantly reduce risk characteristics of the new substance (e.g., disposal techniques that can be easily implemented and substantially reduce waste toxicity).

Initiatives in the New Chemicals Program such as Environmental Technology Initiative (ETI) for Chemicals, and the Pollution Prevention Recognition Project, are geared towards incorporating this type of information into the Agency's risk management decision making and recognizing innovative chemical design or technological innovation that shows potential for environmental and human health benefits.

Describe any pollution prevention benefits here, and indicate if this information is confidential business information. Attempt to quantify the expected benefits to the extent possible and avoid exaggeration and highly speculative statements. The following questions can be used to assess pollution prevention benefits:

- (1) Are there pollution prevention benefits associated with the new PMN chemical?
- (2) Does it allow reduction or elimination of (more) toxic solvents?
- (3) Does it reduce disposal to land, or in safer forms, compared to the chemistry it replaces?
- (4) Can it be recycled more easily than existing materials?
- (5) Does your manufacturing process eliminate or reduce the use/release of hazardous substances?

- **Please [click here](#) to review additional information that should be included on this page:** Click the link to display additional information regarding the pollution information.
- **Check here to claim this information as CBI:** Check the 'Check here to claim this information as CBI' checkbox to claim the pollution prevention information as confidential.
- **Optional Pollution Prevention text box:** Enter information about pollution prevention in this field.
- **Attach Document:** Click the 'Attach Document' button to generate the 'Attach Documents' pop-up window. Refer to **Section 3.6** for additional details regarding the attach document functionality.
- **File Name:** Displays the file name and file extension of a document that is uploaded on the 'Attach Documents' pop-up window. Click the file name link to navigate to the 'Attach Documents' pop-up window to make any edits to an attached document.
- **Description:** Displays the description associated with a document.

- **Pages:** Displays the number of pages a document contains.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire attached document row permanently from the system. A warning message displays to confirm the deletion.

Exhibit 4-48 shows a screen capture of the ‘Optional Pollution Prevention’ screen:

Exhibit 4-48 Optional Pollution Prevention Screen (PMN)

The screenshot shows the 'Optional Pollution Prevention' screen for a Premanufacture Notice (PMN-20170731-11:45:56 EDT). The page includes a navigation tree on the left, a main content area with instructions, and a table at the bottom. The 'Next' button is highlighted with a red box.

File Name	Description	Pages	CBI	Actions
				Previous Next

Navigation: Click the ‘Next’ button to navigate to the ‘Additional Attachments’ screen. You can also access this screen by clicking the ‘Additional Attachments’ link within the navigation tree.

4.1.27 Additional Attachments

You can navigate to the ‘Additional Attachments’ screen by clicking the ‘Next’ button from the ‘Optional Pollution Prevention’ screen. You can also access this screen by clicking the ‘Additional Attachments’ link within the navigation tree.

The ‘Additional Attachments’ screen provides a table for you to add additional attachments that have not been incorporated into the form. This screen allows documents that did not have a suitable place in the application to be uploaded.

- Please [click here](#) to view a list of commonly attached documents and where they should be attached: Click the link to display a list of documents and where they should be attached.
- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window. Refer to **Section 3.6** for additional details regarding the attach document functionality.
- **File Name:** Displays the file name and file extension of a document that is uploaded on the ‘Attach Documents’ pop-up window.
- **Description:** Displays the description associated with a document.
- **Pages:** Displays the number of pages a document contains.
- **Date:** Displays the date a document was uploaded.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’
- **Action:** Click the ‘Delete’ icon (✖) to delete the entire attached document row permanently from the system. A warning message displays to confirm the deletion.

Exhibit 4-49 shows a screen capture of the ‘Additional Attachments’ screen:

Exhibit 4-49 Additional Attachments Screen (PMN)

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

Home Forms User Management Resources

Premanufacture Notice Primary Authorized Official
Primary PMN-20170802-12:01:13 EDT

Premanufacture Notice (Primary PMN-20170802-12:01:13 EDT) > Additional Attachments

ADDITIONAL ATTACHMENTS

Please use this page to attach documents that are not listed on other parts of the form (test data, EPA correspondence, etc). Please [click here](#) to view a list of commonly attached documents and where they should be attached.

File Name	Description	Pages	Date	CBI	Action
<input type="button" value="Previous"/>			<input type="button" value="Next"/>		

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

Navigation: Click the ‘Next’ button to navigate to the ‘Attachment Summary’ screen. You can also access this screen by clicking the ‘Attachment Summary’ link within the navigation tree.

4.1.28 Attachment Summary

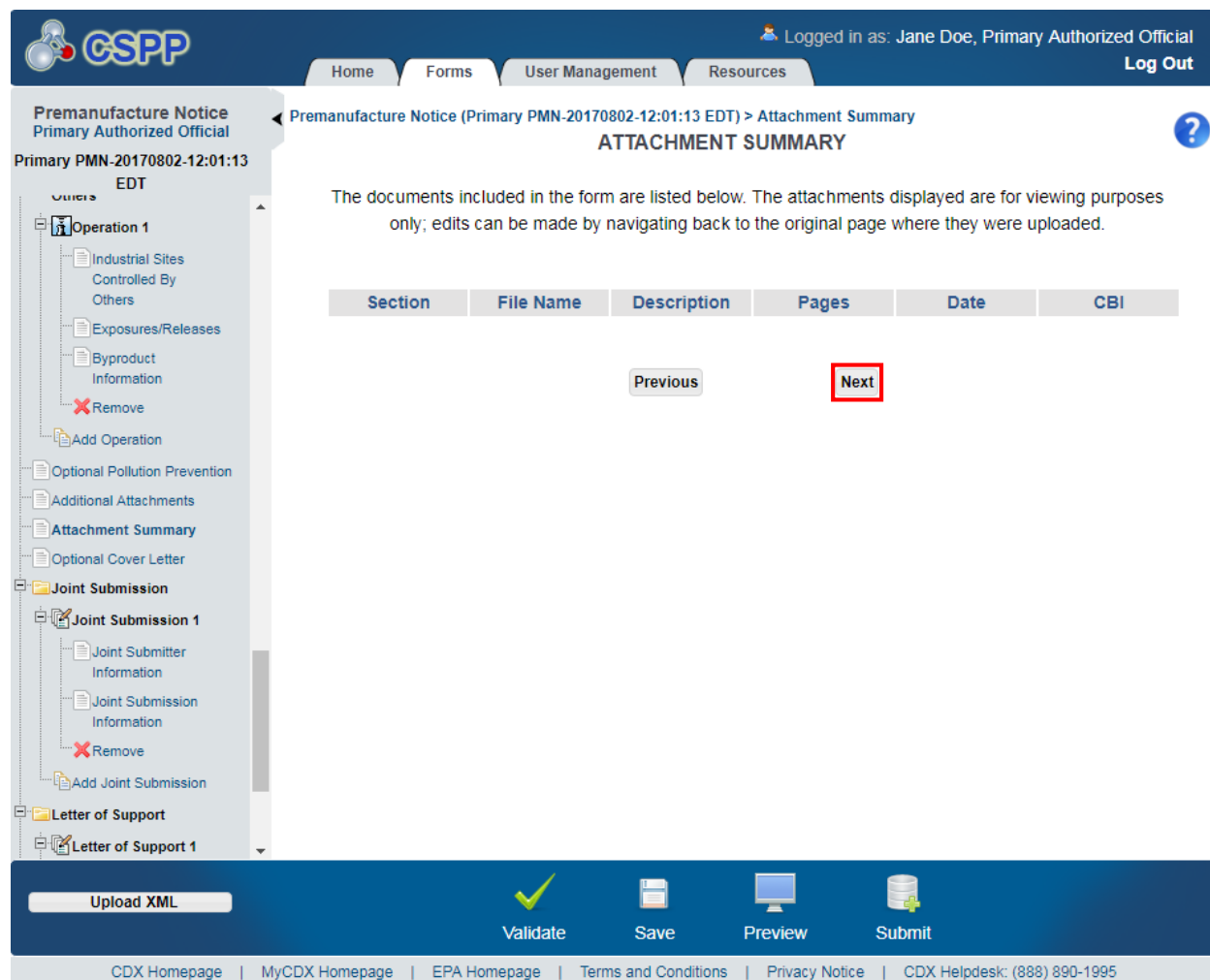
You can navigate to the ‘Attachment Summary’ screen by clicking the ‘Next’ button from the ‘Additional Attachments’ screen. You can also access this screen by clicking the ‘Attachment Summary’ link within the navigation tree.

The ‘Attachment Summary’ screen displays a summary of the documents attached to the PMN form. The attachment table displays the section of the form a document is associated with, file name and file extension of a document, the document description, number of pages in a document, date attached, and whether the document is CBI.

- **Section:** Displays the section of the PMN form that the attached document is associated.
- **File Name:** Displays the file name and file extension of a document that is uploaded on the ‘Attach Documents’ pop-up window.
- **Description:** Displays the description of a document that was uploaded on the ‘Attach Documents’ pop-up window.
- **Pages:** Displays the number of pages a document contains.
- **Date:** Displays the upload date of a document that was uploaded on the ‘Attach Documents’ pop-up window.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’

Exhibit 4-50 shows a screen capture of the ‘Attachment Summary’ screen:

Exhibit 4-50 Attachment Summary Screen (PMN)



Navigation: Click the ‘Next’ button to navigate to the ‘Optional Cover Letter’ screen. You can also access this screen by clicking the ‘Optional Cover Letter’ link within the navigation tree.

4.1.29 Optional Cover Letter

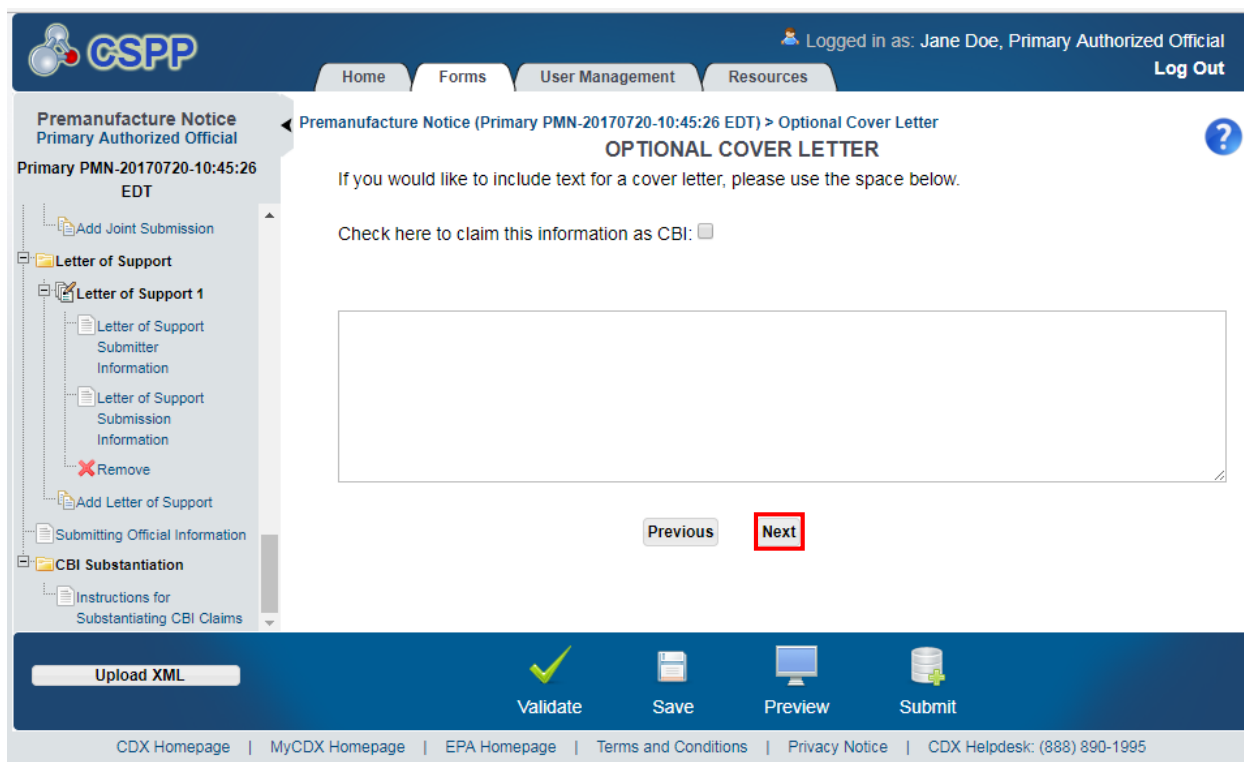
You can navigate to the ‘Optional Cover Letter’ screen by clicking the ‘Next’ button from the ‘Attachment Summary’ screen. You can also access this screen by clicking the ‘Optional Cover Letter’ link within the navigation tree.

The ‘Optional Cover Letter’ screen is used to communicate information with EPA that is not collected elsewhere in the form. The cover letter is used to give OPPT resources and special instructions regarding the application.

- **Check here to claim this information as CBI:** Check the ‘Check here to claim this information as CBI’ checkbox to claim the information as confidential.
- **Optional Cover Letter:** Enter the description and any additional special instructions regarding the form.

Exhibit 4-51 shows a screen capture of the ‘Optional Cover Letter’ screen:

Exhibit 4-51 Optional Cover Letter Screen (PMN)



Navigation: If you are not filing a Joint or Letter of Support submission, please refer to **Section 3.9** for the functionality available within the bottom action bar. If you are submitting a Joint Submission, click the ‘Next’ button to navigate to the ‘Joint Submitter Information’ screen. You can also access this screen by clicking the ‘Joint Submitter Information’ link within the navigation tree. If you have a Letter of Support pending and are not submitting a Joint Submission, click the ‘Next’ button to navigate to the ‘Letter of Support Submitter Information’ screen. You can also navigate to this screen by clicking the ‘Letter of Support Submitter Information’ link within the navigation tree.

4.1.30 Joint Submitter Information

You can access the ‘Joint Submitter Information’ screen by clicking the ‘Next’ button from the ‘Optional Cover Letter’ screen. You can also access this screen by clicking the ‘Joint Submitter Information’ link within the navigation tree. Click the ‘Add Joint Submission’ link within the navigation tree to add an additional joint submitter; a maximum of two joint submitters may be listed in a PMN form.

The ‘Joint Submitter Information’ screen captures contact information regarding the joint submitter that will be submitting separate information regarding the PMN form. The joint submitter will be sent the unique identification number by the primary submitter.

- **Check here to claim this information as CBI:** Check the ‘Check here to claim this information as CBI’ checkbox to claim the joint submitter contact information as confidential.

- **First Name:** Enter the joint submitter's first name. This is a required field.
- **Last Name:** Enter the joint submitter's last name. This is a required field.
- **Position:** Enter the joint submitter's job title.
- **Company Name:** Enter the joint submitter's company name. This is a required field.
- **Phone Number:** Enter the joint submitter's daytime phone number. This field does not accept dashes. This is a required field.
- **Phone Extension:** Enter the joint submitter's U.S. phone number extension if applicable.
- **Email Address:** Enter the joint submitter's email address. The email address must follow the standard email address format: John.Doe@abc.com. This is a required field.
- **Mailing Address 1:** Enter the first line of the joint submitter's mailing address. This is a required field.
- **Mailing Address 2:** Enter the second line of the joint submitter's mailing address.
- **City:** Enter the city of the joint submitter's mailing address. This is a required field.
- **State:** Select the state of the joint submitter's mailing address from the drop-down menu. This is a required field.
- **Postal Code:** Enter the postal code of the joint submitter's mailing address. This is a required field.
- **Country:** Displays 'United States.'

Exhibit 4-52 shows a screen capture of the ‘Joint Submitter Information’ screen:

Exhibit 4-52 Joint Submitter Information Screen (PMN)

Navigation: Click the ‘Next’ button to navigate to the ‘Joint Submission Information’ screen. You can also access this screen by clicking the ‘Joint Submission Information’ link within the navigation tree.

4.1.31 Joint Submission Information

You can access the ‘Joint Submission Information’ screen by clicking the ‘Next’ button from the ‘Joint Submitter Information’ screen. You can also access this screen by clicking the ‘Joint Submission Information’ link within the navigation tree.

The ‘Joint Submission Information’ screen is used as a communication point between two companies. The ‘Joint Submission Information’ screen displays fields that capture information to pass to the joint submitter. A text box captures information to send to the joint submitter in an unencrypted email sent by the primary submitter. A ‘Unique Identifier for Joint Submissions’ box will also display on this screen. The unique identification number auto-generates when a user declares a joint submission is being established.

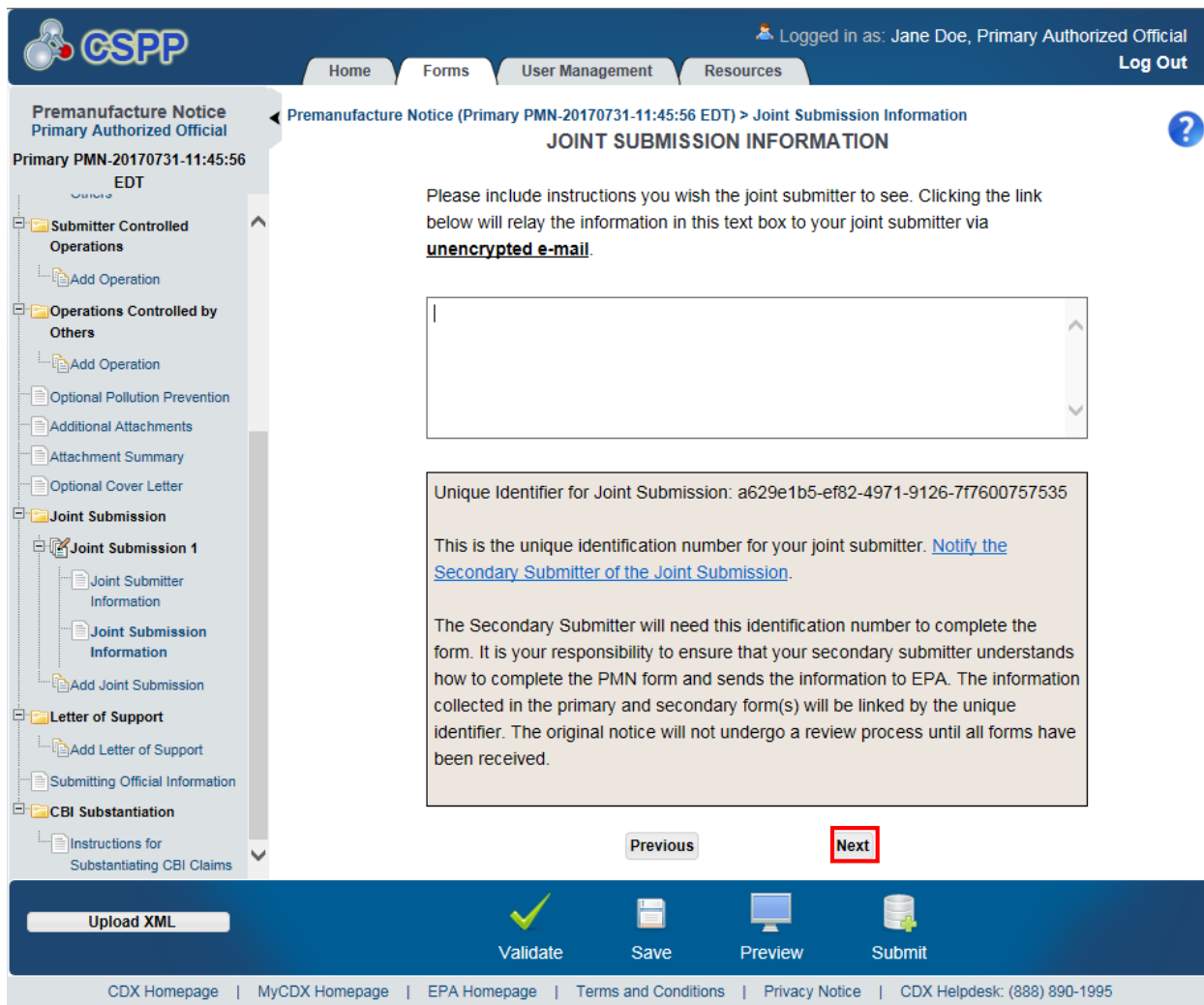
Joint Submission Process: When you designate that a Joint Submission is being filed, you will be asked to enter all the information within the ‘Joint Submission’ folder. When the primary submitter navigates to the ‘Joint Submission Information’ screen, the primary submitter must send an email to the joint submitter identified on the ‘Joint Submitter Information’ screen. The email will contain the unique identification number that will link the two forms.

When the joint submitter accesses the ‘Section 5 Notices and Supports Forms’ screen and creates a new form, the joint submitter will be prompted to enter the unique identification number on the ‘Create Passphrase’ screen. Once the unique identification number has been entered, the system will link the primary and joint forms. The original notice will not undergo a review process until all forms are received.

- **Joint Submission Information Instructions:** Enter the information that the primary submitter is sending to the joint submitter.
- **Joint Submission Informational Text:** Displays instructional text provided by OPPT, the unique identification number automatically generated for the form, and provides functionality to email the unique identification number to the joint submitter by clicking the ‘Notify the Secondary Submitter of the Joint Submission’ link.
- **Unique Identification Number:** The unique identification number is a random, auto-generated number that must be provided to the joint submitter to create a joint submission.

Exhibit 4-53 shows a screen capture of the ‘Joint Submission Information’ screen:

Exhibit 4-53 Joint Submission Information Screen (PMN)



Navigation: Click the ‘Notify the Secondary Submitter of the Joint Submission’ link to access the unique identifier notification pop-up window. Click the ‘Next’ button to navigate to the ‘Letter of Support Submitter Information’ screen if you are submitting a Letter of Support. You can also access this screen by clicking the ‘Letter of Support Submitter Information’ link within the navigation tree. Click the ‘Next’ button to navigate to the ‘Submitting Official Information’ screen if you are not submitting a Letter of Support. A warning generates on this screen after clicking the ‘Next’ or ‘Previous’ button if you have not sent an email notification to the Joint Submitter.

4.1.32 Notify Joint Submitter of Joint Submission Information

You can access the unique identifier notification window by clicking the ‘Notify the Secondary Submitter of the Joint Submission’ link from the ‘Joint Submission Information’ screen.

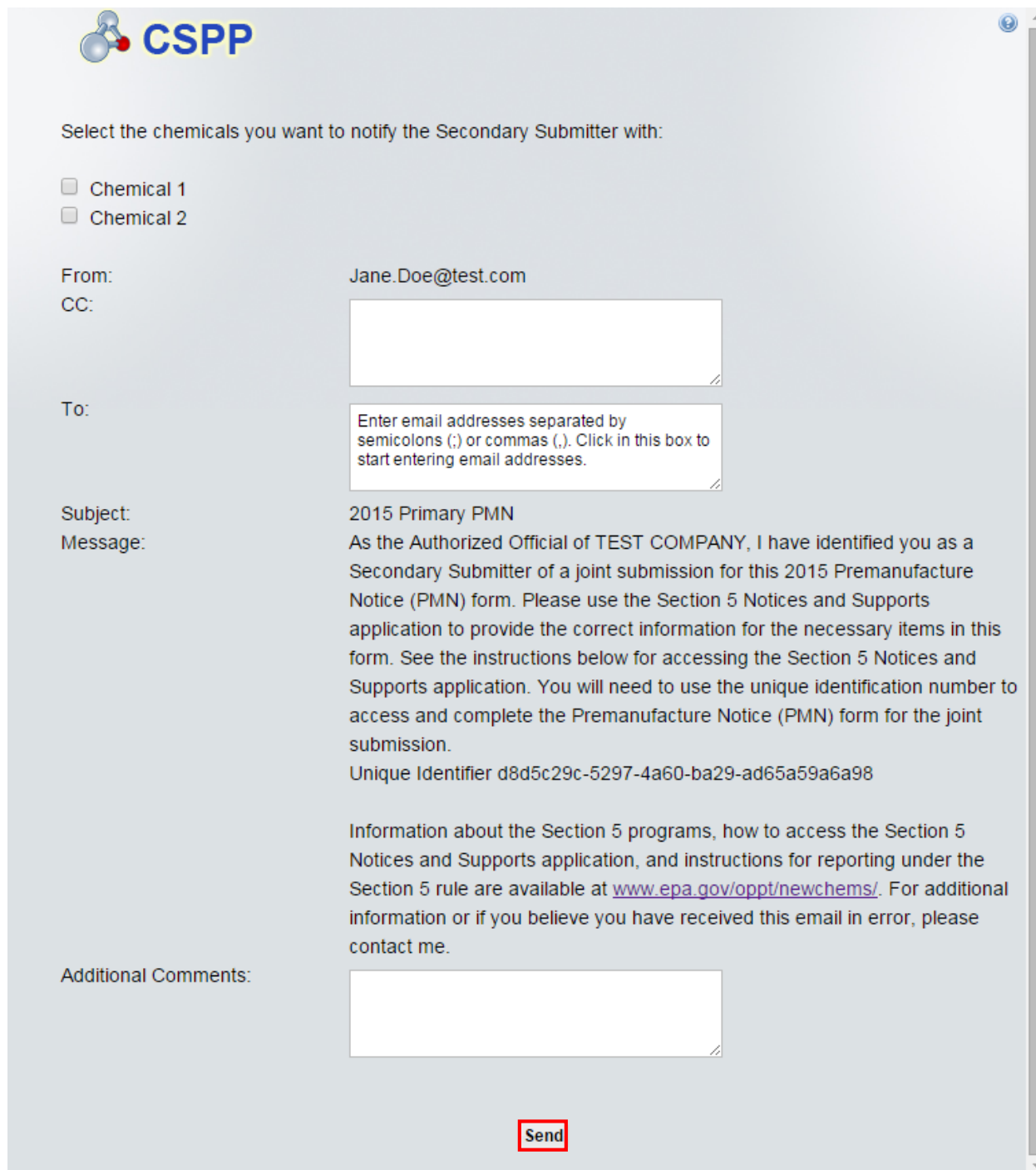
The unique identifier notification window is used to provide the unique identification number to the joint submitter. The unique identifier notification window displays a ‘CC’ field for you to

add other email addresses to the notification (including the original submitter), a 'To' field, and an 'Additional Comments' text box.

- **Chemical Checkbox (es):** The chemical(s) identified within a form displays on the unique identifier notification pop-up window. Check the checkbox (es) for the chemical(s) identified within the form for which the secondary submitter should provide supporting information.
- **From:** Displays the email address of the user that created the form.
- **CC:** This editable field automatically populates with the email address of the user that created the original form and the email address (es) of the technical contact(s) identified within the form.
- **To:** Contains instructional text for you to enter multiple email addresses. Contains the editable email address of the joint submitter specified on the 'Joint Submitter Information' screen; this email address will be pre-populated upon navigating to the window. Enter any additional email addresses to which the email should be sent.
- **Subject:** Displays 'YYYY Primary PMN.'
- **Message:** Contains a pre-determined message that will display in the email sent to a joint submitter.
- **Additional Comments:** Enter any other additional comments or instructions that should be passed onto the joint submitter.
- **Send:** Click the 'Send' button to generate and send the email to the email addresses identified in the 'CC' and 'To' fields.

Exhibit 4-54 shows a screen capture of the Joint Submission unique identifier notification pop-up window:

Exhibit 4-54 Joint Submission Unique Identifier Notification Pop-Up Window (PMN)



Select the chemicals you want to notify the Secondary Submitter with:

Chemical 1
 Chemical 2

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 Primary PMN
 Message: As the Authorized Official of TEST COMPANY, I have identified you as a Secondary Submitter of a joint submission for this 2015 Premanufacture Notice (PMN) 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 Premanufacture Notice (PMN) form for the joint submission.
 Unique Identifier d8d5c29c-5297-4a60-ba29-ad65a59a6a98

 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

Navigation: Click the ‘Send’ button to send the email to the joint submitter and navigate back to the ‘Joint Submission Information’ screen.

4.1.33 Letter of Support Submitter Information

Click the ‘Next’ button from the ‘Joint Submission Information’ screen to access the ‘Letter of Support Submitter Information’ screen if a Letter of Support is pending. You can also access this screen by clicking the ‘Letter of Support Submitter Information’ link within the navigation tree. If you are only filing a Letter of Support, click the ‘Next’ button from the ‘Optional Cover Letter’ screen to navigate to the ‘Letter of Support Submitter Information’ screen. Click the ‘Add Letter of Support’ link within the navigation tree to add extra Letters of Support.

The ‘Letter of Support Submitter Information’ screen captures contact information for the Letter of Support submitter who will enter separate information for the PMN form. The unique identification number will be sent to the Letter of Support submitter via the email address provided.

An unlimited number of Letters of Support can be identified for each form.

- **Check here to claim this information as CBI:** Check the ‘Check here to claim this information as CBI’ checkbox to claim the Letter of Support submitter contact information as confidential.
- **First Name:** Enter the Letter of Support submitter’s first name. This is a required field.
- **Last Name:** Enter the Letter of Support submitter’s last name. This is a required field.
- **Position:** Enter the Letter of Support submitter’s job title.
- **Company Name:** Enter the Letter of Support submitter’s company name. This is a required field.
- **Phone Number:** Enter the Letter of Support submitter’s daytime phone number, U.S. or international. This field does not accept dashes. This is a required field.
- **Phone Extension:** Enter the Letter of Support submitter’s phone number extension if applicable.
- **Email Address:** Enter the Letter of Support submitter’s email address. The email address must follow the standard email address format: John.Doe@abc.com. This is a required field.
- **Mailing Address 1:** Enter the first line of the Letter of Support submitter’s mailing address. This is a required field.
- **Mailing Address 2:** Enter the second line of the Letter of Support submitter’s mailing address.
- **City:** Enter the city of the Letter of Support submitter’s mailing address. This is a required field.
- **State:** Select the state of the Letter of Support submitter’s mailing address from the drop-down menu. This is a required field if ‘United States’ is selected from the ‘Country’ drop-down menu.
- **Postal Code:** Enter the postal code of the Letter of Support submitter’s mailing address. This is a required field if the ‘Country’ field is set to ‘United States.’
- **Country:** Select the country of the Letter of Support submitter’s mailing address from the drop-down menu. This is a required field. If a non-U.S. country is selected, a primary

submitter is responsible for collecting fees from non-U.S. joint submitters; the primary submitter is responsible for the full payment or the joint submitter must have an Agent/Consultant with the ability to pay his/her portion of the fee.

Exhibit 4-55 shows a screen capture of the ‘Letter of Support Submitter Information’ screen:

Exhibit 4-55 Letter of Support Submitter Information Screen (PMN)

Navigation: Click the ‘Next’ button to navigate to the ‘Letter of Support Submission Information’ screen. You can also access this screen by clicking the ‘Letter of Support Submission Information’ link within the navigation tree.

4.1.34 Notify Secondary Submitter of Letter of Support Information

You can access the unique identifier notification window by clicking the ‘Notify the Secondary Submitter of the letter of support submission’ link from the ‘Letter of Support Submission Information’ screen.

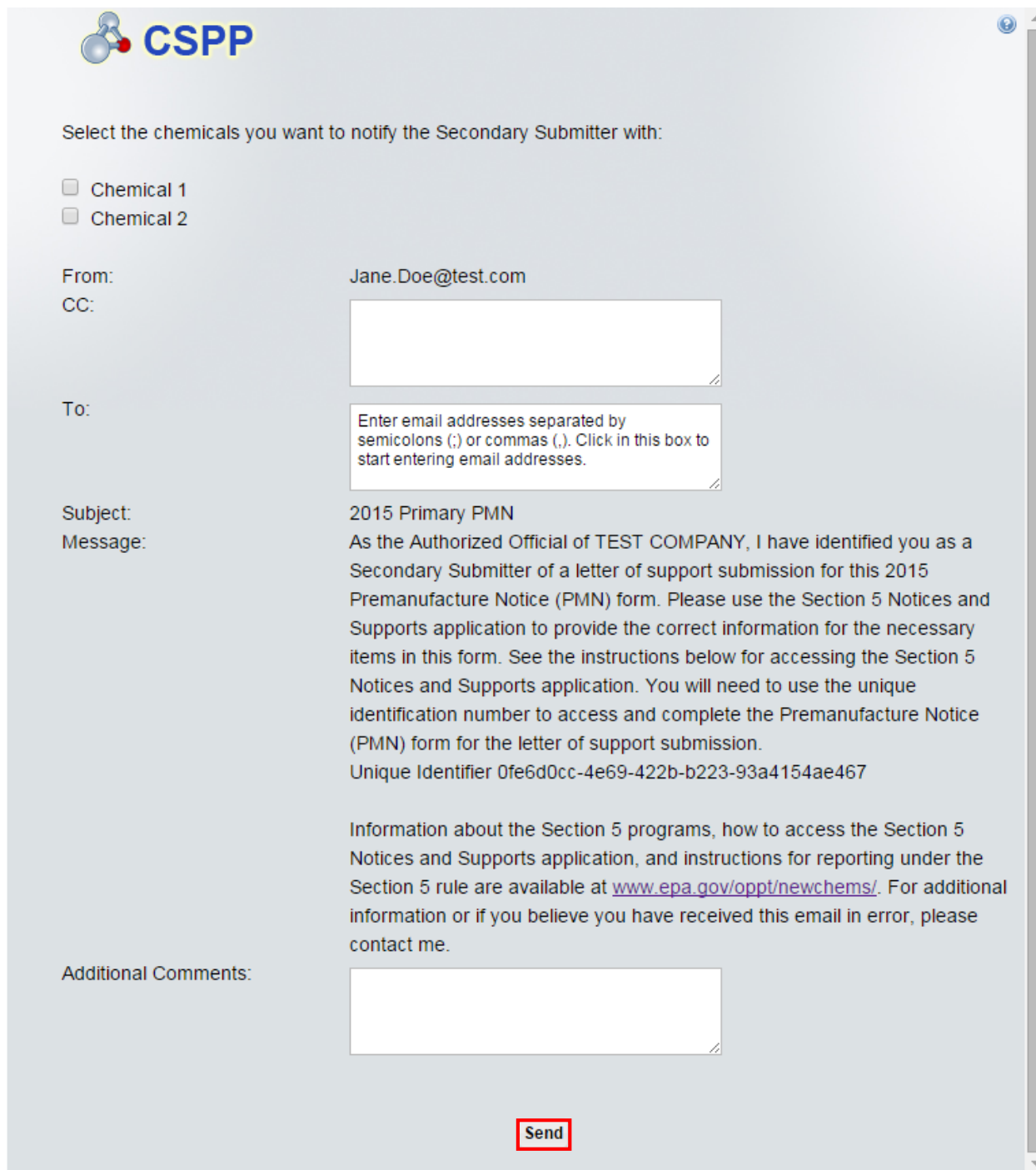
The unique identifier notification window is used to notify the Letter of Support submitter of the unique identification number. The unique identifier notification window displays a ‘CC’ field for

you to add other email addresses to the notification (including the original submitter), a 'To' field, and an 'Additional Comments' text box.

- **Chemical Checkbox(es):** The chemical(s) identified within a form displays on the unique identifier notification pop-up window. Check the checkbox (es) for the chemical(s) identified within the form for which the secondary submitter should provide supporting information.
- **From:** Displays the email address of the logged in user that created the form.
- **CC:** This field automatically populates with the email address of the logged in user that created the form and the email address (es) of the technical contact(s).
- **To:** This field contains instructional text for you to enter multiple email addresses. Contains the editable email address of the Letter of Support submitter specified on the 'Letter of Support Submitter' screen; this field is pre-populated with an email address upon navigating to the unique identifier notification window.
- **Subject:** Displays 'YYYY Primary PMN.'
- **Message:** Displays a pre-determined message in the email sent to a Letter of Support submitter.
- **Additional Comments:** Enter any other additional comments or instructions to pass onto the Letter of Support submitter.
- **Send:** Click the 'Send' button to generate and send the email to the email addresses identified in the 'CC' and 'To' fields.

Exhibit 4-56 shows a screen capture of the Letter of Support unique identifier notification pop-up window:

Exhibit 4-56 Letter of Support Unique Identifier Notification Pop-Up Window (PMN)



Select the chemicals you want to notify the Secondary Submitter with:

Chemical 1

Chemical 2

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 Primary PMN

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 Premanufacture Notice (PMN) 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 Premanufacture Notice (PMN) form for the letter of support submission.
Unique Identifier 0fe6d0cc-4e69-422b-b223-93a4154ae467

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

Navigation: Click the ‘Send’ button to send the email to the Letter of Support submitter and navigate back to the ‘Letter of Support Submission Information’ screen.

4.1.35 Submitting Official Information

You can navigate to the ‘Submitting Official Information’ screen by clicking the ‘Next’ button from the ‘Optional Cover Letter’ screen if neither a Letter of Support nor a joint submission was identified. If applicable, click the ‘Next’ button from the ‘Letter of Support Submission Information’ screen if a letter of support was identified on the ‘Joint Submission Information’ screen if a joint submission was identified. You can also access this screen by clicking the ‘Submitting Official Information’ link within the navigation tree.

Refer to **Section 12** for further information on the ‘Submitting Official Information’ screen.

Exhibit 4-57 shows a screen capture of the ‘Submitting Official Information’ screen:

Exhibit 4-57 Submitting Official Information Screen (PMN)

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

Home Forms User Management Resources

Premanufacture Notice
Primary Authorized Official

Primary PMN-20170720-10:45:26
EDT

Operations Controlled by Others

- Add Operation
- Optional Pollution Prevention
- Additional Attachments
- Attachment Summary
- Optional Cover Letter

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
- Submitting Official Information

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: TEST

Phone Number:

Email Address:

Mailing Address 1: TEST

Mailing Address 2:

City: TEST

State: VA

Postal Code: 22201

Country: US

[Previous](#) [Submit](#)

Upload XML

Validate Save Preview Submit

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

Navigation: Click the ‘Submit’ button to proceed to the submission process. Click the ‘Next’ button to navigate to the ‘Instructions for Substantiating CBI Claims’ screen if any CBI claims


were made in the form. Refer to **Section 12** for further information on the ‘Submitting Official Information’ screen. Refer to **Section 13** for more information on the CBI substantiation process.

4.1.36 Upload XML

You can access the ‘Upload XML’ screen by clicking the ‘Upload XML’ button within the lower-left side of the bottom action bar.

The ‘Upload XML’ screen is used to upload a PMN XML file (created from the PMN thick client with a file type of .pmn_tsca or the ZIP file generated from a CoR) into a current PMN form for PMN forms with numerous chemicals. You also have the option to export a current PMN form into an XML file using the ‘Export XML’ link. The upload XML functionality is only available for a PMN form.

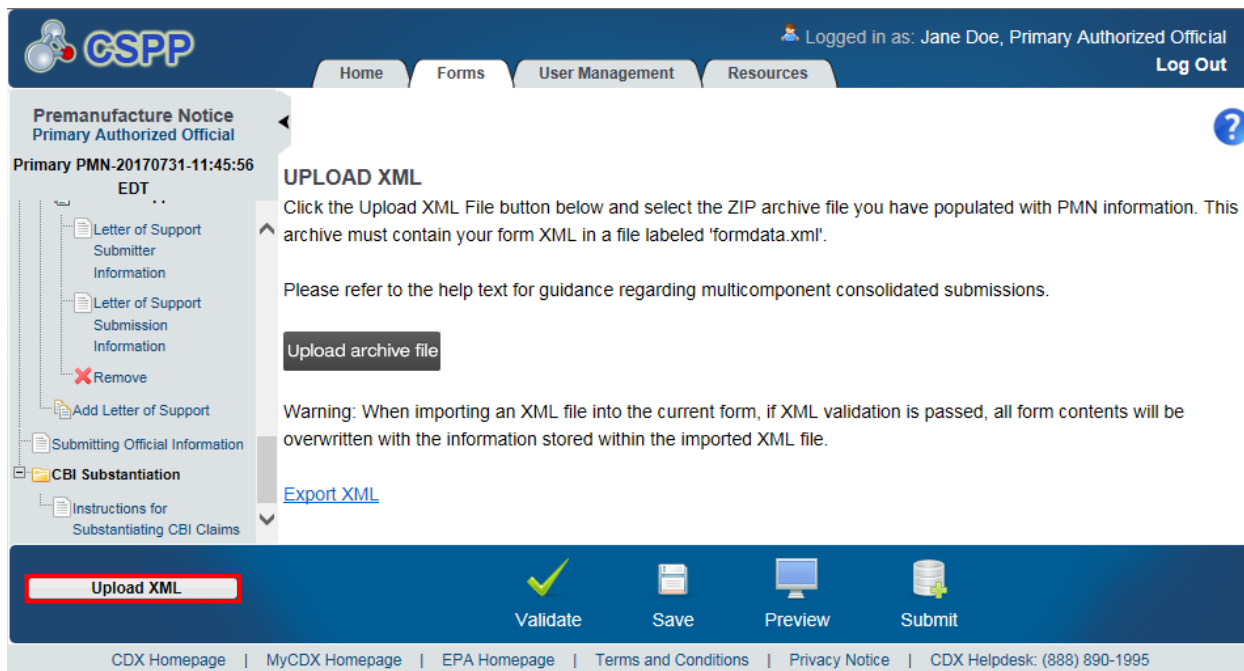
If you upload an XML file into a pre-populated form, the XML file overwrites the contents of the pre-populated form. In addition, uploading any file removes the attached documents within a form, which must be re-attached. You must also add any sites identified within the form to your CDX registration profile.

After uploading a file, click the ‘Preview’ icon () located in the bottom action bar to view a PDF preview of the form ensuring that all the data has populated correctly and any other information is displayed accurately. In particular, review the ‘Letter of Activity (1),’ ‘Protective Equipment/Engineering Controls,’ ‘Physical Form,’ ‘Media of Release,’ ‘Control Technology,’ and ‘% New Substance’ fields of entry to confirm that they have been populated correctly.

- **Upload archive file:** Click the button to generate the ‘File Upload’ window to search for the ZIP copy of record archive file populated with PMN information. The copy of record archive file must contain the XML form in a file labeled ‘formdata.xml.’ The application processes the ZIP copy of record archive file and displays any applicable error messages.
- **Export XML:** Click the button to generate the XML file of the current PMN form that a user can download.

Exhibit 4-58 shows a screen capture of the ‘Upload XML’ screen:

Exhibit 4-58 Upload XML Screen (PMN)



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 form. Click the ‘Submit’ icon (🗄️) located in the bottom action bar to begin the submission process.

5 Create Biotechnology Form

The Biotechnology form is used to collect information about “intergeneric” microorganisms that will be manufactured or imported into the United States. EPA collects the information provided in a Biotechnology form through a free text box and attachments. The Biotechnology form does not have a structured data format, but there are several types of Biotechnology notices that can be filed. The different types are as follows: ‘Microbial Commercial Activity Notice (MCAN),’ ‘TSCA Experimental Release Application (TERA),’ ‘Tier I Exemption,’ ‘Tier II Exemption,’ and ‘Biotechnology Test Market Exemption (TME)’ forms. All the forms have the same upload requirements, and EPA will retain responsibility for verifying the correct information is received.

5.1 Create Biotechnology Form

To create a new Biotechnology form, navigate to the ‘Section 5 Notices and Supports Forms’ screen and select ‘Biotechnology’ from the ‘Form Type’ drop-down menu. Refer to **Section 3.4** for additional details regarding the ‘Section 5 Notices and Supports Forms’ screen.

Refer to **Section 3.5** for additional details regarding the create passphrase process.

5.1.1 General Form Information

You can access the ‘General Form Information’ screen by creating a passphrase on the ‘Create Passphrase’ screen or by entering the passphrase on the ‘Enter Passphrase’ screen.

The ‘General Form Information’ screen presents a list of text fields and drop-down menus for you to input identifying information for the specific form. You will have the option to assign a ‘Form Alias’ to help you identify the form. A form alias is helpful when a user or company has multiple forms and/or when you must differentiate between forms to the help desk. Upon navigating to the ‘General Form Information’ screen, the system auto-generates a default alias in the following format: <Form Type-YYYYMMDD-HH:MM:SS Time Zone>.

Select the submission type from the ‘Type of Submission’ drop-down menu. The ‘Type of Submission’ drop-down menu displays the following values:

- MCAN (Microbial Commercial Activity Notice)
- TERA (TSCA Experimental Release Application)
- Tier I Exemption
- Tier II Exemption
- Biotechnology TME (Text Market Exemption)

The system will provide a ‘TS Number’ field for you to enter a TS number to tie support forms or Joint Submissions to the original Biotechnology form. The TS number must be a six (6) character alphanumeric combination and should include two (2), three (3), or four (4) letters. Company names, recognizable words, and numerical series are not recommended.

The ‘Text/Comments’ text box captures information regarding the submission/attachment. A ‘CBI’ checkbox displays above the ‘Text/Comments’ text box to claim the information as confidential.

The 'General Form Information' screen displays the option to attach a document by clicking the 'Attach Document' button. For more information regarding the attach document functionality, please refer to **Section 3.6**.

- **Form Alias:** Enter a custom form alias, if applicable. Upon navigating to the screen, the system auto-generates an editable alias comprised of <Form Type-YYYYMMDD-HH:MM:SS Time Zone>. This is a required field and is non-editable when amending a Biotechnology submission.
- **Type of Submission:** Select the submission type from the drop-down menu. This drop-down menu contains the following values: 'MCAN (Microbial Commercial Activity Notice),' 'TERA (TSCA Experimental Release Application),' 'Tier I Exemption,' 'Tier II Exemption,' and 'Biotechnology TME (Test Market Exemption).' This is a required field and is non-editable when amending a Biotechnology submission.
- **TS Number:** Enter the TS number. The TS number can be any six (6) character alphanumeric combination and should include two (2), three (3), or four (4) letters. Company names, recognizable words and numerical series are not recommended. This is a required field and is non-editable when amending a Biotechnology submission.
- **Text/Comments:** Enter a description of the form and/or attachment.
- **CBI:** Check the 'CBI' checkbox to claim the 'Text/Comments' information as confidential.
- **Attach Document:** Click the 'Attach Document' button to generate the 'Attach Documents' pop-up window. Upload attachments including published literature, regulations and certifications, ID data, construct data, effects data, MSDS, manufacturing details, use details, inactivation data, and/or other types of documents. At least one document is required to be uploaded even if a Letter of Support or Joint Submission is claimed. Please refer to **Section 3.6** for additional details regarding the attach document process.
- **File Name:** Displays the file name and file extension of a document that is uploaded on the 'Attach Documents' pop-up window.
- **Description:** Displays the description of a document.
- **Pages:** Displays the number of pages a document contains.
- **CBI:** Indicates the CBI status of a document by displaying either a 'Y' or an 'N.'
- **Actions:** Click the 'Delete' icon (✖) to delete the entire attached document row permanently from the system. A warning message displays to confirm the deletion.
- **Check here if you are filing a consolidated Biotechnology form:** Check the 'Check here if you are filing a consolidated Biotechnology form' checkbox to indicate you will be submitting a consolidated form. Checking this field will generate the 'Number of Microorganisms' text field. This field is non-editable when amending a Biotechnology submission.
- **Number of Microorganisms:** Enter the number of microorganisms in the consolidated submission; this number should be a value from two (2) through twenty (20). This field is required if the 'Check here if you are filing a consolidated Biotechnology form' checkbox is checked. This field is non-editable when amending a Biotechnology submission.

- **Check here if you are filing a joint Biotechnology form:** Check the ‘Check here if you are filing a joint Biotechnology form’ checkbox to indicate you will be submitting a joint form. This field is non-editable when amending a Biotechnology submission.
- **Check here if you have a Letter of Support pending:** Check the ‘Check here if you have a Letter of Support pending’ checkbox to indicate the form is pending a Letter of Support. This field is non-editable when amending a Biotechnology submission.

Exhibit 5-1 shows a screen capture of the ‘General Form Information’ screen:

Exhibit 5-1 General Form Information Screen (Biotech)

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

Logged in as: Jane Doe, Primary Authorized Official

Home | Forms | User Management | Resources | Log Out

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:

III. Type of Submission:

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:	<input checked="" type="checkbox"/>	Number of Microorganisms: <input type="text"/> (2-20)	
	Check here if you are filing a joint Biotechnology form:	<input checked="" type="checkbox"/>		
	Check here if you have a Letter of Support pending:	<input checked="" type="checkbox"/>		

Next

Validate | Save | Preview | Submit

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Navigation: Click the ‘Next’ button to navigate to the ‘Fees Certification’ screen for an MCAN, Biotechnology TME, Tier II Exemption, or TERA form subtype. Click the ‘Next’ button to navigate to the ‘Joint Submitter Information’ or ‘Letter of Support Submitter Information’ screen if a joint submitter or LOS submitter, respectively, is identified for a Tier I Exemption subtype. Click the ‘Next’ button to navigate to the ‘Technical Contact Information’ screen for a Tier I Exemption form subtype if (a) secondary submitter(s) are not identified. You can also access this screen by clicking the ‘Fees Certification’ link within the navigation tree after clicking the ‘Save’ icon within the bottom action bar.

5.1.2 Fees Certification

The ‘Fees Certification’ screen presents radio buttons for you to indicate the applicable fee certification statement.

You can access the ‘Fees Certification’ screen by selecting:

- MCAN (Microbial Commercial Activity Notice),
- Biotechnology TME (Test Market Exemption),
- Tier II Exemption,
- or TERA (TSCA Experimental Release Application)

from the ‘Type of Submission’ drop-down menu and clicking the ‘Next’ button from the ‘General Form Information’ screen. You can also access this screen by clicking the ‘Fees Certification’ link within the navigation tree for an in progress form. If (a) joint submitter(s) is/are identified, the joint submitter(s) may be responsible for paying part of the fee. If more than one secondary submitter is identified, the last secondary submitter that completes a joint form is required to pay the remaining fee balance.

The purpose of the ‘Fees Certification’ screen is to inform EPA of the fee amount that a primary submitter (and potential secondary submitters) pays on behalf of the reporting organization based on the business size. For TMEs, a user that reports as a graduate of the Sustainable Futures program is exempt from fees. The certification statement selected on the ‘Fees Certification’ screen is non-editable when amending a Biotechnology submission.

The ‘User Fees Certification’ screen used prior to the new Fees rule will still appear in amendments to submissions made prior to the new rule’s effective date – October 1, 2018.

Exhibit 5-2 shows the fee structure implemented for the Biotechnology form type:

Exhibit 5-2 Biotechnology Fee Structure

Form Subtype	Business Size	Fee Amount
MCAN	Average	• \$16,000
	Small	• \$2,800
TME, Tier II Exemption, TERA	Average	• \$4,700
	Small	• \$940



Form Subtype	Business Size	Fee Amount
TME	Sustainable Futures Graduate	<ul style="list-style-type: none">• N/A – Exempt From Fees

If the MCAN form subtype is selected, the following certification statements display:

- **The Company named in Part I will remit the fee of \$16,000.00 as specified in 40 CFR 700.45(c):** Select this radio button to indicate that the primary submitter will submit a fee of \$16,000. One of the certification statements must be selected.
- **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):** Select this radio button to indicate that the primary submitter will submit a fee of \$2,800. One of the certification statements must be selected.
- **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):** Select this radio button to indicate that a fee of \$16,000 will be paid between the primary and joint submitter(s). This displays if a joint/LOS is pending. One of the certification statements must be selected.

Exhibit 5-3 shows a screen capture of the 'Fees Certification' screen (MCAN, pending Joint/LOS):

Exhibit 5-3 Fees Certification Screen (MCAN, Pending Joint/LOS)

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.](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.

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If the TME, Tier II Exemption, or TERA form subtype is selected, the following certification statements display:

- **The Company named in Part I will remit the fee of \$4,700.00 as specified in 40 CFR 700.45(c):** Select this radio button option to indicate an average business size. One of the certification statements must be selected.
- **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):** Select this radio button option to indicate a small business size. One of the certification statements must be selected.
- **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): Select this radio button option to indicate that the fee will be paid between the main and joint submitter(s). One of the certification statements must be selected.

- **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:** Select this radio button to indicate that the reporting company has graduated from EPA's Sustainable Futures Program and is therefore not responsible for paying fees. This displays if the form subtype is 'TME.' One of the certification statements must be selected.

Exhibit 5-4 shows a screen capture of the 'Fees Certification' screen (TME, pending Joint/LOS):

Exhibit 5-4 Fees Certification Screen (TME, Pending Joint/LOS)

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

Home Forms User Management Resources **Log Out**

Logged in as: Jane Doe, Primary Authorized Official

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.*

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Navigation: If you are filing a joint Biotechnology form, click the 'Next' button to navigate to the 'Joint Submitter Information' screen. You can also access this screen by clicking the 'Joint Submitter Information' link within the navigation tree after clicking the 'Save' icon within the bottom action bar. If you are filing a Letter of Support and not a joint Biotechnology form, click the 'Next' button to navigate to the 'Letter of Support Submitter Information' screen. You can

also access this screen by clicking the ‘Letter of Support Submitter Information’ link within the navigation tree after clicking the ‘Save’ icon within the bottom action bar. Click the ‘Next’ button to navigate to the ‘Technical Contact Information’ screen if you are not filing either a Letter of Support or a Joint Biotechnology form. You can also navigate to this screen by clicking the ‘Technical Contact Information’ link within the navigation tree.


5.1.3 Small Business Concern Definition

Click the ‘View the updated definition of a small business concern’ link to generate the ‘Small Business Concern Definition’ window. The window displays a table of the North American Industry Classification System (NAICS) codes, NAICS descriptions, and applicable small business concern size in number of employees.

If there are codes that are not listed within the NAICS table, a small business definition applies to 500 or fewer employees that a company “owns or controls.”

Exhibit 5-5 shows a screen capture of the ‘Small Business Concern Definition’ window (Scroll 1):

Exhibit 5-5 Small Business Concern Definition Window (Scroll 1)



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

Exhibit 5-6 shows a screen capture of the ‘Small Business Concern Definition’ window (Scroll 2):

Exhibit 5-6 Small Business Concern Definition Window (Scroll 1)

325320	Pesticide and Other Agricultural Chemical Manufacturing	1000 or fewer
325411	Medicinal and Botanical Manufacturing	1000 or fewer
325510	Paint and Coating Manufacturing	1000 or fewer
325611	Soap and Other Detergent 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 Manufacturing	1250 or fewer
325412	Pharmaceutical Preparation Manufacturing	1250 or fewer
325413	InVitro Diagnostic Substance Manufacturing	1250 or fewer
325414	Biological Product (except Diagnostic) Manufacturing	1250 or fewer
325620	Toilet Preparation Manufacturing	1250 or fewer
424690	Other Chemical and Allied Products Merchant Wholesalers	150 or fewer
324110	Petroleum Refineries	1500 or fewer
325992	Photographic Film, Paper, Plate and Chemical Manufacturing	1500 or fewer
424710	Petroleum Bulk Stations and Terminals	200 or fewer
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	200 or fewer

Exhibit 5-7 shows a screen capture of the ‘Small Business Concern Definition’ window (Scroll 3):

Exhibit 5-7 Small Business Concern Definition Window (Scroll 3)

325413	In Vitro Diagnostic Substance Manufacturing	1250 or fewer
325414	Biological Product (except Diagnostic) Manufacturing	1250 or fewer
325620	Toilet Preparation Manufacturing	1250 or fewer
424690	Other Chemical and Allied Products Merchant Wholesalers	150 or fewer
324110	Petroleum Refineries	1500 or fewer
325992	Photographic Film, Paper, Plate and Chemical Manufacturing	1500 or fewer
424710	Petroleum Bulk Stations and Terminals	200 or fewer
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	200 or fewer
325314	Fertilizer (Mixing Only) Manufacturing	500 or fewer
325520	Adhesive Manufacturing	500 or fewer
325910	Printing Ink Manufacturing	500 or fewer
325991	Custom Compounding of Purchased Resins	500 or fewer
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	500 or fewer
325312	Phosphatic Fertilizer Manufacturing	750 or fewer
325612	Polish and Other Sanitation Good Manufacturing	750 or fewer
325613	Surface Active Agent Manufacturing	750 or fewer
325920	Explosives Manufacturing	750 or fewer

Navigation: Click the ‘X’ icon in the upper right-hand corner to close the ‘Small Business Concern Definition’ window and navigate back to the ‘Fees Certification’ screen.

5.1.4 Joint Submitter Information

You can access the ‘Joint Submitter Information’ screen by clicking the ‘Next’ button from the ‘Fees Certification’ screen if you are filing a MCAN, TERA, TME, or TIER II Exemption. If you are filing a TIER I Exemption, you can access this screen by clicking the ‘Next’ button from the ‘General Form Information’ screen. You can also access this screen by clicking the ‘Joint Submitter Information’ link within the navigation tree after clicking the ‘Save’ icon within the bottom action bar. You may add a maximum of two (2) total Joint Submissions by clicking the ‘Add Joint Submission’ link within the navigation tree. Click the ‘Remove’ link (✖) within the navigation tree to remove a Joint Submission.

The 'Joint Submitter Information' screen presents a list of text fields and drop-down menus used to enter contact information for the joint submitter who will be submitting separate information for the Biotechnology form. The provided email address will be used to send the joint submitter the unique identification number.

- **Check here to claim this information as CBI:** Check the 'CBI' checkbox to claim the joint submitter information as confidential. When you claim CBI, you are stating that the information is confidential and should not be released to the public.
- **First Name:** Enter the joint submitter's first name. This is a required field.
- **Last Name:** Enter the joint submitter's last name. This is a required field.
- **Position:** Enter the joint submitter's job title.
- **Company Name:** Enter the joint submitter's company name. This is a required field.
- **Phone Number:** Enter the joint submitter's U.S. phone number. This is a required field.
- **Phone Extension:** Enter the joint submitter's U.S. phone number extension if applicable.
- **Email Address:** Enter the joint submitter's email address. The email address must follow the standard email address format: John.Doe@abc.com. This is a required field.
- **Mailing Address 1:** Enter the first line of the mailing address of the joint submitter. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the joint submitter.
- **City:** Enter the U.S. city of the mailing address of the joint submitter. This is a required field.
- **State:** Select the state of the mailing address of the joint submitter from the drop-down menu. This is a required field.
- **Postal Code:** Enter the postal code of the mailing address of the joint submitter. This is a required field.
- **Country:** Displays 'United States.'

Exhibit 5-8 shows a screen capture of the ‘Joint Submitter Information’ screen:

Exhibit 5-8 Joint Submitter Information Screen (Biotech)

Navigation: Click the ‘Next’ button to navigate to the ‘Joint Submission Information’ screen. You can also access this screen by clicking the ‘Joint Submission Information’ link within the navigation tree.

5.1.5 Joint Submission Information

You can access the ‘Joint Submission Information’ screen by clicking the ‘Next’ button from the ‘Joint Submitter Information’ screen. You can also access this screen by clicking the ‘Joint Submission Information’ link within the navigation tree.

The ‘Joint Submission Information’ screen is used as a communication point between two companies. The ‘Joint Submission Information’ screen displays fields that capture information to pass to the joint submitter. A text box captures information to send to the joint submitter in an unencrypted email sent by the primary submitter. A ‘Unique Identifier for Joint Submissions’ box will also display on this screen. The unique identification number auto-generates when a user declares a joint submission is being established.

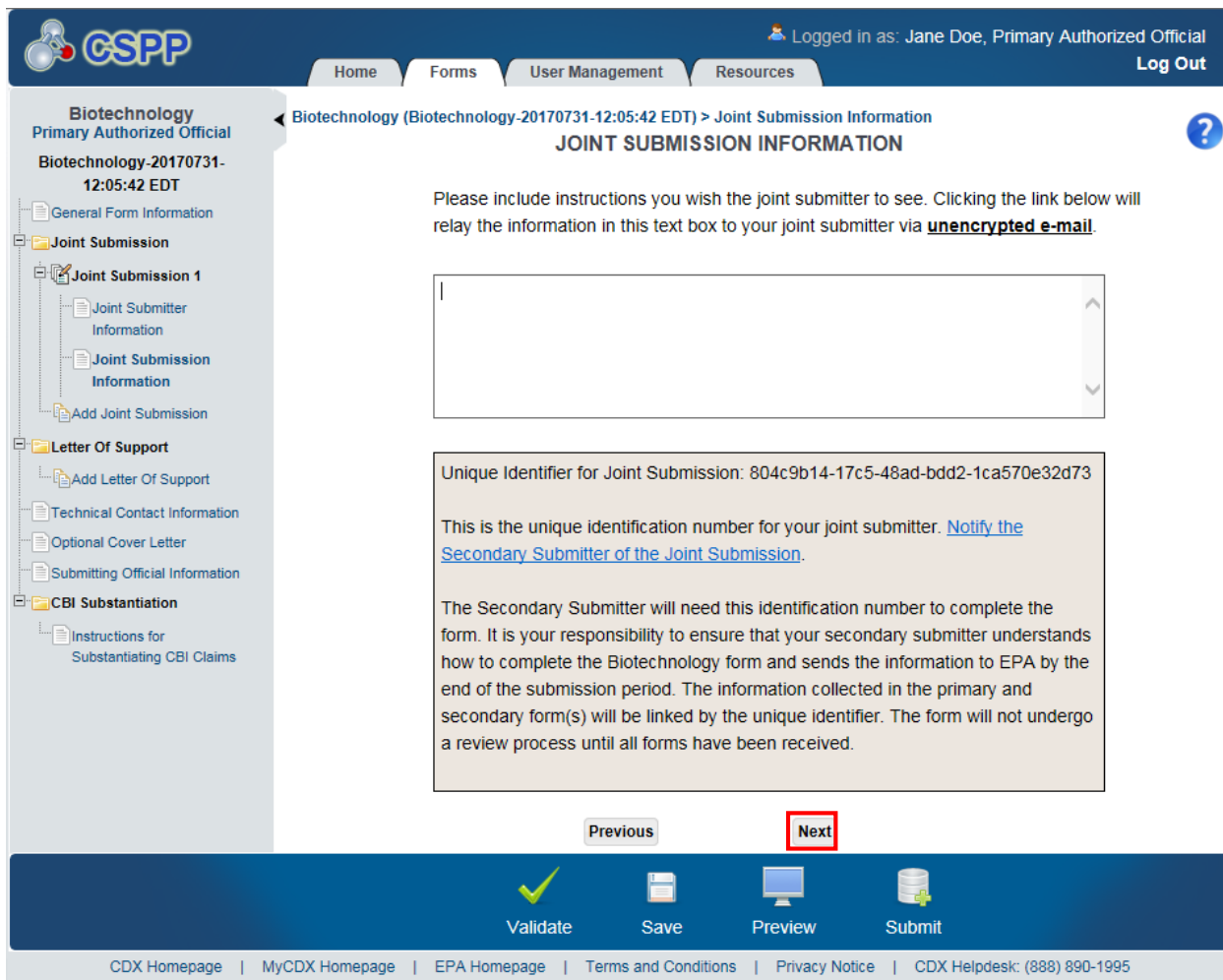
Joint Submission Process: A ‘Special Information’ field will be used to send information to the joint submitter in an email sent by the primary submitter.

When the secondary submitter accesses the ‘Section 5 Notices and Supports Forms’ screen and creates a new form, the secondary submitter will be prompted to enter the unique identification number on the ‘Create Passphrase’ screen.

- **Joint Submission Information Instructions:** Enter the information that the primary submitter is sending to the joint submitter.
- **Joint Submission Informational Text:** Displays instructional text provided by OPPT, the unique identification number automatically generated for the form, and provides functionality to email the unique identification number to the joint submitter by clicking the ‘Notify the Secondary Submitter of the Joint Submission’ link.
- **Unique Identification Number:** The unique identification number is a random number auto-generated to pass on to the joint submitter to create a joint submission.

Exhibit 5-9 shows a screen capture of the ‘Joint Submission Information’ screen:

Exhibit 5-9 Joint Submission Information Screen (Biotech)



Navigation: If you are filing a Letter of Support, click the ‘Next’ button to navigate to the ‘Letter of Support Submitter Information’ screen. You can also access this screen by clicking the ‘Letter of Support Submitter Information’ link within the navigation tree. If you are not filing a Letter of Support, click the ‘Next’ button to navigate to the ‘Technical Contact Information’ screen. You can also navigate to this screen by clicking the ‘Technical Contact Information’ link within the navigation tree.

5.1.6 Notify Secondary Submitter of Joint Submission Information

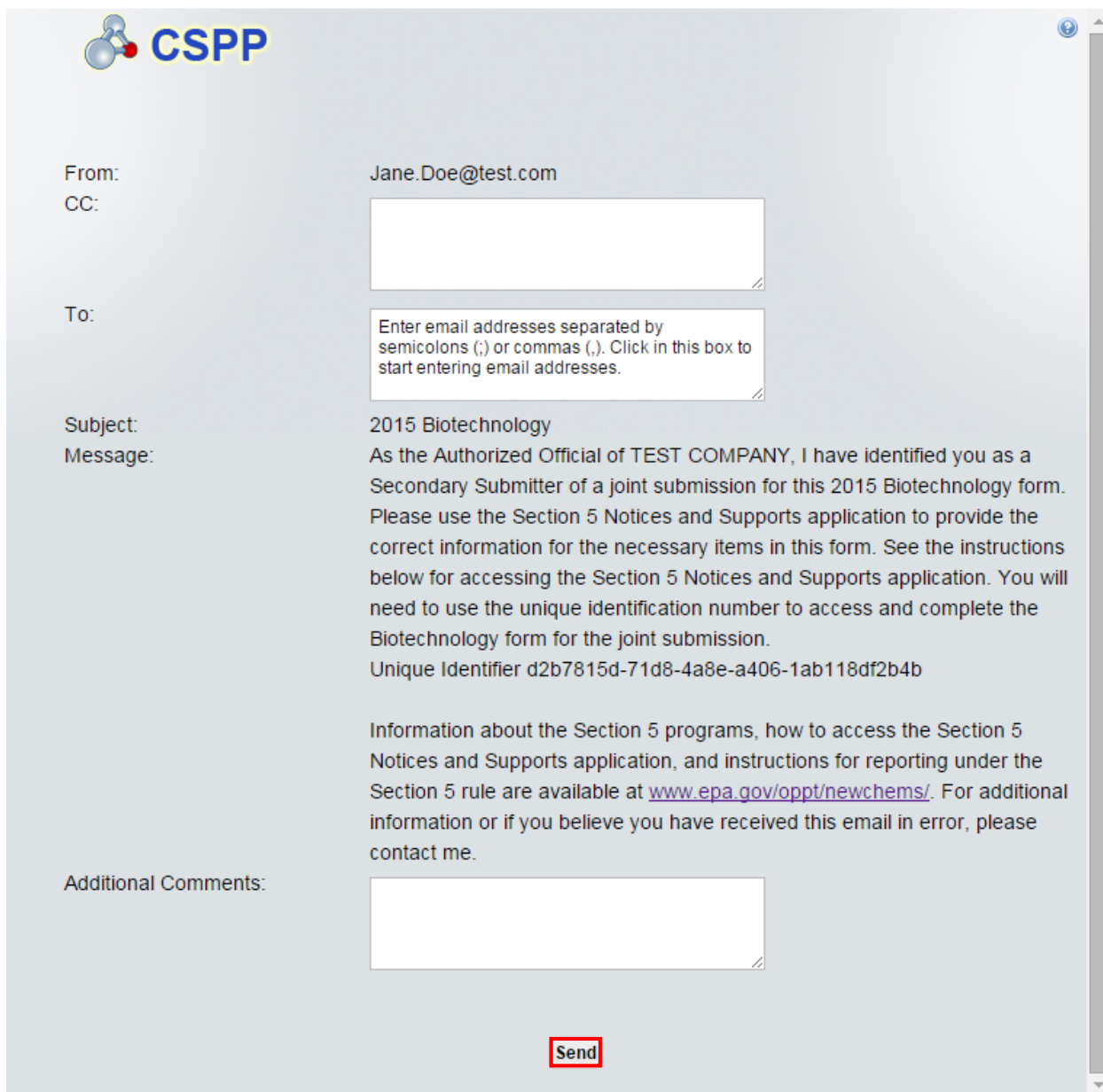
You can access the unique identifier notification pop-up window by clicking the ‘Notify the Secondary Submitter of the Joint Submission’ link from the ‘Joint Submission Information’ screen.

The unique identifier notification pop-up window is used to notify the secondary submitter of the unique identification number. The unique identifier notification window displays a ‘CC’ field to add other email addresses to the notification (including the original submitter), a ‘To’ field, and an ‘Additional Comments’ text box.

-
- **From:** Displays the email address of the original submitter.
 - **CC:** Contains the email address from CDX registration information, and the editable email address of the technical contact.
 - **To:** Contains instructional text to enter multiple email addresses. Contains the editable email address of the joint submitter specified on the 'Joint Submitter Information' screen; this email address will be automatically populated upon navigating to the window.
 - **Subject:** Displays 'YYYY Biotechnology.'
 - **Message:** Displays a pre-determined message that will display in the email sent to a secondary submitter.
 - **Additional Comments:** Enter any other additional comments or instructions that should be passed onto the secondary submitter.
 - **Send:** Click the button to generate and send an email to the email addresses identified in the 'CC' and 'To' fields.

Exhibit 5-10 shows a screen capture of the ‘Unique Identifier Notification’ pop-up window:

Exhibit 5-10 Unique Identifier Notification Pop-Up Window (Biotech)



CSPP

From: Jane.Doe@test.com

CC:

To:

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

Navigation: Click the ‘Send’ button to send the email to the Joint Submitter and navigate back to the ‘Joint Submission Information’ screen. Click the ‘X’ button in the upper right-hand corner to cancel the process of notifying a Joint Submitter and navigate back to the ‘Joint Submission Information’ screen.

5.1.7 Letter of Support Submitter Information

You can access the ‘Letter of Support Submitter Information’ screen by clicking the ‘Next’ button from the ‘Fees Certification’ screen if you are not filing a Joint Submission or Tier I Exemption. If you are filing a Tier I Exemption, you can access this screen by clicking the

'Next' button from the 'General Form Information' screen. You can also access this screen by clicking the 'Next' button from the 'Joint Submission Information' screen if you are filing a joint submission. You can also access this screen by clicking the 'Letter of Support Submitter Information' link within the navigation tree when you have indicated that a Letter of Support form is pending. Click the 'Add Letter of Support' link within the navigation tree to add a Letter of Support. The system will allow an unlimited number of Letters of Support to be filed. Remove a Letter of Support by clicking the 'Remove' link (✖) within the navigation tree.

The 'Letter of Support Submitter Information' screen presents a list of text fields and drop-down menus used to enter contact information for the Letter of Support submitter who will be submitting separate information for the Biotechnology form. The provided email address will be used to send the Letter of Support submitter the unique identification number to create the Letter of Support at the discretion of the primary submitter.

- **Check here to claim this information as CBI:** Check the 'Check here to claim this information as CBI' checkbox to claim the Letter of Support submitter information as confidential. When you claim the Letter of Support submitter contact information as CBI, you are stating that the information is confidential and should not be released to the public.
- **First Name:** Enter the Letter of Support submitter's first name. This is a required field.
- **Last Name:** Enter the Letter of Support submitter's last name. This is a required field.
- **Position:** Enter the Letter of Support submitter's job title.
- **Company Name:** Enter the Letter of Support submitter's company name. This is a required field.
- **Phone Number:** Enter the Letter of Support submitter's phone number. This is a required field.
- **Phone Extension:** Enter the Letter of Support submitter's phone number extension if applicable.
- **Email Address:** Enter the Letter of Support submitter's email address. The email address must follow the standard email address format: John.Doe@abc.com. This is a required field.
- **Mailing Address 1:** Enter the first line of the Letter of Support submitter's mailing address. This is a required field.
- **Mailing Address 2:** Enter the second line of the Letter of Support submitter's mailing address.
- **City:** Enter the city of the mailing address of the Letter of Support submitter. This is a required field.
- **State:** Select the state of the mailing address of the Letter of Support submitter from the drop-down menu. This is a required field if the 'Country' field is set to 'United States.'
- **Postal Code:** Enter the postal code of the mailing address for the Letter of Support submitter.
- **Country:** Select the country of the mailing address for the Letter of Support submitter. This is a required field. If a non-U.S. country is selected, a primary submitter is responsible for collecting fees from non-U.S. joint submitters; the primary submitter is responsible for the

full payment or the joint submitter must have an Agent/Consultant with the ability to pay his/her portion of the fee.

Exhibit 5-11 shows a screen capture of the ‘Letter of Support Submitter Information’ screen:

Exhibit 5-11 Letter of Support Submitter Information Screen (Biotech)

Navigation: Click the ‘Next’ button to navigate to the ‘Letter of Support Submission Information’ screen. You can also access this screen by clicking the ‘Letter of Support Submission Information’ link within the navigation tree.

5.1.8 Letter of Support Submission Information

You can navigate to the ‘Letter of Support Submission Information’ screen by clicking the ‘Next’ button from the ‘Letter of Support Submitter Information’ screen. You can also access this screen by clicking the ‘Letter of Support Submission Information’ link within the navigation tree.

The ‘Letter of Support Submission Information’ screen is used as a communication point between two companies. The ‘Letter of Support Submission Information’ screen presents fields

to enter information to pass to the secondary submitter. A text box is used to send information in an email to the secondary submitter. A ‘Unique Identifier for Letter of Support Submissions’ box will also display on this screen. The unique identifier auto-generates when a Letter of Support submission is being established.

Letter of Support Submission Process: A field titled ‘Special Information’ will be used to send information to the Joint Submitter in an email sent at the discretion of the primary submitter.

When the secondary submitter accesses the ‘Section 5 Notices and Supports Forms’ screen and creates a new form, the secondary submitter will be prompted to enter the unique identifier on the ‘Create Passphrase’ screen. Once the unique identifier has been entered, the application will tie the two forms together.

- **Letter of Support Submission Information Instructions:** Enter the information that the primary submitter is sending to the Letter of Support submitter.
- **Letter of Support Submission Informational Text:** Displays instructional text provided by EPA, the unique identification number generated for the form, and provides functionality to email the unique identification number to the Letter of Support submitter by clicking the ‘Notify the Secondary Submitter of the Letter of Support submission’ link.
- **Unique Identification Number:** The unique identification number is a random number auto-generated to pass on to the Letter of Support submitter to create a Letter of Support.

Exhibit 5-12 shows a screen capture of the ‘Letter of Support Submission Information’ screen:

Exhibit 5-12 Letter of Support Submission Information Screen (Biotech)

The screenshot shows the 'Letter of Support Submission Information' screen. At the top, the user is logged in as 'Jane Doe, Primary Authorized Official'. The navigation menu on the left includes 'Biotechnology Primary Authorized Official', 'General Form Information', 'Fees Certification', 'Joint Submission', and 'Letter Of Support'. The main content area contains the following text:

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**.

Below this text is a large empty text box for input.

A unique identifier is displayed: 501d098b-23fc-415d-b895-4ef5bc91f9bf. Below it, instructions state: '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.](#)'

Further instructions state: '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.'

At the bottom, there are 'Previous' and 'Next' buttons. The 'Next' button is highlighted with a red box. Below the buttons is a footer with icons for 'Validate', 'Save', 'Preview', and 'Submit'.

Navigation: Click the ‘Next’ button to navigate to the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Technical Contact Information’ link within the navigation tree.

5.1.9 Notify Secondary Submitter of Letter of Support Information

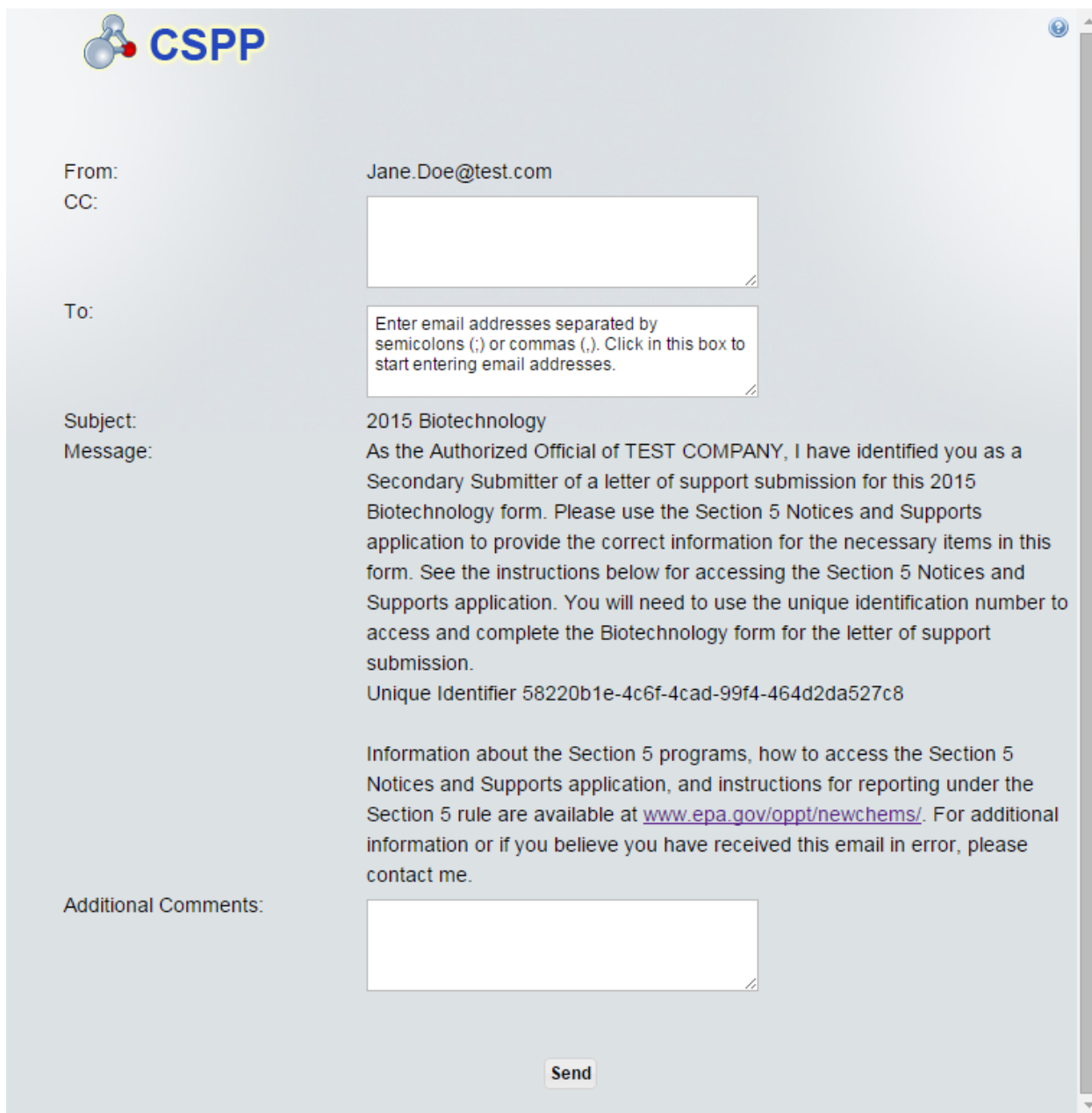
You can access the unique identifier notification pop-up window by clicking the ‘Notify the Secondary Submitter of the Letter of Support submission’ link from the ‘Letter of Support Submission Information’ screen.

The unique identifier notification pop-up window is used to notify the secondary submitter of the unique identification number. The unique identifier notification window displays a ‘CC’ field to add other email addresses to the notification (including the original submitter), a ‘To’ field, and an ‘Additional Comments’ text box.

-
- **From:** Displays the email address of the original submitter.
 - **CC:** This editable text field automatically populates with the email address from CDX registration information, and the email address of the technical contact.
 - **To:** Contains instructional text to enter multiple email addresses. Contains the editable email address of the joint submitter specified on the 'Joint Submitter Information' screen; this email address automatically populates upon navigating to the window.
 - **Subject:** Displays 'YYYY Biotechnology.'
 - **Message:** Displays a pre-determined message that will display in the email sent to a secondary submitter.
 - **Additional Comments:** Enter any other additional comments or instructions that can be passed onto the secondary submitter.
 - **Send:** Click the button to generate and send the email to the email addresses identified in the 'CC' and 'To' fields.

Exhibit 5-13 shows a screen capture of the unique identifier notification pop-up window:

Exhibit 5-13 Unique Identifier Notification Pop-Up Window (Biotech)



The screenshot shows a web-based email composition window titled "CSPP". The header includes the CSPP logo and a close button. The email fields are as follows:

- From:** Jane.Doe@test.com
- CC:** [Empty text box]
- To:** [Text box containing instructions: "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:** [Empty text box]

At the bottom center of the window is a "Send" button.

Navigation: Click the ‘Send’ button to send the email to the secondary submitter and navigate back to the ‘Letter of Support Submission Information’ screen. Click the ‘X’ in the upper right-hand corner to cancel the unique identification number notification process and navigate back to the ‘Letter of Support Submission Information’ screen.

5.1.10 Technical Contact Information

You can access the ‘Technical Contact Information’ screen by clicking the ‘Next’ button from the ‘General Form Information’ screen if you are not filing a Joint Submission or Letter of

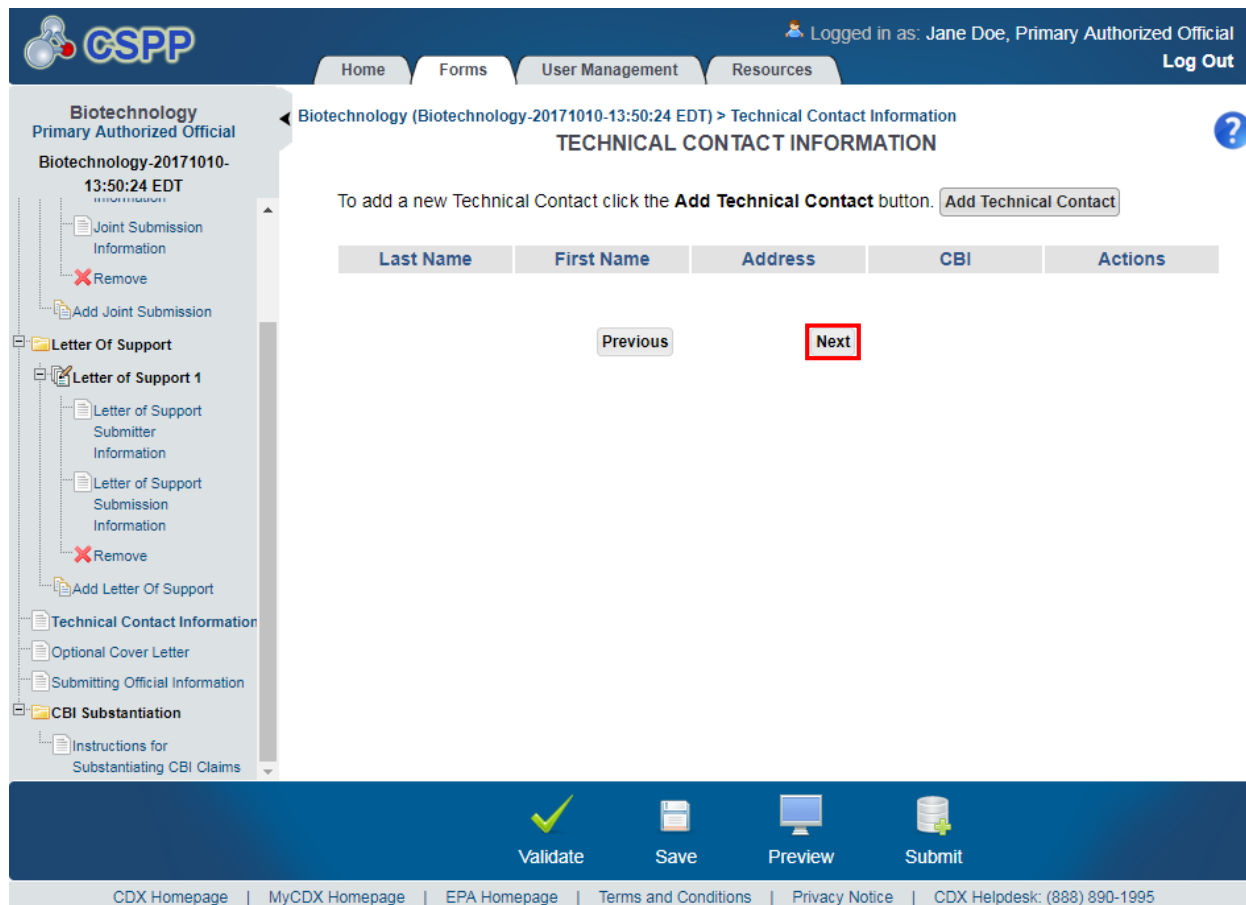
Support. You can also access this screen by clicking the ‘Next’ button from the ‘Joint Submission Information’ screen if you are not filing a Letter of Support. You can also access this screen by clicking the ‘Next’ button from the ‘Letter of Support Submission Information’ screen if you are filing a Letter of Support. You can also navigate to the ‘Technical Contact Information’ screen by clicking the ‘Technical Contact Information’ link within the navigation tree.

The ‘Technical Contact Information’ screen displays an ‘Add Technical Contact’ button. Click the ‘Add Technical Contact’ button to generate an ‘Add Technical Contact’ pop-up window to enter information into the text fields. Click the ‘Copy CDX Registration’ button to populate the text fields using your CDX registration information. Check the ‘Check here to claim this information as CBI’ checkbox to indicate that the information is confidential and will not be released to the public.

- **Add Technical Contact:** Click the ‘Add Technical Contact’ button to generate the ‘Add Technical Contact’ pop-up window.
- **Last Name:** Displays the last name of the reported technical contact.
- **First Name:** Displays the first name of the reported technical contact.
- **Address:** Displays the address of the reported technical contact.
- **CBI:** Indicates the CBI status of the reported technical contact information by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete the technical contact information from the table. A warning message displays to confirm the deletion.

Exhibit 5-14 shows a screen capture of the ‘Technical Contact Information’ screen:

Exhibit 5-14 Technical Contact Information Screen (Biotech)



Navigation: Click the ‘Next’ button from the ‘Technical Contact Information’ screen to navigate to the ‘Optional Cover Letter’ screen. You can also access this screen by clicking the ‘Optional Cover Letter’ link within the navigation tree.

5.1.10.1 Add Technical Contact

You can access the ‘Add Technical Contact’ pop-up window by clicking the ‘Add Technical Contact’ button on the ‘Technical Contact Information’ screen.

- **Copy CDX Registration:** Click the ‘Copy CDX Registration’ button to copy your information from CDX registration; a message displays confirming the import of CDX registration information.
- **Check here to claim this information as CBI:** Check the ‘Check here to claim this information as CBI’ checkbox to claim the technical contact information as confidential.
- **First Name:** Enter the technical contact’s first name. Click the ‘Copy CDX Registration’ button to populate the fields with information entered during CDX registration. This is a required field.

- **Last Name:** Enter the technical contact's last name. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Position:** Enter the technical contact's job title.
- **Company Name:** Enter the technical contact's company name. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Phone Number:** Enter the daytime U.S. phone number of the technical contact; this must be at least 10 characters long and does not accept dashes. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Phone Extension:** Enter the technical contact's phone number extension if applicable.
- **Email Address:** Enter the technical contact's email address. The email address must follow the standard email address format: John.Doe@abc.com. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration.
- **Mailing Address 1:** Enter the first line of the technical contact's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Mailing Address 2:** Enter the second line of the technical contact's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration.
- **City:** Enter the city of the technical contact's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **State:** Select the state of the technical contact's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Postal Code:** Enter the postal code of the technical contact's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Country:** Displays 'United States.'

Exhibit 5-15 shows a screen capture of the ‘Add Technical Contact’ pop-up window:

Exhibit 5-15 Add Technical Contact Pop-Up Window (Biotech)

Navigation: Click the ‘Cancel’ button to stop populating technical contact information and navigate back to the ‘Technical Contact Information’ screen. Click the ‘OK’ button to save and populate the entered technical contact information and navigate back to the ‘Technical Contact Information’ screen.

5.1.11 Optional Cover Letter

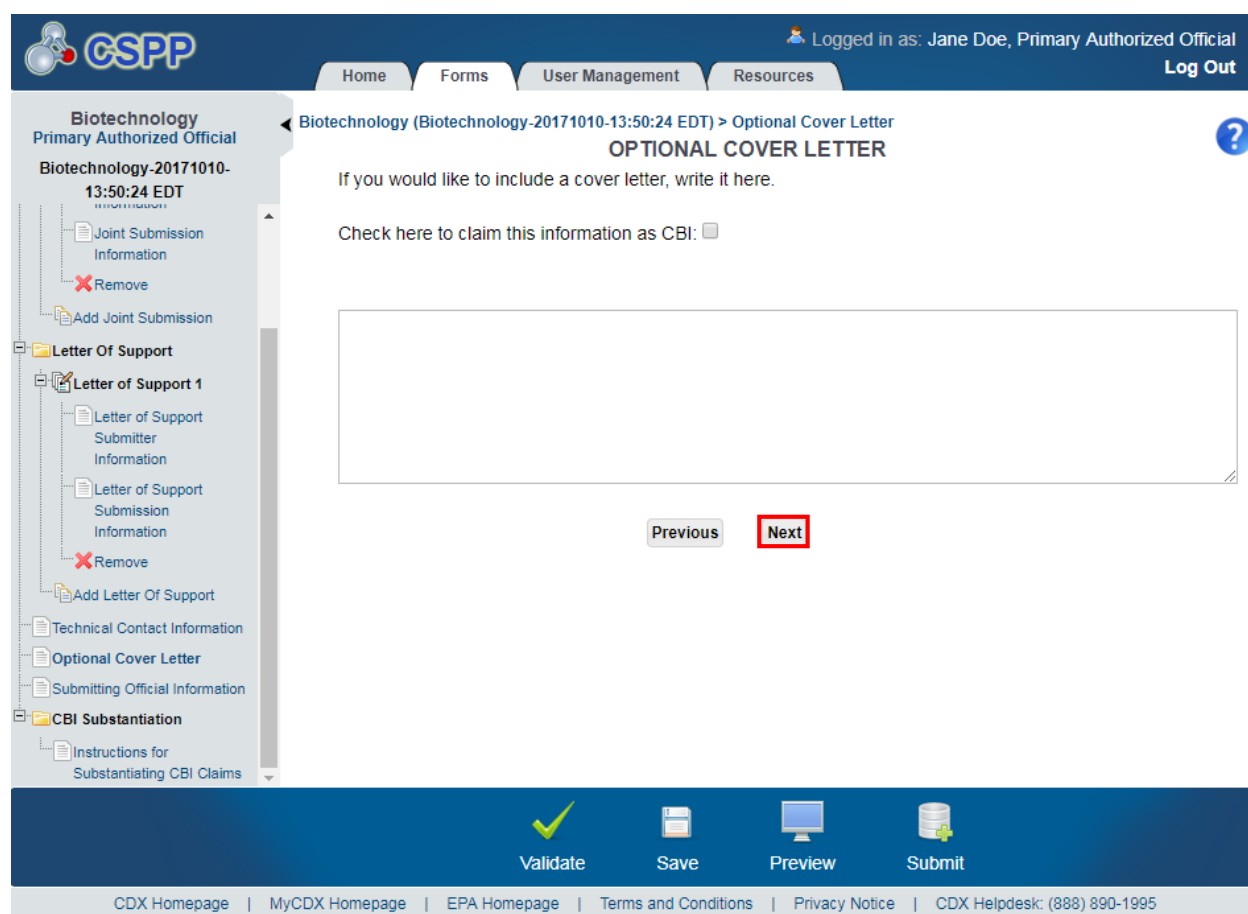
You can access the ‘Optional Cover Letter’ screen by clicking the ‘Next’ button from the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Optional Cover Letter’ link within the navigation tree.

The ‘Optional Cover Letter’ screen is used to communicate information to EPA not collected elsewhere in the form. The cover letter is used to give OPPT resources and special instructions regarding the application; enter any necessary instructions into the blank text field. The cover letter should be either fully CBI or non-CBI to eliminate user error to promote transparency between the company and EPA.

- **Check here to claim this information as CBI:** Check the ‘Check here to claim this information as CBI’ checkbox to claim the cover letter information as confidential.
- **Optional Cover Letter:** Enter the description and any additional special instructions regarding the form.

Exhibit 5-16 shows a screen capture of the ‘Optional Cover Letter’ screen:

Exhibit 5-16 Optional Cover Letter Screen (Biotech)



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 form. Click the ‘Next’ button to navigate to the ‘Submitting Official Information’ page.

5.1.12 Submitting Official Information

You can navigate to the ‘Submitting Official Information’ screen by clicking the ‘Next’ button from the ‘Optional Cover Letter’ screen. You can also access this screen by clicking the ‘Submitting Official Information’ link within the navigation tree.

Exhibit 5-17 shows a screen capture of the ‘Submitting Official Information’ screen:

Exhibit 5-17 Submitting Official Information Screen (Biotech)

Biotechnology Primary Authorized Official
 Biotechnology-20170731-12:05:42 EDT
 Logged in as: Jane Doe, Primary Authorized Official

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:	<input checked="" type="checkbox"/>
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

Navigation: Click the ‘Submit’ button to proceed to the submission process. Refer to **Section 12** for further information on the ‘Submitting Official Information’ screen. If any CBI claims were made in the form, click the ‘Next’ button to proceed to CBI substantiation. Refer to **Section 13** for more information on the CBI substantiation process.

6 Create Notice of Commencement (NOC) Form

The Notice of Commencement (NOC) form allows industry users to notify EPA when a new chemical or microorganism, submitted under a Biotechnology or PMN form, has already started manufacture or import. A NOC form cannot be submitted before the chemical or microorganism has gone through the review period by EPA. The NOC must be submitted within thirty (30) days after the start date of the first manufacture or import.

6.1 Create NOC Form

To create a new NOC form, navigate to the ‘Section 5 Notices and Supports Forms’ screen and select ‘Notice of Commencement (NOC)’ from the ‘Form Type’ drop-down menu and click the ‘Start New Form’ button. Refer to **Section 3.4** for additional details regarding the ‘Section 5 Notices and Supports Forms’ screen.

Refer to **Section 3.5** for additional details regarding the create passphrase process.

6.1.1 General Form Information

You can access the ‘General Form Information’ screen by creating a passphrase on the ‘Create Passphrase’ screen or entering the passphrase on the ‘Enter Passphrase’ screen. The ‘General Form Information’ screen provides fields to identify information that notifies EPA of the form alias, case number, and manufacture or import information.

The ‘General Form Information’ screen presents a list of text fields and drop-down menus to capture information about the originally filed form. The ‘Manufacture/Import Information’ field presents radio buttons for you to state whether the company intends to manufacture or import the new chemical substance. When a manufacture/import radio button is selected, a calendar widget appears for you to enter the date of commencement.

- **Form Alias:** Enter a custom form alias, if applicable. Upon navigating to the screen, the system auto-generates an editable form alias in the following format: <Form Type-YYYYMMDD-HH:MM:SS Time Zone>. This is a required field.
- **Case Number:** Enter the case number pertaining to the reported chemical substance or mixture. The case number must be in the following format: P-XX-0999 for Premanufacture Notice cases or J-XX-0999 for MCAN Biotechnology cases where ‘XX’ indicates the fiscal year in which the case number is generated, and the leading ‘0’ is required. This is a required field.
- **First Commercial Manufacture:** Enter the date for the first commercial manufacture. Select the ‘First Commercial Manufacture’ radio button to generate a date field and calendar widget to select the appropriate date. If you select a future date past the current date, an error displays when navigating away from the screen. Either the ‘First Commercial Manufacture’ radio button or the ‘First Commercial Importation’ field is required.
- **First Commercial Importation:** Enter the date for the first commercial importation. Select the ‘First Commercial Importation’ radio button to generate a date field and calendar widget to select the appropriate date. If you select a future date past the current date, an error displays when navigating away from the screen. Either the ‘First Commercial Manufacture’ or the ‘First Commercial Importation’ field is required.

Exhibit 6-1 shows a screen capture of the ‘General Form Information’ screen:

Exhibit 6-1 General Form Information Screen (NOC)

Navigation: Click the ‘Next’ button to navigate to the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Technical Contact Information’ link within the navigation tree.

6.1.2 Technical Contact Information

You can access the ‘Technical Contact Information’ screen by clicking the ‘Next’ button from the ‘General Form Information’ screen. You can also access this screen by clicking the ‘Technical Contact Information’ link within the navigation tree.

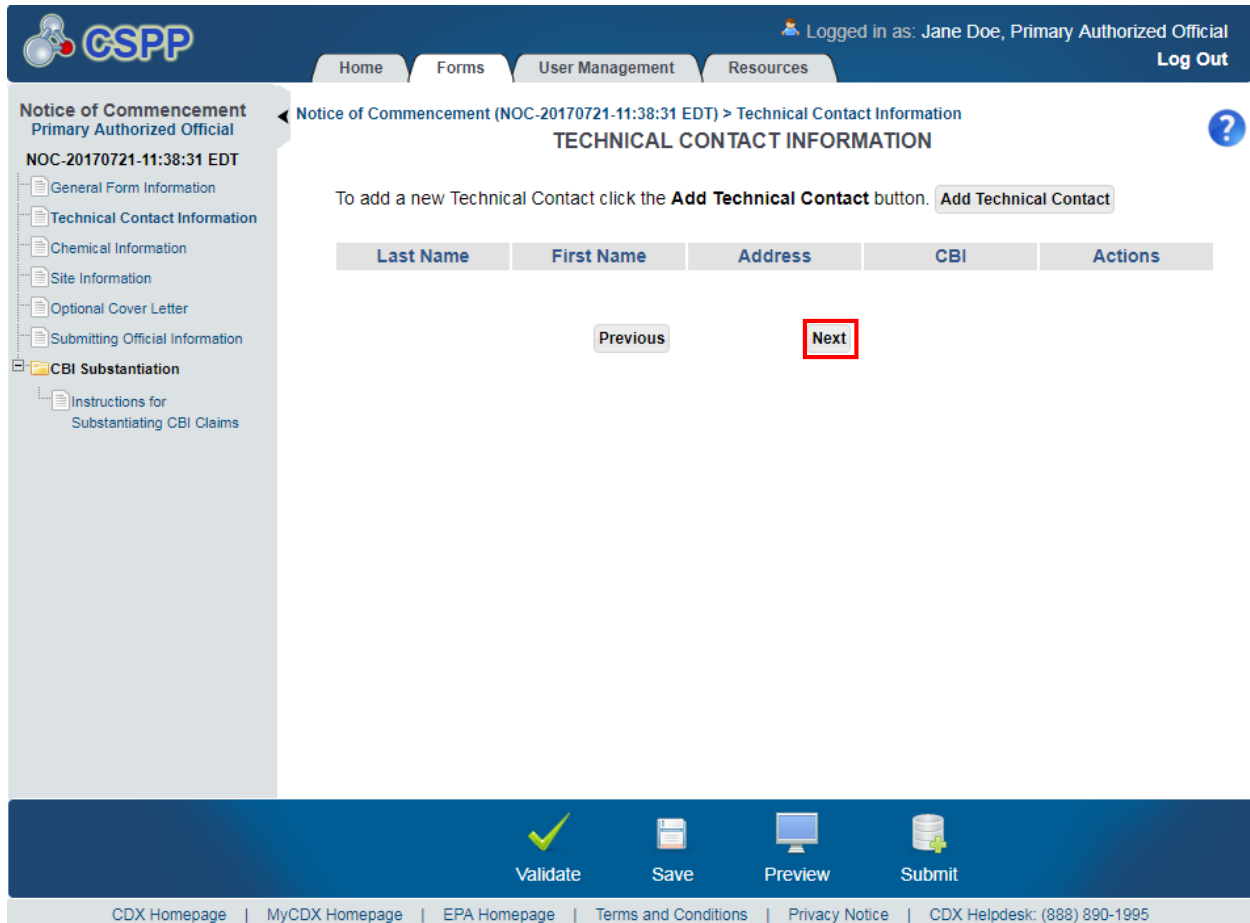
The ‘Technical Contact Information’ screen displays an ‘Add Technical Contact’ button. Click the ‘Add Technical Contact’ button to generate an ‘Add Technical Contact’ pop-up window to enter technical contact information into the list of text fields. Click the ‘Copy CDX Registration’ button to populate the text fields with your contact information entered during CDX registration. Check the ‘Check here to claim this information as CBI’ checkbox to claim the technical contact information as confidential to indicate that the information will not be released to the public.

- **Add Technical Contact:** Click the ‘Add Technical Contact’ button to generate the ‘Add Technical Contact’ pop-up window.
- **Last Name:** Displays the technical contact’s last name.

- **First Name:** Displays the technical contact’s first name.
- **Address:** Displays the technical contact’s address.
- **CBI:** Indicates the technical contact’s CBI status by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete the technical contact. A warning message displays to confirm the deletion of the technical contact.

Exhibit 6-2 shows a screen capture of the ‘Technical Contact Information’ screen:

Exhibit 6-2 Technical Contact Information Screen (NOC)



Navigation: Click the ‘Next’ button to navigate to the ‘Chemical Information’ screen. You can also access this screen by clicking the ‘Chemical Information’ link within the navigation tree.

6.1.2.1 Add Technical Contact

Click the ‘Add Technical Contact’ button to begin the process of adding technical contacts.

- **Copy CDX Registration:** Click the ‘Copy CDX Registration’ button to import contact information from CDX registration; a confirmation will display.
- **Check here to claim this information as CBI:** Check the ‘Check here to claim this information as CBI’ checkbox to claim the technical contact information as confidential.

- **First Name:** Enter the technical contact's first name. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Last Name:** Enter the technical contact's last name. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Company Name:** Enter the technical contact's company name. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Phone Number:** Enter the technical contact's daytime U.S. phone number; this must be at least 10 characters long and does not accept dashes. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Phone Extension:** Enter the technical contact's phone number extension, if applicable.
- **Email Address:** Enter the technical contact's email address. The email address must follow the standard email address format: John.Doe@abc.com. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration.
- **Mailing Address 1:** Enter the first line of the technical contact's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Mailing Address 2:** Enter the second line of the technical contact's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration.
- **City:** Enter the city of the technical contact's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **State:** Select the state of the technical contact's mailing address from the drop-down menu. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Postal Code:** Enter the postal code of the technical contact's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Country:** Displays 'United States.'

Exhibit 6-3 shows a screen capture of the ‘Add Technical Contact’ pop-up window:

Exhibit 6-3 Add Technical Contact Pop-Up Window (NOC)

Navigation: Click the ‘Cancel’ button or ‘X’ icon at the top left corner of the window to return to the ‘Technical Contact Information’ screen without saving the technical contact information. Click the ‘OK’ button to save the entered technical contact information and return to the ‘Technical Contact Information’ screen.

6.1.3 Chemical Information



You can access the ‘Chemical Information’ screen by clicking the ‘Next’ button from the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Chemical Information’ link within the navigation tree.

The ‘Chemical Information’ screen provides fields to identify the chemical the submitter has begun to manufacture or import. The ‘Specific Chemical Identity’ section provides fields to input

information describing the chemical for which the NOC is to be filed. This screen outlines the unique chemical properties and displays the name and CASRN of the chemical. Most of the chemicals submitted under a NOC will not be found in the ‘Search Substance Registry Services’ window, and a new chemical will have to be created. To create a new chemical, click the ‘Search SRS’ button, found in the ‘Chemical Information’ screen, and then the ‘Create New Chemical’ button to generate the ‘Chemical Not Found In Substance Registry Services’ pop-up window.

If you claim a chemical as CBI, the ‘Generic Chemical Name’ text box generates. A ‘CBI Substantiation’ folder displays within the navigation tree upon navigating away from the screen.

If you claim chemical identity as confidential, you must provide a generic chemical name for your substance that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Please note that EPA will be closely assessing the generic name at this time; please make sure that your generic name is a good generic name that only hides the proprietary parts of the chemical information.

- **Add New Chemical:** Click the ‘Add New Chemical’ button to generate the ‘Specific Chemical Identity’ expandable/collapsible field set. At least one chemical is required.
- **Search SRS:** Click the ‘Search SRS’ button to generate the ‘Search SRS’ window. Refer to **Section 3.10** for additional details regarding the search SRS functionality.
- **CASRN:** Displays the CASRN of the chemical being reported, if applicable.
- **Chemical Name:** Displays the chemical name of the substance being reported.
- **CBI:** Check the ‘CBI’ checkbox to claim the ‘Specific Chemical Identity’ information as confidential and generate the ‘Generic Chemical Name’ text box. If you claim the chemical as confidential, a ‘CBI Substantiation’ folder displays within the navigation tree after clicking the ‘Next’ button from the ‘Chemical Information’ screen.
- **Generic Chemical Name:** Enter the generic name to associate with a chemical. This field displays only when the ‘Specific Chemical Identity’ is claimed CBI. This is a required field if there is no pending Letter of Support or Joint Submission for the form.
- **Save:** Click the button to save the information entered within the expandable/collapsible field set. You must click this button instead of the ‘Save’ icon () located within the bottom action bar to successfully save the entered information within the field set before being able to navigate away from the screen using the ‘Previous’ and ‘Next’ buttons. Refer to **Section 3.9** for more information regarding the save functionality in an expandable/collapsible field set.
- **Cancel:** Click the ‘Cancel’ link located in the upper right-hand corner of the expandable/collapsible field set to prevent edits from saving and to remove a field set. The ‘Cancel’ link displays when the expandable/collapsible field set is open for editing. A confirmation message displays to confirm the action.
- **Edit:** Click the ‘Edit’ link located in the upper right-hand corner of the expandable/collapsible field set to modify the information entered in the fields. The ‘Edit’ link displays when the expandable/collapsible field set has been saved and the data is not currently editable.
- **Delete:** Click the ‘Delete’ icon () located in the upper right-hand corner of the expandable/collapsible field set to delete the field set. A confirmation message displays to

confirm the deletion. The ‘Delete’ icon (✖) displays when the user has clicked the ‘Add New Chemical’ button.

- **Expand All:** Click the ‘Expand All’ link located at the upper right-hand corner of the expandable/collapsible field sets to expand a series of field sets.
- **Collapse All:** Click the ‘Collapse All’ link located at the upper right-hand corner of the expandable/collapsible field sets to collapse a series of field sets.
- **Substance Identity Confidentiality Status:** You will only be able to select a single radio button. If you claim the chemical as CBI, after clicking the ‘Save’ button in the ‘Specific Chemical Identity’ expandable/collapsible field set, the system enables the first radio button and disables the second and third radio buttons. If you do not claim the chemical as CBI, after clicking the ‘Save’ button in the ‘Specific Chemical Identity’ expandable/collapsible field set, the system disables the first radio button and enables the second and third radio button options. This section displays the following options:
 - I wish to claim the substance identity confidential, and the substantiation to support this claim is attached. Failure to submit the required substantiation in accordance with 40 CFR 720.85(b) will result in waiver of your claim.
 - I previously claimed the substance identity as confidential and hereby relinquish that claim.
 - I did not claim the substance identity as confidential in my original PMN submission.

Exhibit 6-4 shows a screen capture of the ‘Chemical Information’ screen:

Exhibit 6-4 Chemical Information Screen (NOC)

Navigation: Click the ‘Next’ button to navigate to the ‘Site Information’ screen. You can also access this screen by clicking the ‘Site Information’ link within the navigation tree.

6.1.4 Site Information

You can access the ‘Site Information’ screen by clicking the ‘Next’ button from the ‘Chemical Information’ screen. You can also access this screen by clicking the ‘Site Information’ link within the navigation tree.

The ‘Site Information’ screen identifies the site at which the manufacture or import of the chemical occurs. You are able to identify sites via the ‘Add Site’ pop-up window. To do so, click the ‘Add Site’ button. You must select a site before moving on to the ‘CBI Substantiation Part 1’ screen or to the ‘Optional Cover Letter’ screen.

- **Add Site:** Click the ‘Add Site’ button to generate the ‘Add Site’ pop-up window. Refer to **Section 3.11** for additional details regarding the add site functionality.

- **Registry ID:** Displays the EPA registry ID of the site.
- **Site Name:** Displays the site name associated with a site.
- **Address:** Displays the site address of a site.
- **CBI:** Indicates the CBI status of a site by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete the site row permanently from the system. A confirmation prompt displays to confirm the deletion.

Exhibit 6-5 shows a screen capture of the ‘Site Information’ screen.

Exhibit 6-5 Site Information Screen (NOC)

The screenshot displays the 'Site Information' screen for a Notice of Commencement (NOC-20170721-11:38:31 EDT). The page features a navigation tree on the left with 'Site Information' selected. The main content area is titled 'SITE INFORMATION' and contains a table with columns: Registry ID, Site Name, Address, CBI, and Actions. Below the table are 'Previous' and 'Next' buttons. The 'Next' button is highlighted with a red box. At the bottom of the screen are buttons for 'Validate', 'Save', 'Preview', and 'Submit'.

Navigation: Click the ‘Next’ button to navigate to the ‘Optional Cover Letter’ screen. You can also navigate to this screen by clicking on the ‘Optional Cover Letter’ link in the navigation tree.

6.1.5 CBI Substantiation Part 1

You can access the ‘CBI Substantiation Part 1’ screen by clicking the ‘Next’ button from the ‘Site Information’ screen if a chemical was claimed CBI on the ‘Chemical Information’ screen. You can also access this screen by clicking the ‘CBI Substantiation Part 1’ link within the navigation tree.

The ‘CBI Substantiation Part 1’ screen presents substantiation questions that require you to provide answers into the text fields as free text or enter ‘N/A’ if the question does not apply. The ‘CBI Substantiation Part 1’ screen consists of questions A through D, which read as follows:

- **(A) What harmful effects to your competitive position, if any, do you think would result if EPA publishes on the Inventory the identity of the chemical substance? How could a competitor use such information given the fact that the identity of the substance otherwise would appear on the inventory of chemical substances with no link between the substance and your company or industry? How substantial would the harmful effects of disclosure be? What is the causal relationship between the disclosure and the harmful effects?:** Enter the answer to substantiation question A. This is a required field.
- **(B) For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?:** Enter the answer to substantiation question B. This is a required field.
- **(C) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential for purposes of the Inventory?:** Enter the answer to substantiation question C. This is a required field.
- **(D) Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured or imported for a commercial purpose by anyone?:** Enter the answer to substantiation question D. This is a required field.

Exhibit 6-6 shows a screen capture of the ‘CBI Substantiation Part 1’ screen (Scroll 1):

Exhibit 6-6 CBI Substantiation Part 1 Screen (NOC) (Scroll 1)

The screenshot displays the 'CBI Substantiation Part 1' screen. The header includes the GSPP logo, navigation tabs (Home, Forms, User Management, Resources), and user information: 'Logged in as: Jane Doe, Primary Authorized Official' with a 'Log Out' button. The left sidebar contains a tree view with categories like 'Notice of Commencement' and 'CBI Substantiation'. The main content area shows the title 'CBI SUBSTANTIATION PART 1' and a question: 'Substantiate confidentiality of claims if you mark the substance identity (Part V) as CBI by answering the following questions. Please enter N/A if the question does not apply.' Below this are two questions, (A) and (B), each followed by a large text input box. At the bottom of the page, there is a dark blue bar with four buttons: 'Validate' (with a green checkmark icon), 'Save' (with a floppy disk icon), 'Preview' (with a monitor icon), and 'Submit' (with a database icon). The footer contains links to 'CDX Homepage', 'MyCDX Homepage', 'EPA Homepage', 'Terms and Conditions', 'Privacy Notice', and 'CDX Helpdesk: (888) 890-1995'.

Exhibit 6-7 shows a screen capture of the ‘CBI Substantiation Part 1’ screen (Scroll 2):

Exhibit 6-7 CBI Substantiation Part 1 Screen (NOC) (Scroll 2)

Navigation: Click the ‘Next’ button to navigate to the ‘CBI Substantiation Part 2’ screen. You can also access this screen by clicking the ‘CBI Substantiation Part 2’ link within the navigation tree.

6.1.6 CBI Substantiation Part 2

You can access the ‘CBI Substantiation Part 2’ screen by clicking the ‘Next’ button from the ‘CBI Substantiation Part 1’ screen. You can also access this screen by clicking the ‘CBI Substantiation Part 2’ link within the navigation tree.

The ‘CBI Substantiation Part 2’ screen presents substantiation questions that require answers to be entered into the text fields as free text or enter ‘N/A’ if the question does not apply. The ‘CBI Substantiation Part 2’ screen consists of questions E through H, which read as follows:

- **(E) Is the fact that someone is manufacturing or importing this chemical substance for commercial purposes available to the public, e.g. in technical journals or other publications; in libraries; or in State, local or Federal agency public files?:** Enter the answer to substantiation question E. This is a required field.

- **(F) What measures have you taken to prevent undesired disclosure of the fact that you are manufacturing or importing this substance for a commercial purpose?:** Enter the answer to substantiation question F. This is a required field.
- **(G) To what extent has the fact that you are manufacturing or importing this chemical substance for a commercial purpose been disclosed to others? What precautions have you taken in regard to these disclosures? Has this information been disclosed to the public, or to competitors?:** Enter the answer to substantiation question G. This is a required field.
- **(H) In what form does this particular chemical substance leave the site of manufacture, e.g. as part of a product, in effluent or emission stream? If so, what measures have you taken to guard against discovery of its identity?:** Enter the answer to substantiation question H. This is a required field.

Exhibit 6-8 shows a screen capture of the ‘CBI Substantiation Part 2’ screen (Scroll 1):

Exhibit 6-8 CBI Substantiation Part 2 Screen (NOC) (Scroll 1)

The screenshot displays the 'CBI SUBSTANTIATION PART 2' screen. At the top, it shows the user is logged in as 'Jane Doe, Primary Authorized Official'. The navigation menu on the left includes sections for 'General Form Information', 'Technical Contact Information', 'Chemical Information', 'Site Information', and 'CBI Substantiation'. Under 'CBI Substantiation', 'CBI Substantiation Part 2' is highlighted. The main content area contains the following text:

Substantiate confidentiality of claims if you mark the substance identity (Part V) as CBI by answering the following questions. Please enter N/A if the question does not apply.

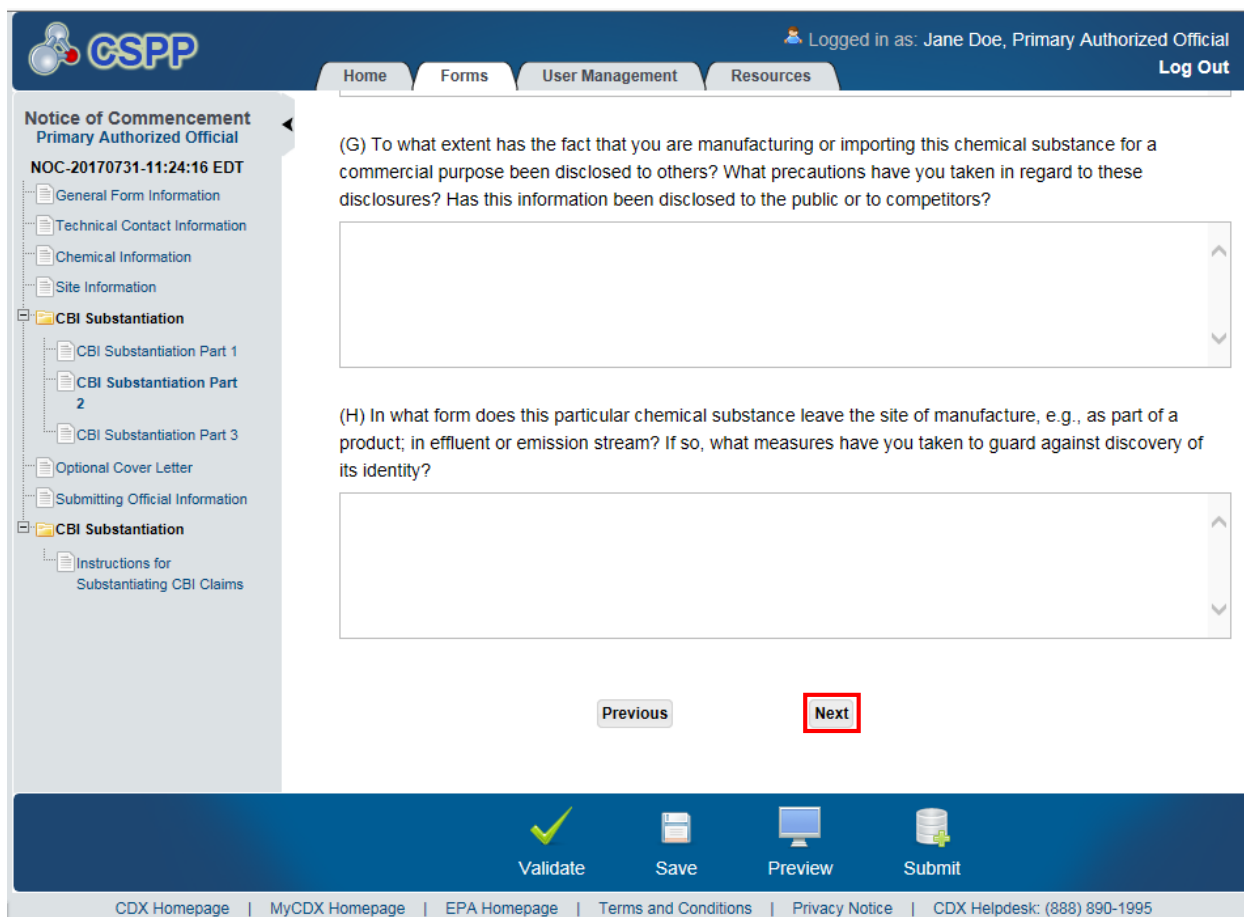
(E) Is the fact that someone is manufacturing or importing this chemical substance for commercial purposes available to the public, e.g. in technical journals or other publications; in libraries; or in State, local, or Federal agency public files?

(F) What measures have you taken to prevent undesired disclosure of the fact that you are manufacturing or importing this substance for a commercial purpose?

At the bottom of the screen, there are four buttons: 'Validate' (with a green checkmark icon), 'Save' (with a floppy disk icon), 'Preview' (with a monitor icon), and 'Submit' (with a database icon). The footer contains the following links: CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995.

Exhibit 6-9 shows a screen capture of the ‘CBI Substantiation Part 2’ screen (Scroll 2):

Exhibit 6-9 CBI Substantiation Part 2 Screen (NOC) (Scroll 2)



Navigation: Click the ‘Next’ button to navigate to the ‘CBI Substantiation Part 3’ screen. You can also access this screen by clicking the ‘CBI Substantiation Part 3’ link within the navigation tree.

6.1.7 CBI Substantiation Part 3

You can access the ‘CBI Substantiation Part 3’ screen by clicking the ‘Next’ button from the ‘CBI Substantiation Part 2’ screen. You can also access this screen by clicking the ‘CBI Substantiation Part 3’ link within the navigation tree.

The ‘CBI Substantiation Part 3’ screen presents substantiation questions that require answers to be entered into the text fields as free text or enter ‘N/A’ if the question does not apply. The ‘CBI Substantiation Part 3’ screen consists of questions I through L, which read as follows:

- **(I) If the chemical substance leaves the site of manufacture in a product that is available to either the public or your competitors, can they identify the substance by analyzing the product?:** Enter the answer to substantiation question I. This is a required field.
- **(J) For what purpose do you manufacture or import the substance?:** Enter the answer to substantiation question J. This is a required field.

- **(K) Has EPA, another Federal agency, or any Federal court made any persistent confidentiality determinations regarding this chemical substance? If so, copies of such determinations must be included in the substantiation.:** Enter the answer to substantiation question K. This is a required field.
- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window and attach supporting documentation for substantiation question K. Refer to **Section 3.6** for additional details regarding the attach document functionality.
- **File Name:** Displays the file name and file extension of the file that is uploaded on the ‘Attach Documents’ pop-up window.
- **Description:** Displays the description associated with a document.
- **Pages:** Displays the number of pages a document contains.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire attached document row permanently from the system. A warning message displays to confirm the deletion of the document.
- **(L) If the notice includes a health and safety study concerning the new chemical substance, the submitter must also answer the question in 40 CFR 720.90(b)(2). Persons must answer this question if a health and safety study was provided at any time in the new chemical process.:** Enter the answer to substantiation question L. This is a required field.

Exhibit 6-10 shows a screen capture of the ‘CBI Substantiation Part 3’ screen (Scroll 1):

Exhibit 6-10 CBI Substantiation Part 3 Screen (NOC) (Scroll 1)

The screenshot displays the 'CBI Substantiation Part 3' screen within the GSPP (Global Substantiation and Reporting Portal) interface. The user is logged in as Jane Doe, a Primary Authorized Official. The interface includes a navigation menu on the left with options like 'General Form Information', 'Technical Contact Information', 'Chemical Information', 'Site Information', and 'CBI Substantiation' (with sub-items for Part 1, 2, and 3). The main content area contains three questions (I, J, and K) related to confidentiality substantiation, each with a corresponding text input field. At the bottom, there are buttons for 'Validate', 'Save', 'Preview', and 'Submit'. The footer contains links to CDX, MyCDX, EPA, and other resources.

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

Home Forms User Management Resources

Notice of Commencement Primary Authorized Official
NOC-20170731-11:24:16 EDT

Notice of Commencement (NOC-20170731-11:24:16 EDT) > CBI Substantiation Part 3
CBI SUBSTANTIATION PART 3

Substantiate confidentiality of claims if you mark the substance identity (Part V) as CBI by answering the following questions. Please enter N/A if the question does not apply.

(I) If the chemical substance leaves the site of manufacture in a product that is available to either the public or your competitors, can they identify the substance by analyzing the product?

(J) For what purpose do you manufacture or import the substance?

(K) Has EPA, another Federal agency, or any Federal court made any persistent confidentiality determinations regarding this chemical substance? If so, copies of such determinations must be included in the substantiation.

Validate Save Preview Submit

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

Exhibit 6-11 shows a screen capture of the ‘CBI Substantiation Part 3’ screen (Scroll 2):

Exhibit 6-11 CBI Substantiation Part 3 Screen (NOC) (Scroll 2)

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

Home Forms User Management Resources

Notice of Commencement
Primary Authorized Official
NOC-20170731-11:24:16 EDT

- General Form Information
- Technical Contact Information
- Chemical Information
- Site Information
- CBI Substantiation**
 - CBI Substantiation Part 1
 - CBI Substantiation Part 2
 - CBI Substantiation Part 3**
 - Optional Cover Letter
 - Submitting Official Information
 - CBI Substantiation**
 - Instructions for Substantiating CBI Claims

(K) Has EPA, another Federal agency, or any Federal court made any persistent confidentiality determinations regarding this chemical substance? If so, copies of such determinations must be included in the substantiation.

Attach Document

File Name	Description	Pages	CBI	Actions
<p>(L) If the notice includes a health and safety study concerning the new chemical substance, the submitter must also answer the questions in 40 CFR 720.90(b)(2). (Persons must answer this question if a health and safety study was provided at any time in the new chemical process.)</p>				

Previous **Next**

Validate Save Preview Submit

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

Navigation: Click the ‘Next’ button to navigate to the ‘Optional Cover Letter’ screen. You can also access this screen by clicking the ‘Optional Cover Letter’ link within the navigation tree.

6.1.8 Optional Cover Letter

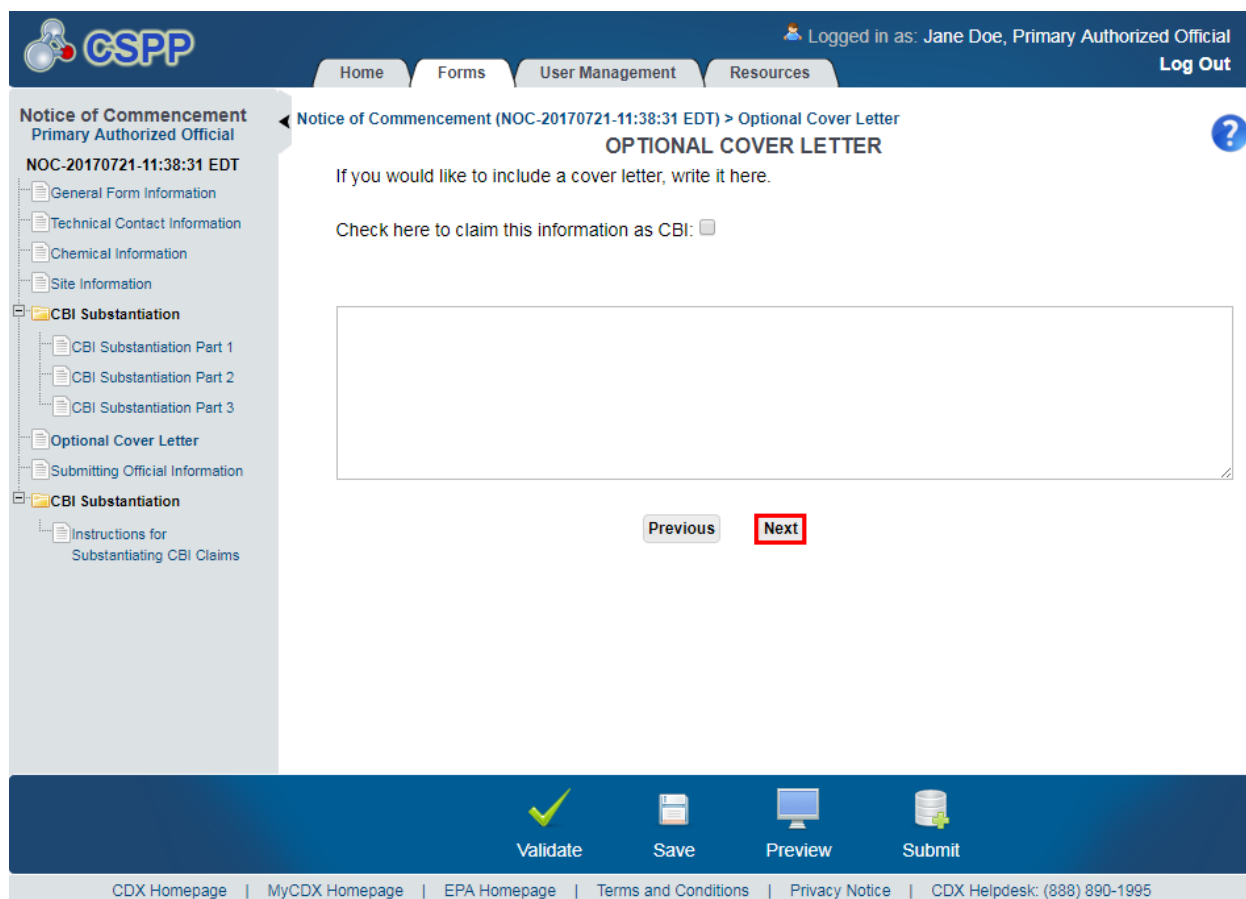
If no chemical was claimed confidential, click the ‘Next’ button from the ‘Site Information’ screen to navigate to the ‘Optional Cover Letter’ screen. If a chemical was claimed confidential, click the ‘Next’ button from the ‘CBI Substantiation Part 3’ screen to navigate to the ‘Optional Cover Letter’ screen. You can also access this screen by clicking the ‘Optional Cover Letter’ link within the navigation tree.

The ‘Optional Cover Letter’ screen is used to communicate information to EPA not collected elsewhere in the form. The cover letter is used to give OPPT resources and special instructions regarding the application. The cover letter should be either fully CBI or non-CBI to eliminate user error and to promote transparency between the company and EPA.

- **Check here to claim this information as CBI:** Check the ‘Check here to claim this information as CBI’ checkbox to claim the cover letter as confidential.
- **Cover Letter:** Enter any additional information or special instructions associated with the form.

Exhibit 6-12 shows a screen capture of the ‘Optional Cover Letter’ screen:

Exhibit 6-12 Optional Cover Letter Screen (NOC)



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 (🖨️) to generate a PDF preview of the form. Click the ‘Next’ button to navigate to the ‘Submitting Official Information’ screen.

6.1.9 Submitting Official Information

You can navigate to the ‘Submitting Official Information’ screen by clicking the ‘Next’ button from the ‘Optional Cover Letter’ screen. You can also access this screen by clicking the ‘Submitting Official Information’ link within the navigation tree.

Exhibit 6-13 shows a screen capture of the ‘Submitting Official Information’ screen.

Exhibit 6-13 Submitting Official Information Screen (NOC)

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

Home Forms **User Management** Resources

Notice of Commencement
Primary Authorized Official
NOC-20170731-11:24:16 EDT

- General Form Information
- Technical Contact Information
- Chemical Information
- Site Information
- Optional Cover Letter
- 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.

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

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

Navigation: Click the ‘Next’ button to proceed to the ‘Instructions for Substantiating CBI Claims’ screen if any claims of confidentiality were made in the form. If no CBI claims were made, click the ‘Submit’ button to begin the submission process. Refer to **Section 12** for further information on the ‘Submitting Official Information’ screen. Refer to **Section 13** for more information on CBI substantiation.

7 Create Support Form

The Section 5 Notices and Supports application allows support forms to be submitted such as ‘Amendment,’ ‘Other Correspondence,’ ‘Suspension Request,’ ‘Transfer of Ownership,’ ‘Withdrawal Requests,’ and ‘Test Data.’ Support forms are filed separately from PMN forms due to access restrictions and/or to provide information not included in the original PMN. The Support form is used to supplement the original PMN by providing additional data that was not provided originally, withdraw a PMN application, or provide data that was requested later.

7.1 Create Support Form

To create a new Support form, navigate to the ‘Section 5 Notices and Supports Forms’ screen and select ‘Support’ from the ‘Form Type’ drop-down menu. Refer to **Section 3.4** for additional details regarding the ‘Section 5 Notices and Supports Forms’ screen.

Refer to **Section 3.5** for additional details regarding the create passphrase process.

7.1.1 General Form Information

You can access the ‘General Form Information’ screen by entering a passphrase on the ‘Enter Passphrase’ screen or creating a passphrase on the ‘Create Passphrase’ screen.

The ‘General Form Information’ screen provides a list of text fields and drop-down menus for you to input information about the originally filed form.

- **Form Alias:** Enter the form alias. Upon navigating to the screen, the system auto-generates an editable form alias comprised of <Form Type-YYYYMMDD-HH:MM:SS Time Zone>. This is a required field.
- **Case Number:** Enter the case number that connects to the original submission in the system. This is a type-ahead field that displays the forms that have been submitted under the same organization. If the case number is in the application, the remaining fields on the ‘General Form Information’ screen will populate. In the case of legacy submissions, case numbers must be manually entered. The case number must be in one of the following formats: P-XX-XXXX for PMN, SN-XX-XXXX for SNUN, L-XX-XXXX for LVE, LM-XX-XXXX for LVE Modifications, X-XX-XXXX for LOREX, XM-XX-XXXX for LOREX Modifications, T-XX-XXXX for TMEA, I-XX-XXXX for Mock PMN, J-XX-XXXX for MCAN, R-XX-XXXX for TERA, G-XX-XXXX for Tier-I, H-XX-XXXX for Tier-II, or BF-XX-XXXX for Bona Fide. This field does not accept -0000 as a case number suffix. This is a required field.
- **TS Number:** Enter the TS number; this field accepts any six (6) character alphanumeric combination. This value is determined by the company to identify the form for both payments and connecting related submissions (Letters of Support, Joint Submissions and corrections). This field will auto-populate if the ‘Case Number’ field is linked to a form that is recognized by the application. The TS number should include two (2), three (3), or four (4) letters. Company names, recognizable words and numerical series are not recommended.
- **Type of Support:** Select the type of support from the drop-down menu. This field contains the following values: ‘Amendment,’ ‘Suspension Request,’ ‘Test Data,’ ‘Transfer of Ownership,’ ‘Withdrawal Request,’ and ‘Other Correspondence.’ The ‘Amendment’ type is unavailable when creating an amendment. This is a required field.






- **Check if requested by EPA/Contractor:** Check the ‘Check if requested by EPA/Contractor’ checkbox to display fields to enter information to identify the requestor that asked you to submit support information.
- **Last Name:** Enter the requestor’s last name. This field displays if the ‘Check if requested by EPA/Contractor’ checkbox is checked and is required if displayed.
- **First Name:** Enter the requestor’s first name. This field displays if the ‘Check if requested by EPA/Contractor’ checkbox is checked and is required if displayed.
- **EPA/Contractor:** Select a value from the drop-down menu to identify whether the requestor is an EPA official, a contractor, or unknown. This drop-down menu contains the following options: ‘EPA,’ ‘Contractor,’ and ‘Unknown.’
- **Actions:** Click the ‘Save’ icon () to save an individual EPA/contractor entry. Click the ‘Form’ icon () to edit an individual EPA/contractor entry. Click the ‘Delete’ icon () to delete an individual EPA/contractor entry. Click the ‘Add’ icon () to add another entry to enter EPA/contractor information.
- **CBI:** Check the ‘CBI’ checkbox to claim the support description or explanation of support as confidential.
- **Description or Explanation of Support:** Enter the support description or explanation of support. Either the ‘Description or Explanation of Support’ field is required, or an attached document is required.
- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window and attach documents describing the Support form. Attachments that are uploaded include individual toxicity studies, GPC data, spectra, exposure monitoring evaluations, physical and chemical properties data, SAR modeling, test samples characterization data, explanatory comments, etc. Analytical tests should be provided with their complete data set. For example, provide a GPC test report with time interval data and all graphs. For ease of review, group attachments by type of data, e.g., physical/chemical properties, fate information. Refer to **Section 3.6** for additional details regarding the attach document functionality.
- **File Name:** Displays the file name and file extension of a file that is uploaded on the ‘Attach Documents’ pop-up window.
- **Description:** Displays the description of a file that is uploaded on the ‘Attach Documents’ pop-up window.
- **Subtype:** Displays the subtype of a document.
- **Pages:** Displays the number of pages a document contains.
- **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon () to delete the entire attached document row permanently from the system. A warning message displays to confirm the deletion.

Exhibit 7-1 shows a screen capture of the ‘General Form Information’ screen for a Support form:

Exhibit 7-1 General Form Information Screen (Support)

The screenshot displays the 'GENERAL FORM INFORMATION' screen for a support form. The page includes a navigation tree on the left, a header with user information, and a main content area with various form fields and sections.

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

Home Forms User Management Resources

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

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
<input type="button" value="Next"/>					

Validate Save Preview Submit

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

Navigation: Click the ‘Next’ button to navigate to the ‘Original Submitter Information’ screen. You can also access this screen by clicking the ‘Original Submitter Information’ link within the navigation tree.

7.1.2 Original Submitter Information

You can access the ‘Original Submitter Information’ screen by clicking the ‘Next’ button from the ‘General Form Information’ screen. You can also access this screen by clicking the ‘Original Submitter Information’ link within the navigation tree.

The 'Original Submitter Information' screen provides a list of text fields to enter the contact information of the Authorized Official who submitted the original PMN form for whom you are filing the Support form.

- **Click here to copy your information from CDX Registration:** Click the 'Copy CDX Registration' button to import your CDX registration information. A prompt will generate to confirm the import of registration information.
- **Check here to claim this information as CBI:** Check the 'Check here to claim this information as CBI' checkbox to claim the original submitter contact information as confidential.
- **First Name:** Enter the original submitter's first name. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Last Name:** Enter the original submitter's last name. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Position:** Enter the original submitter's job title.
- **Company Name:** Enter the original submitter's company name. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Phone Number:** Enter the original submitter's daytime phone number; U.S. or international. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Phone Extension:** Enter the original submitter's phone number extension, if applicable.
- **Email Address:** Enter the original submitter's email address. The email address must follow the standard email address format: John.Doe@abc.com. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration.
- **Mailing Address 1:** Enter the first line of the original submitter's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Mailing Address 2:** Enter the second line of the original submitter's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration.
- **City:** Enter the city of the original submitter's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **State:** Select the original submitter's state from the drop-down menu. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Postal Code:** Enter the postal code of the original submitter's mailing address for the original submitter. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.

- **Country:** Displays ‘United States.’

Exhibit 7-2 shows a screen capture of the ‘Original Submitter Information’ screen:

Exhibit 7-2 Original Submitter Information Screen (Support)

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. Click the ‘Next’ button to navigate to the ‘Submitting Official Information’ screen.

7.1.3 Submitting Official Information

You can navigate to the ‘Submitting Official Information’ screen by clicking the ‘Next’ button from the ‘Original Submitter Information’ screen. You can also access this screen by clicking the ‘Submitting Official Information’ link within the navigation tree.

Exhibit 7-3 shows a screen capture of the ‘Submitting Official Information’ screen:

Exhibit 7-3 Submitting Official Information Screen (Support)

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

Home Forms User Management Resources **Log Out**

Logged in as: Jane Doe, Primary Authorized Official

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:	<input checked="" type="checkbox"/>
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

Navigation: Click the ‘Next’ button to proceed to the ‘Instructions for Substantiating CBI Claims’ screen if any claims of confidentiality were made in the form. If no CBI claims were made, click the ‘Submit’ button to begin the submission process. Refer to **Section 12** for further information on the ‘Submitting Official Information’ screen. Refer to **Section 13** for more information on CBI substantiation.

8 Create Bona Fide Form

The purpose of the Bona Fide module is to receive an official determination from EPA as to whether a substance is on the TSCA inventory. Submitters may attempt to avoid submitting a PMN by completing a Bona Fide form to establish that the chemical already exists on the inventory. The Bona Fide process is covered in a thirty (30) day period.

8.1 Create Bona Fide Form

To create a new Bona Fide form, navigate to the ‘Section 5 Notices and Supports Forms’ screen and select ‘Bona Fide’ from the ‘Form Type’ drop-down menu. Refer to **Section 3.4** for additional details regarding the ‘Section 5 Notices and Supports Forms’ screen.

Refer to **Section 3.5** for additional details regarding the create passphrase process.

8.1.1 General Document Information

You can access the ‘General Document Information’ screen by clicking the ‘Start New Form’ button and creating a new passphrase, or by accessing a Section 5 Notices and Supports Bona Fide form that is ‘In Progress’ and entering the passphrase associated with the selected form.

The ‘General Document Information’ screen presents text fields and checkboxes for you to input identifying information for the specific form. You will have the option to assign a ‘Form Alias’ by which the form can be identified. The form alias is helpful when you or the company has multiple forms and/or when a user must differentiate between forms to the help desk. If a form alias is not entered, the system will provide a default alias comprised of a form type and date and time stamp in the following format: <Form Type-YYYYMMDD-HH:MM:SS Time Zone>.

You can claim the entirety of the form as CBI. The entire form will be claimed as CBI if you check the ‘I claim the entirety of the submission as CBI’ checkbox. The entire form will be considered non-CBI if you leave the ‘I claim the entirety of the submission as CBI’ checkbox unchecked.

You can indicate that a technical contact will be identified by checking the ‘Technical Contact’ checkbox. The technical contact must possess sufficient knowledge to answer any questions EPA may have about the chemical reported in the form. The application generates a ‘Technical Contact Information’ screen when you check the ‘Technical Contact’ checkbox.

You can indicate that a Letter of Support is expected to be filed by a secondary submitter by checking the ‘Letter of Support’ checkbox. The Secondary Authorized Official will have a unique identification number that will link the forms. The unique identification number will be sent to the Letter of Support submitter, via email. At submission of the primary Bona Fide form, the unique identification number will link the two forms together. The information submitted in both forms will be kept separate, but linked, by the system. The Primary and Secondary AO will only be able to view information submitted by their own company.

- **Form Alias:** Enter the form alias. Upon navigating to the screen, the screen auto-generates an editable form alias comprised of <Form Type-YYYYMMDD-HH:MM:SS Time Zone>. This is a required field.
- **I claim the entirety of this submission as CBI:** Check the ‘I claim the entirety of this submission as CBI’ checkbox to flag all data contained within the form as confidential.

- **Technical Contact:** Check the ‘Technical Contact’ checkbox to generate a ‘Technical Contact Information’ screen for you to enter contact information about the technical contact associated with the reported chemical.
- **Letter of Support:** Check the ‘Letter of Support’ checkbox to indicate that the form is pending a Letter of Support and to generate the ‘Letter of Support’ folder within the navigation tree. The ‘Letter of Support’ folder contains the following screens: ‘Letter of Support Submitter Information’ and ‘Letter of Support Submission Information.’

Exhibit 8-1 shows a screen capture of the ‘General Document Information’ screen (Scroll 1):

Exhibit 8-1 General Document Information Screen (Bona Fide) (Scroll 1)

The screenshot shows the GSPP (Global Support Portal) interface. At the top, the user is logged in as Jane Doe, a Primary Authorized Official. The navigation menu includes Home, Forms, User Management, and Resources. The main content area is titled 'GENERAL DOCUMENT INFORMATION' and contains the following text:

The form alias is a required field that allows the user to give the Bona Fide a name to be displayed in the ‘Alias’ field on the Section 5 Notices and Supports Forms screen. Its purpose is to make it easier for you to distinguish between multiple forms. If an alias is not selected, the field will default to the date and time the Bona Fide was created. The form alias may be changed at any time.

Form Alias:

Please check all applicable checkboxes below:

This Bona Fide Notice can be claimed entirely as Confidential Business Information (CBI). Please check the 'I claim the entirety of the submission as CBI' checkbox to claim your entire submission as CBI.

I claim the entirety of the submission as CBI:

The technical contact is a subject matter expert (SME) who is capable of answering questions related to the chemical within the Bona Fide. The technical contact does not have to physically work at the site reported but must possess extensive knowledge on the chemical reported in order to answer EPA's questions pertaining to the submission. Please check the ‘Technical Contact’ checkbox below to identify a technical contact for your submission.

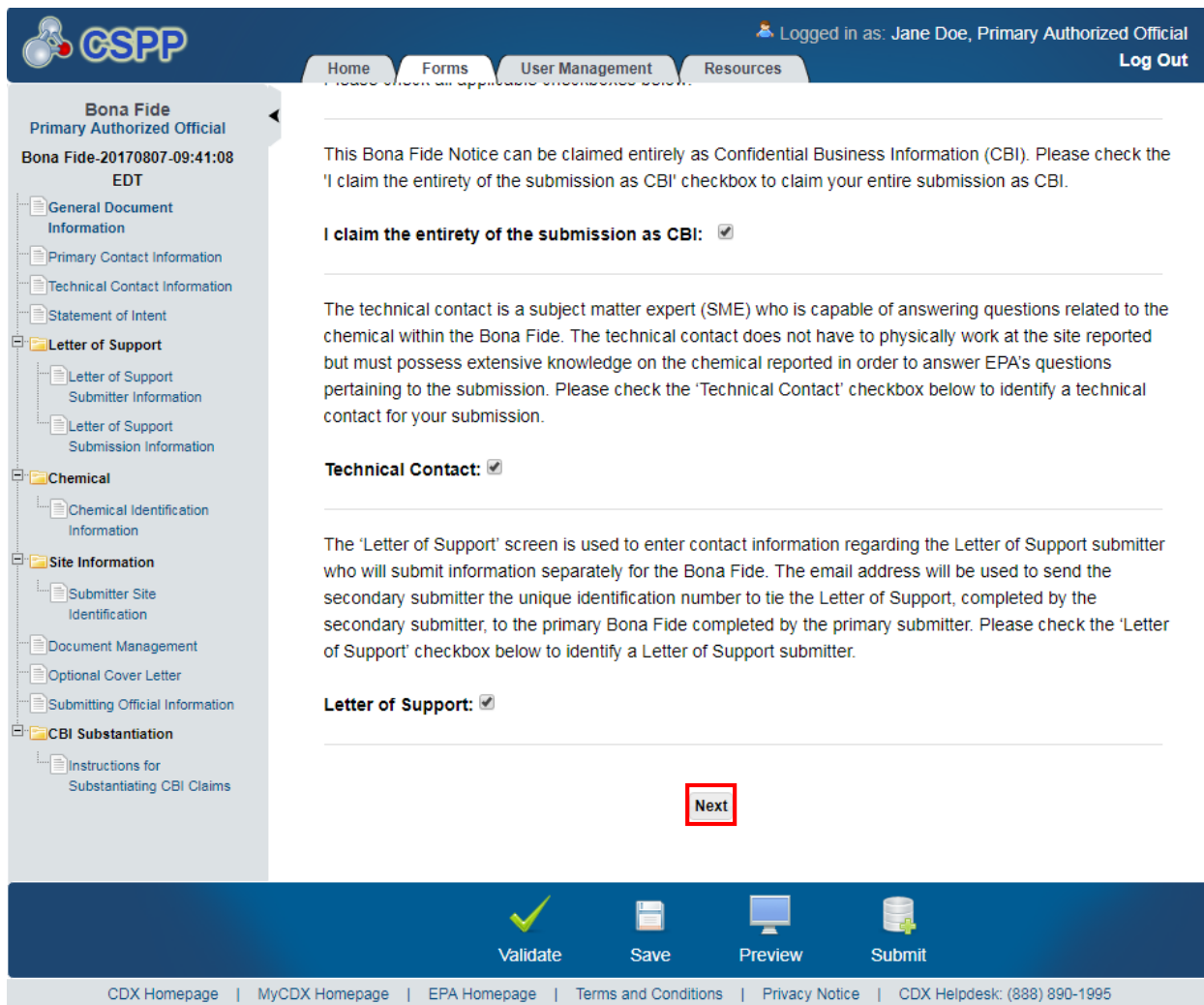
Technical Contact:

The ‘Letter of Support’ screen is used to enter contact information regarding the Letter of Support submitter who will submit information separately for the Bona Fide. The email address will be used to send the

At the bottom of the screen, there are four action buttons: Validate (with a green checkmark), Save, Preview, and Submit. The footer contains links to CDX Homepage, MyCDX Homepage, EPA Homepage, Terms and Conditions, Privacy Notice, and CDX Helpdesk: (888) 890-1995.

Exhibit 8-2 shows a screen capture of the ‘General Document Information’ screen (Scroll 2):

Exhibit 8-2 General Document Information Screen (Bona Fide) (Scroll 2)



Navigation: Click the ‘Next’ button to navigate to the ‘Primary Contact Information’ screen. You can also access this screen by clicking the ‘Primary Contact Information’ link within the navigation tree.

8.1.2 Primary Contact Information

You can access the ‘Primary Contact Information’ screen by clicking the ‘Next’ button from the ‘General Document Information’ screen. You can also access this screen by clicking the ‘Primary Contact Information’ link within the navigation tree.

The data fields on the ‘Primary Contact Information’ screen are pre-populated based on information entered during CDX registration. All fields are editable allowing for necessary updates. The ‘Job Title’ field on this screen is not pre-populated from CDX registration and is a required field.

If you checked the ‘I claim the entirety of the submission as CBI’ checkbox on the ‘General Document Information’ screen, all entered primary contact information is flagged as CBI.

The following fields are captured and displayed from the logged in user's CDX registration information:

- **Prefix:** Select the primary contact's prefix from the drop-down menu.
- **First Name:** Enter the primary contact's first name. This is a required field.
- **Middle Initial:** Enter the primary contact's middle initial.
- **Last Name:** Enter the primary contact's last name. This is a required field.
- **Suffix:** Select the primary contact's suffix from the drop-down menu.
- **Title:** Enter the primary contact's job title. This is a required field.
- **Company Name:** Enter the primary contact's company name.
- **Phone Number:** Enter the primary contact's daytime phone number; dashes are not allowed. This is a required field.
- **Phone Extension:** Enter the extension to the primary contact's daytime phone number.
- **Email Address:** Enter the primary contact's email address. The email address must follow the standard email address format: John.Doe@ABC.com. This is a required field.
- **Mailing Address 1:** Enter the first line of the primary contact's mailing address. This is a required field.
- **Mailing Address 2:** Enter the second line of the primary contact's mailing address.
- **City:** Enter the city of the primary contact's mailing address.
- **State:** Select the state of the primary contact's mailing address from the drop-down menu. The state field is required if the user selects 'United States' from the 'Country' drop-down menu.
- **Postal Code:** Enter the postal code of the primary contact's mailing address. This is a required field.
- **Country:** Select the country of the primary contact's mailing address. This is a required field.

Exhibit 8-3 shows a screen capture of the ‘Primary Contact Information’ screen:

Exhibit 8-3 Primary Contact Information Screen (Bona Fide)

Navigation: Click the ‘Next’ button to navigate to the ‘Technical Contact Information’ screen if you checked the ‘Technical Contact’ checkbox on the ‘General Document Information’ screen. You can also access this screen by clicking the ‘Technical Contact Information’ link within the navigation tree. Click the ‘Next’ button to navigate to the ‘Statement of Intent’ screen if you left the ‘Technical Contact’ checkbox unchecked on the ‘General Document Information’ screen. You can also access this screen by clicking the ‘Statement of Intent’ link within the navigation tree.

8.1.3 Technical Contact Information

If you indicated on the ‘General Document Information’ screen that technical contact information would be provided, click the ‘Next’ button from the ‘Primary Contact Information’ screen to navigate to the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Technical Contact Information’ link within the navigation tree.

The technical contact is a subject matter expert (SME) who is capable of answering questions related to the chemical submitted to EPA within the Bona Fide form. The technical contact does not have to work at the port or site reported on the form but must possess sufficient knowledge to answer EPA’s questions pertaining to the chemical reported in the form.

The text fields on the ‘Technical Contact Information’ screen will be blank upon accessing the screen. To add information, you will enter data into the blank text boxes for the listed text fields. If you checked the ‘I claim the entirety of the submission as CBI’ checkbox on the ‘General Document Information’ screen, all entered technical contact information will be flagged as CBI.

- **Prefix:** Select the technical contact’s prefix from the drop-down menu.
- **First Name:** Enter the technical contact’s first name. This is a required field.
- **Middle Initial:** Enter the technical contact’s middle initial.
- **Last Name:** Enter the technical contact’s last name. This is a required field.
- **Suffix:** Select the technical contact’s suffix from the drop-down menu.
- **Title:** Enter the technical contact’s job title.
- **Company Name:** Enter the technical contact’s company name.
- **Phone Number:** Enter the technical contact’s daytime U.S. phone number; dashes are not allowed. This is a required field.
- **Phone Extension:** Enter the technical contact’s phone number extension.
- **Email Address:** Enter the technical contact’s email address. The email address must follow the standard email address format: John.Doe@ABC.com. This is a required field.
- **Mailing Address 1:** Enter the first line of the technical contact’s mailing address.
- **Mailing Address 2:** Enter the second line of the technical contact’s mailing address.
- **City:** Enter the city of the technical contact’s mailing address.
- **State:** Select the state of the technical contact’s mailing address from the drop-down menu.
- **Postal Code:** Enter the postal code of the technical contact’s mailing address.
- **Country:** Displays ‘United States.’

Exhibit 8-4 shows a screen capture of the ‘Technical Contact Information’ screen (Scroll 1):

Exhibit 8-4 Technical Contact Information Screen (Bona Fide) (Scroll 1)

CDX **GSPP** 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

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
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) > Technical Contact Information **TECHNICAL CONTACT INFORMATION** ?

Please enter the information for the technical contact who will be responsible for providing additional information if required.

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Title:

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.

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

Exhibit 8-5 shows a screen capture of the ‘Technical Contact Information’ screen (Scroll 2):

Exhibit 8-5 Technical Contact Information Screen (Bona Fide) (Scroll 2)

The screenshot displays the GSPP (Global Support Portal) interface. At the top, it shows the user is logged in as 'Jane Doe, Primary Authorized Official'. The navigation menu on the left includes sections like 'Bona Fide Primary Authorized Official', 'Letter of Support', 'Chemical', 'Site Information', and 'CBI Substantiation'. The 'Technical Contact Information' section is currently active. The form fields are as follows:

- Last Name:
- Suffix:
- Title:
- 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: United States

Navigation buttons at the bottom include 'Previous' and 'Next' (highlighted with a red box). Below the form are icons for 'Validate', 'Save', 'Preview', and 'Submit'. The footer contains links to CDX, MyCDX, EPA, and other resources.

Navigation: Click the ‘Next’ button to navigate to the ‘Statement of Intent’ screen. You can also access this screen by clicking the ‘Statement of Intent’ link within the navigation tree.

8.1.4 Statement of Intent

You can access the ‘Statement of Intent’ screen by clicking the ‘Next’ button from the ‘Primary Contact Information’ if you left the ‘Technical Contact’ checkbox unchecked on the ‘General Document Information’ screen. You can also navigate to this screen by clicking the ‘Next’ button on the ‘Technical Contact Information’ screen if you checked the ‘Technical Contact’ checkbox on the ‘General Document Information’ screen. You can also access this screen by clicking the ‘Statement of Intent’ link within the navigation tree.

The ‘Statement of Intent’ screen requires you to indicate whether your intent is to manufacture and/or import the chemical substance for which you are requesting a TSCA inventory determination from EPA. You must indicate the activities of ‘Manufacture’ and/or ‘Import’ by checking the provided checkboxes. If you indicate that you intend to manufacture the chemical

substance, a prompt to identify the ‘Site of Manufacture’ after clicking the ‘Add Site’ button on the ‘Submitter Site Identification’ screen will display. Similarly, if you indicate that you intend to import the chemical substance, a prompt to identify a ‘Port of Entry’ after clicking the ‘Add Site’ button on the ‘Submitter Site Identification’ screen will display.

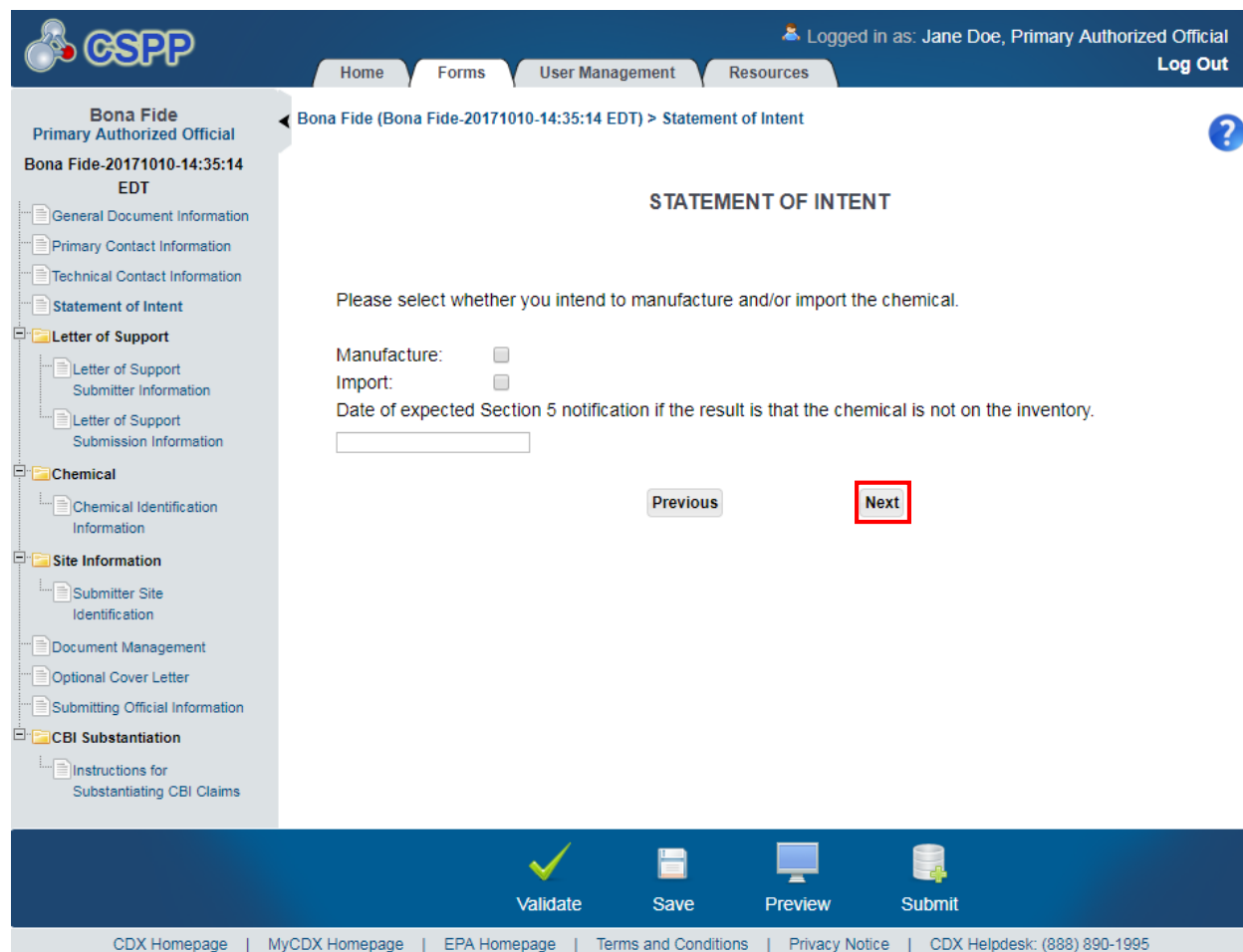
On this screen, you are required to enter the date you expect to submit a Section 5 notification if the result is that the chemical is not found on the inventory.

If you checked the ‘I claim the entirety of the submission as CBI’ checkbox on the ‘General Document Information’ screen, all information entered on the ‘Statement of Intent’ screen will be flagged as CBI.

- **Manufacture:** Check the ‘Manufacture’ checkbox to indicate the chemical substance will be manufactured. Either the ‘Manufacture’ or ‘Import’ checkbox is required to be checked.
- **Import:** Check the ‘Import’ checkbox to indicate the chemical substance will be imported. Either the ‘Manufacture’ or ‘Import’ checkbox is required to be checked.
- **Date of expected Section 5 notification if the result is that the chemical is not on the inventory:** Enter the date you are expecting to submit a Section 5 notification, if the result is that the chemical is not found on the inventory. This data can be entered in any format (e.g. ‘Quarter 1 of 2014,’ ‘10/01/14’). This is a required field.

Exhibit 8-6 shows a screen capture of the ‘Statement of Intent’ screen:

Exhibit 8-6 Statement of Intent Screen (Bona Fide)



Navigation: Click the ‘Next’ button to navigate to the ‘Letter of Support Submitter Information’ screen if you checked the ‘Letter of Support’ checkbox on the ‘General Document Information’ screen. You can also access this screen by clicking the ‘Letter of Support Submitter Information’ link within the navigation tree. Click the ‘Next’ button to navigate to the ‘Chemical Identification Information’ screen if the ‘Letter of Support’ checkbox was not checked on the ‘General Document Information’ screen.

8.1.5 Letter of Support Submitter Information

You can access the ‘Letter of Support Submitter Information’ screen by clicking the ‘Next’ button from the ‘Statement of Intent’ screen if you checked the ‘Letter of Support’ checkbox on the ‘General Document Information’ screen. You can also access this screen by clicking the ‘Letter of Support Submitter Information’ link within the navigation tree.

The ‘Letter of Support Submitter Information’ screen captures contact information regarding the Letter of Support submitter who will provide additional, separate information regarding the Bona Fide form. The email address provided for the Letter of Support submitter will be used to send

the unique identification number, which is used to link the primary and secondary submissions, to the Letter of Support submitter.

If you checked the ‘I claim the entirety of the submission as CBI’ checkbox on the ‘General Document Information’ screen, all information entered on the ‘Letter of Support Submitter Information’ screen will be flagged as CBI.

- **Prefix:** Select the Letter of Support submitter’s prefix from the drop-down menu.
- **First Name:** Enter the Letter of Support submitter’s first name. This is a required field.
- **Middle Initial:** Enter the Letter of Support submitter’s middle initial.
- **Last Name:** Enter the Letter of Support submitter’s last name. This is a required field.
- **Suffix:** Select the Letter of Support submitter’s suffix from the drop-down menu.
- **Title:** Enter the Letter of Support submitter’s job title.
- **Company Name:** Enter the Letter of Support submitter’s company name. This is a required field.
- **Phone Number:** Enter the Letter of Support submitter’s U.S. or international daytime phone number; dashes are not allowed. This is a required field.
- **Phone Extension:** Enter the Letter of Support submitter’s U.S. or international daytime phone number extension.
- **Email Address:** Enter the Letter of Support submitter’s email address. The email address must follow the standard email address format: John.Doe@ABC.com. This is a required field.
- **Mailing Address 1:** Enter the first line of the Letter of Support submitter’s mailing address. This is a required field.
- **Mailing Address 2:** Enter the second line of the Letter of Support submitter’s mailing address.
- **City:** Enter the city of the Letter of Support submitter’s mailing address. This is a required field.
- **State:** Select the state of the Letter of Support submitter’s mailing address from the drop-down menu. This is a required field when the ‘Country’ field is identified as ‘United States.’
- **Postal Code:** Enter the postal code of the Letter of Support submitter’s mailing address. This is a required field.
- **Country:** Select the country of the Letter of Support submitter’s mailing address from the drop-down menu. This is a required field.

Exhibit 8-7 shows a screen capture of the ‘Letter of Support Submitter Information’ screen:

Exhibit 8-7 Letter of Support Submitter Information Screen (Bona Fide)

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

Home Forms User Management Resources

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
Site Information
Submitter Site Identification
Document Management
Optional Cover Letter
Submitting Official Information
CBI Substantiation
Instructions for Substantiating CBI Claims

Bona Fide (Bona Fide-20171010-14:35:14 EDT) > Letter of Support Submitter Information

LETTER OF SUPPORT SUBMITTER INFORMATION

Please enter the contact information for the Letter of Support submitter who will be completing the Letter of Support.

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Title:

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:

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Navigation: Click the ‘Next’ button to navigate to the ‘Letter of Support Submission Information’ screen. You can also access this screen by clicking the ‘Letter of Support Submission Information’ link within the navigation tree.

8.1.6 Letter of Support Submission Information

You can access the ‘Letter of Support Submission Information’ screen by clicking the ‘Next’ button from the ‘Letter of Support Submitter Information’ screen. You can also access this screen by clicking the ‘Letter of Support Submission Information’ link within the navigation tree.

The ‘Letter of Support Submission Information’ screen is used as a communication point between two companies. The ‘Letter of Support Submission Information’ screen displays a comment box for you to enter information that will be passed on to the Letter of Support

submitter. A text field captures information to send to the Letter of Support submitter in an email sent by the primary submitter. A 'Unique Identification Number for Letter of Support Submissions' box will also display on this screen. The unique identification number generates when you declare a Letter of Support submission is being established.

Letter of Support Submission Process: When you designate that a Letter of Support submission is being filed, you will be asked to enter all the information within the 'Letter of Support Submission' folder. The forms from the primary submitter will be linked, but not combined by the system.

When the primary submitter chooses to notify the Letter of Support submitter of the unique identification number, the system will send an email to the Letter of Support submitter designated on the 'Letter of Support Submitter Information' screen. The email will contain the 'Unique Identifier Number' that will link the two forms.

When the Letter of Support submitter accesses the 'Section 5 Notices and Supports Forms' screen and creates a form to be filed, the user will be prompted to enter the unique identification number on the 'Create Passphrase' screen. Once the unique identification number has been entered, the system will link the primary and Letter of Support forms. You may add additional Letters of Supports by clicking the 'Add Letter of Support' link within the navigation tree.

- **Letter of Support Submission Information Instructions:** Enter the information that the Primary AO is sending to the Letter of Support submitter.
- **Letter of Support Submission Informational Text:** Displays instructional text provided by OPPT, the unique identifier number generated for the form, and allows you to email the unique identifier number to the Letter of Support submitter by clicking the 'Notify the Secondary Submitter of the letter of support submission' link.
- **Unique Identification Number:** The unique identification number is a random number auto-generated to pass on to the Letter of Support submitter to create a Letter of Support submission.

Exhibit 8-8 shows a screen capture of the ‘Letter of Support Submission Information’ screen:

Exhibit 8-8 Letter of Support Submission Information Screen (Bona Fide)

The screenshot displays the 'Letter of Support Submission Information' screen for a Bona Fide submission. The page includes a navigation tree on the left, a breadcrumb trail, and a main content area with instructions and a unique identifier. The 'Next' button is highlighted with a red box.

Navigation Tree:

- Bona Fide
 - Primary Authorized Official
 - Bona Fide-20170720-13:27:12 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
 - Site Information
 - Submitter Site Identification
 - Document Management
 - Optional Cover Letter
 - Submitting Official Information
 - CBI Substantiation
 - Instructions for Substantiating CBI Claims

Breadcrumb: Bona Fide (Bona Fide-20170720-13:27:12 EDT) > Letter of Support Submission Information

Page Title: LETTER OF SUPPORT SUBMISSION INFORMATION

Instructions: 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: Unique Identifier for Letter of Support Submission: a44c8d27-bf90-42b6-91c2-2692412a14ba

Notification: This is the unique identification number for your joint submitter. [Notify the Secondary Submitter of the letter of support submission.](#)

Additional Information: 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 Bona Fide 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.

Buttons: Previous, Next (highlighted)

Footer: Validate, Save, Preview, Submit

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

Navigation: Click the ‘Notify the Secondary Submitter of the letter of support submission’ link to access the ‘Unique Identifier Notification’ pop-up window. Click the ‘Next’ button to navigate to the ‘Chemical Identification Information’ screen. You can also access the ‘Chemical Identification Information’ screen by clicking the ‘Chemical Identification Information’ link within the navigation tree.

8.1.7 Notify Secondary Submitter of Letter of Support Information

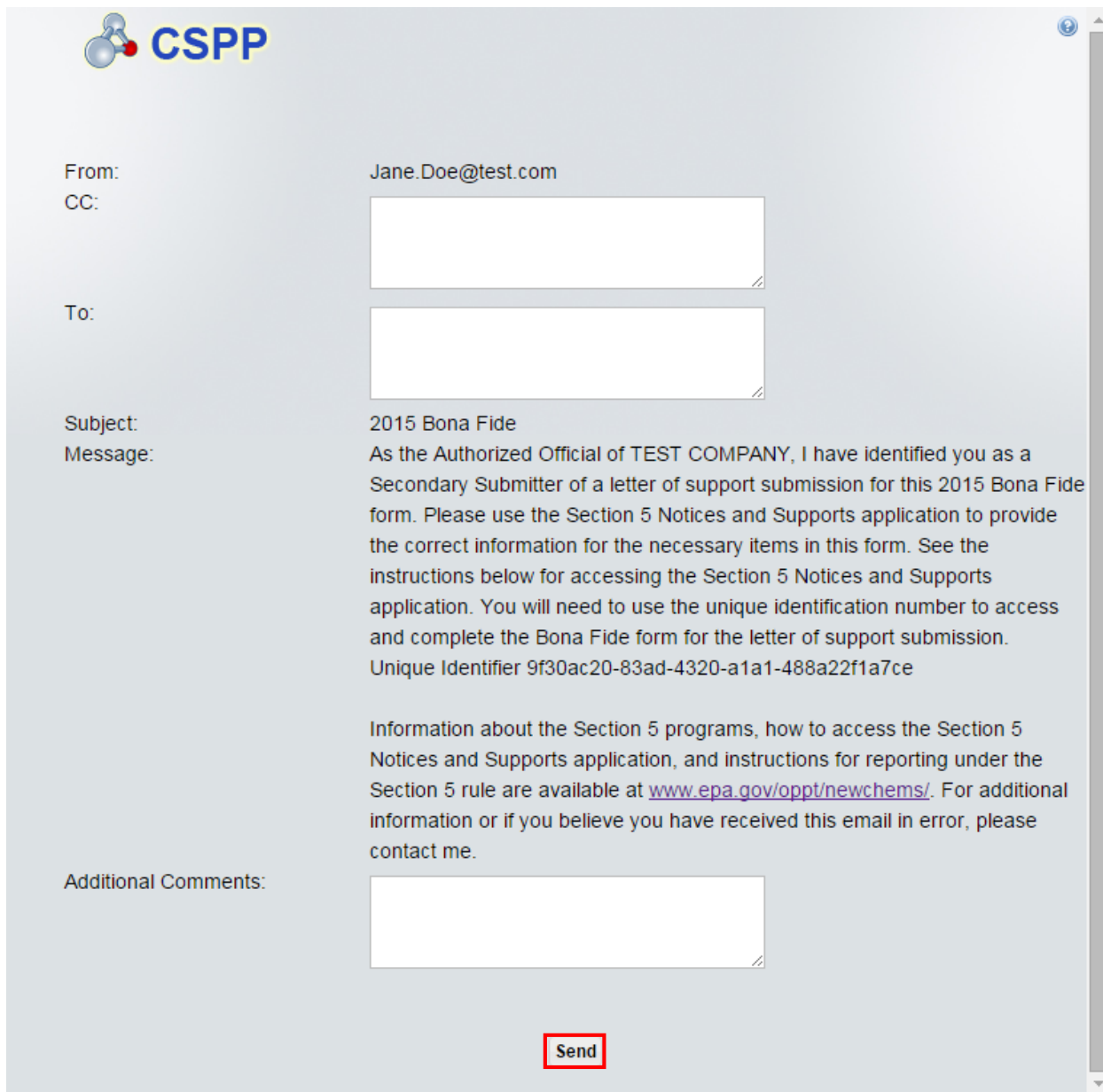
You can access the ‘Unique Identifier Notification’ pop-up window by clicking the ‘Notify the Secondary Submitter of the letter of support submission’ link from the ‘Letter of Support Submission Information’ screen.

The ‘Unique Identifier Notification’ pop-up window is used to notify the Secondary Submitter of the ‘Unique Identifier Number.’ The ‘Unique Identifier Notification’ pop-up window displays a ‘CC’ field for you to add other email addresses to the notification (including the original submitter), a ‘To’ field, and an ‘Additional Comments’ text box.

- **From:** Displays the email address of the logged in user that created the form.
- **CC:** Contains instructional text for a user to enter multiple email addresses. This will automatically populate with the email address of the logged in user, and the email address of the technical contact.
- **To:** Contains the editable email address of the Letter of Support submitter specified on the ‘Letter of Support Submitter Information’ screen; this email address will be automatically populated upon navigating to the window.
- **Subject:** Displays ‘YYYY Bona Fide.’
- **Message:** Displays a pre-determined message in the email sent to a Letter of Support submitter.
- **Additional Comments:** Enter any other additional comments or instructions to be passed onto the Letter of Support submitter.
- **Send:** Click the ‘Send’ button to generate and send the email to the email addresses identified in the ‘CC’ and ‘To’ fields.

Exhibit 8-9 shows a screen capture of the ‘Notify Letter of Support Submitter’ pop-up window:

Exhibit 8-9 Notify Letter of Support Submitter Pop-Up Window (Bona Fide)



From: Jane.Doe@test.com

CC:

To:

Subject: 2015 Bona Fide

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 Bona Fide 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 Bona Fide form for the letter of support submission. Unique Identifier 9f30ac20-83ad-4320-a1a1-488a22f1a7ce

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

Navigation: Click the ‘Send’ button to send the email to the Letter of Support submitter and navigate back to the ‘Letter of Support Submission Information’ screen. Click the ‘X’ button in the upper right-hand corner to cancel the unique identifier notification process.

8.1.8 Chemical Identification Information

You can navigate to the ‘Chemical Identification Information’ screen by clicking the ‘Next’ button from the ‘Statement of Intent’ screen if you left the ‘Letter of Support’ checkbox unchecked on the ‘General Document Information’ screen. You can also access the ‘Chemical Identification Information’ screen from the ‘Letter of Support Submission Information’ screen if

you checked the ‘Letter of Support’ checkbox on the ‘General Document Information’ screen. You can also access this screen by clicking the ‘Chemical Identification Information’ link within the navigation tree.

The ‘Chemical Identification Information’ screen identifies the type of chemical the submitter will be entering into the application. You will be able to file a Bona Fide form for a class 1 or 2/Biotechnology chemical substance or a polymer. Based on your selection, the appropriate screens for the respective chemical will appear.

This screen also provides a text field for you to identify an alias for the chemical substance.

- **Class 1 or 2/Biotechnology Chemical Substance:** Select the ‘Class 1 or 2/Biotechnology Chemical Substance’ radio button to indicate that the chemical is a class 1 or 2/biotechnology substance. If you select the ‘Polymer’ radio button after initially selecting the ‘Class 1 or 2/Biotechnology Chemical Substance’ radio button, the application generates a notification message warning you that you will lose all data for this chemical if the chemical type changes. The user is required to select one of the two radio button options displayed in the ‘Chemical Type’ section.
- **Polymer:** Select the ‘Polymer’ radio button to indicate that the chemical is a polymer. If you select the ‘Class 1 or 2/Biotechnology Chemical Substance’ radio button after initially selecting the ‘Polymer’ radio button, the application generates a notification message warning you that you will lose all data for this chemical if the chemical type changes. The user is required to select one of the two radio button options displayed in the ‘Chemical Type’ section.
- **Chemical Alias:** Enter the chemical alias to associate with a chemical.

Exhibit 8-10 shows a screen capture of the ‘Chemical Identification Information’ screen:

Exhibit 8-10 Chemical Identification Information Screen (Bona Fide)

Navigation: If you selected the ‘Class 1 or 2/Biotechnology Chemical Substance’ radio button, click the ‘Next’ button to navigate to the ‘Class 1 or 2/Biotechnology Chemical Substances’ screen. If you selected the ‘Polymer’ radio button, click the ‘Next’ button to navigate to the ‘Polymer Identification Information’ screen.

8.1.9 Class 1 or 2/Biotechnology Chemical Substances

If you selected the ‘Class 1 or 2/Biotechnology Chemical Substance’ radio button, click the ‘Next’ button to navigate to the ‘Class 1 or 2/Biotechnology Chemical Substances’ screen.

The ‘Class 1 or 2/Biotechnology Chemical Substances’ screen provides fields for you to enter information describing the chemical for the Bona Fide which is to be filed, including its name, composition, and structure.

You can add a chemical component by clicking the ‘Add New Chemical’ button. Upon clicking the ‘Add New Chemical’ button, an expandable/collapsible field set generates that contains numerous fields to identify the chemical in question. You will be able to enter multiple chemical

substances, each with unique information, by clicking the ‘Add New Chemical’ button for each chemical substance you wish to identify.

After the document(s) is/are attached and you have clicked the ‘OK’ button, the ‘Attach Chemical Structure’ pop-up window closes and the document information will be displayed in a table format on the ‘Class 1 or 2/Biotechnology Chemical Substances’ screen. The attachment table displays the file name of the document and user-provided description of the document. Click the ‘Delete’ icon (✖) located under the ‘Actions’ column to delete unwanted documents. Click the appropriate file name of the document within the ‘File Name’ column of the attachment table to access or edit previously attached documents.

- **Add New Chemical:** Click the button to generate the class 1 or 2/Biotechnology chemical substances field set.
- **Cancel:** Click the ‘Cancel’ link located in the upper right-hand corner of the expandable/collapsible field set to prevent edits from saving and to remove a field set. The ‘Cancel’ link displays when the expandable/collapsible field set is open for editing. A confirmation message displays to confirm the action.
- **Edit:** Click the ‘Edit’ link located in the upper right-hand corner of the expandable/collapsible field set to modify the information entered in the fields. The ‘Edit’ link displays when the expandable/collapsible field set has been saved and the data is not currently editable.
- **Delete:** Click the ‘Delete’ icon (✖) located in the upper right-hand corner of the expandable/collapsible field set to delete the field set. A confirmation message displays to confirm the deletion.
- **Expand All:** Click the ‘Expand All’ link located at the upper right-hand corner of the expandable/collapsible field sets to expand a series of field sets.
- **Collapse All:** Click the ‘Collapse All’ link located at the upper right-hand corner of the expandable/collapsible field sets to collapse a series of field sets.
- **Class of Substance:** In the section, ‘Class of Substance,’ you identify whether a ‘Class 1’ or ‘Class 2/Biotechnology’ chemical substance is being reported. When you select the ‘Class 2/Biotechnology’ chemical substance radio button, you are indicating that some portions of the structure may not be known and an additional screen will appear within the navigation tree that provides fields for you to enter information concerning how the chemical was created. If multiple class 2 chemical substances are added, one ‘Class 2/Biotechnology Substances’ screen will apply to all chemical substances.
- **Add Chemical ID:** You can access the ‘Add Chemical ID’ pop-up window by clicking the ‘Add Chemical ID’ button within the ‘Chemical Identification Information’ field set. You can search for the reported chemical(s), either by the ‘CASRN’ or ‘CA Index Name or Other Synonym.’ If you retrieve zero results, the system provides fields for you to enter the chemical information by filling in the ‘Chemical Name’ and the ‘Chemical Abstract Services Registry Number’ under the manual entry field set. The system provides functionality to enter the selected chemical by clicking the ‘OK’ button located at the bottom of the ‘Add Chemical ID’ window.
- **Chemical Name:** The system provides fields for you to identify the ‘Chemical Name’ and the ‘CASRN’ (if available). The system provides functionality for you to search for the chemical

substance using the 'Add Chemical ID' search or manually enter the chemical information in the 'Add Chemical ID' pop-up window.


- **ID Method:** The system shall require that you identify which ID method was used to determine the chemical identity. If you select 'Method 1,' you are required to attach an IES report. You can also select 'Method 2 (Other Method).'
- **Attach IES Report:** To access the 'Attach IES Report' pop-up window, click the 'Attach IES Report' button that displays within the 'Chemical Identification Information' field set. After you attach the document(s), and click the 'OK' button, the 'Attach IES Report' pop-up window closes and the document information displays in a table format on the 'Class 1 or 2/Biotechnology Chemical Substances' screen. The document attachment table displays the file name of the document(s) and the user-provided description of the document(s). Click the 'Delete' icon (✖) located under the 'Actions' column to delete unwanted documents. Click the file name link under the 'File Name' column to access or edit previously attached documents.
- **Molecular Formula:** Enter a molecular formula in a text field using a free text format. This field is optional.
- **Chemical Structure Diagram:** The system allows you to attach a chemical structure diagram. This field is optional.
- **Attach Chemical Structure:** Click the 'Attach Chemical Structure' button within the 'Chemical Identification Information' field set to access the 'Attach Chemical Structure' pop-up window. You can attach the file(s) and enter a description of the document regarding the chemical structure.
- **File Name:** Displays the file name and file extension of the file that is uploaded on the 'Attach Chemical Structure' window.
- **Description:** Displays the description of the chemical structure.
- **Actions:** Click the 'Delete' icon (✖) to delete the entire attached chemical structure row permanently from the system. A warning message displays to confirm the deletion of the document.
- **Save:** Click the button to save the information entered within the expandable/collapsible field set. You must click this button instead of the 'Save' icon (💾) located within the bottom action bar to successfully save the entered information within the field set before being able to navigate away from the screen using the 'Previous' and 'Next' buttons. Refer to **Section 3.9** for more information regarding the save functionality in an expandable/collapsible field set.

Exhibit 8-11 shows a screen capture of the ‘Class 1 or 2/Biotechnology Chemical Substances’ screen:

Exhibit 8-11 Class 1 or 2/Biotechnology Chemical Substances Screen (Bona Fide)

Navigation: If you selected the ‘Class 1’ radio button, click the ‘Save’ button within the expandable/collapsible field, then click the ‘Next’ button to navigate to the ‘Use Information’ screen. If you selected the ‘Class 2/Biotechnology’ radio button, click the ‘Save’ button within the expandable/collapsible field set, then click the ‘Next’ button to navigate to the ‘Class 2/Biotechnology Substances’ screen.

8.1.10 Class 2/Biotechnology Substances

You can navigate to the ‘Class 2/Biotechnology Substances’ screen by clicking the ‘Next’ button from the ‘Class 1 or 2/Biotechnology Chemical Substances’ screen when you select the ‘Class 2/Biotechnology’ radio button. You can also access this screen by clicking the ‘Save’ icon () within the action bar and clicking the ‘Class 2/Biotechnology Substances’ link within the navigation tree.

The ‘Class 2/Biotechnology Substances’ screen provides fields for you to enter in information regarding a class 2/biotechnology chemical substance. A class 2/biotechnology chemical substance is a substance that may not have a defined chemical structure that has been identified. This screen provides fields for you to identify specific elements in the creation of the chemical using the following fields: ‘Precursor Substances,’ ‘Nature of Reaction,’ and ‘Range of Composition (Optional).’

You will be able to enter precursor substances by searching SRS or by the manual entry fields when the substance is not in SRS. The substances will display in a table listing the ‘Chemical Name’ and CASRN.

The system provides fields for you to capture ‘Nature of Reaction’ and ‘Range of Composition’ in text boxes.



- **Precursor Substances:** This table captures the chemicals identified as immediate precursor substances, along with the respective CASRNs.
- **Search SRS:** Click the ‘Search SRS’ button to display the ‘Search Substance Registry Services’ pop-up window. Refer to **Section 3.10** for additional details regarding the search SRS functionality.
- **Chemical Name:** Displays the chemical name associated with a precursor substance. Click the ‘Chemical Name’ link to navigate to the ‘Search SRS’ pop-up window for edits.
- **CASRN:** Displays the CASRN associated with a precursor substance.
- **Action:** Click the ‘Delete’ icon () to delete the entire chemical row permanently from the system. A warning message will display to confirm the deletion of the chemical.
- **Nature of Reaction:** Enter the ‘Nature of Reaction’ description. This is a required field.
- **Range of Composition:** Enter the ‘Range of Composition’ description.
- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window and upload a document. Refer to **Section 3.6** for further details regarding the attach document functionality.
- **File Name:** Displays the file name and file extension of the file that is uploaded on the ‘Attach Documents’ window.
- **Description:** Displays the description associated with a document.
- **Action:** Click the ‘Delete’ icon () to delete the entire document row permanently from the system. A warning message displays to confirm the deletion.

Exhibit 8-12 shows a screen capture of the ‘Class 2/Biotechnology Substances’ screen (Scroll 1):

Exhibit 8-12 Class 2/Biotechnology Substances Screen (Bona Fide) (Scroll 1)

GSPP 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

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

CLASS 2/BIO TECHNOLOGY 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)

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

Exhibit 8-13 shows a screen capture of the ‘Class 2/Biotechnology Substances’ screen (Scroll 2):

Exhibit 8-13 Class 2/Biotechnology Substances Screen (Bona Fide) (Scroll 2)

Navigation: Click the ‘Next’ button to navigate to the ‘Use Information’ screen. You can also access this screen by clicking the ‘Use Information’ link within the navigation tree.

8.1.11 Polymer Identification Information

You can navigate to the ‘Polymer Identification Information’ screen by clicking the ‘Next’ button from the ‘Chemical Identification Information’ screen when you select the ‘Polymer’ radio button. You can also access this screen by clicking the ‘Polymer Identification Information’ link within the navigation tree after clicking the ‘Save’ icon within the bottom action bar.

Click the ‘Add New Chemical’ button to create a chemical substance. Upon clicking the ‘Add New Chemical’ button, an expandable/collapsible field set generates that contains numerous fields that pertain to the particular polymer. The system provides numerous fields for you to enter multiple chemical substances, each with unique information, by clicking the ‘Add New Chemical’ button for each chemical you wish to identify.

For a single component submission, create the field set by clicking the ‘Add New Chemical’ button. Upon clicking the ‘Add New Chemical’ button, the application generates a field set containing numerous fields for you to enter information pertaining to that particular chemical.

For a multi-component submission, create individual field sets by clicking the ‘Add New Chemical’ button. Multi-component chemical submissions occur when two or more chemicals always generate together in a single pot and are never isolated. Upon clicking the ‘Add New Chemical’ button, the application generates a field set containing numerous fields for you to enter information pertaining to that particular chemical. Enter additional chemical components, each with unique identifying information, by clicking the ‘Add New Chemical’ button for each additional chemical that is part of the multi-component mixture. All multi-component chemicals will reside in one chemical folder in the navigation tree.

- **Add New Chemical:** Click the button to generate the ‘Polymer Identification Information’ field set.
- **Cancel:** Click the ‘Cancel’ link located in the upper right-hand corner of the expandable/collapsible field set to prevent edits from saving and to remove a field set. The ‘Cancel’ link displays when the expandable/collapsible field set is open for editing. A confirmation message displays to confirm the action.
- **Edit:** Click the ‘Edit’ link located in the upper right-hand corner of the expandable/collapsible field set to modify the information entered in the fields. The ‘Edit’ link displays when the expandable/collapsible field set has been saved and the data is not currently editable.
- **Delete:** Click the ‘Delete’ icon (✖) located in the upper right-hand corner of the expandable/collapsible field set to delete the field set. A confirmation message displays to confirm the deletion.
- **Expand All:** Click the ‘Expand All’ link located at the upper right-hand corner of the expandable/collapsible field sets to expand a series of field sets.
- **Collapse All:** Click the ‘Collapse All’ link located at the upper right-hand corner of the expandable/collapsible field sets to collapse a series of field sets.
- **Add Chemical ID:** Click the ‘Add Chemical ID’ button within the ‘Polymer Identification Information’ field set to generate the ‘Add Chemical ID’ pop-up window. You can search for the reported chemical(s), by either the ‘CASRN’ or CA Index Name or Other Synonym. If you retrieve zero results, the system provides fields for you to enter the chemical information by filling in the ‘Chemical Name’ and the ‘Chemical Abstract Services Registry Number’ (CASRN) under the manual entry field set. The system provides functionality for you to enter the selected chemical by clicking the ‘OK’ button located at the bottom of the ‘Add Chemical ID’ window.
- **Chemical Name:** The system provides fields for you to identify the ‘Chemical Name’ and the CASRN (if available). The system provides functionality for you to search for the chemical substance using the ‘Add Chemical ID’ search or manually enter the chemical information in the ‘Add Chemical ID’ pop-up.
- **ID Method:** The system shall require that you identify which ID method was used to determine the chemical identity. When you select ‘Method 1 (CAS Inventory Expert

Service),’ the system generates an ‘Attach IES Report’ button for you to attach an IES report. If you select ‘Method 1,’ you are required to attach an IES report. You can also select ‘Method 2 (Other Method).’

- **Attach IES Report:** Click the ‘Attach IES Report’ button within the ‘Polymer Identification Information’ field set after selecting the ‘Method 1 (CAS Inventory Expert Service)’ radio button to access the ‘Attach IES Report’ pop-up window. After you attach the document(s), and click the ‘OK’ button, the ‘Attach IES Report’ pop-up window closes and the document information displays in a table format on the ‘Polymer Identification Information’ screen. The attachment table displays the file name of the document and the user-provided description of the document. Click the ‘Delete’ icon (✖) located under the ‘Actions’ column to delete unwanted documents. Click the file name link under the ‘File Name’ column to access or edit previously attached documents.
- **Chemical Structure Diagram:** The system allows you to attach a chemical structure diagram.
- **Attach Chemical Structure:** Click the ‘Attach Chemical Structure’ button within the ‘Polymer Identification Information’ field set to access the ‘Attach Chemical Structure’ pop-up window. You can attach the file(s) and enter a description of the document.
- **File Name:** Displays the file name and file extension of the document that is uploaded on the ‘Attach Chemical Structure’ window.
- **Description:** Displays the description of the chemical structure.
- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire attached chemical structure row permanently from the system. A warning message displays to confirm the deletion.
- **Save:** Click the button to save the information entered within the expandable/collapsible field set. You must click this button instead of the ‘Save’ icon (💾) located within the bottom action bar to successfully save the entered information within the field set before being able to navigate away from the screen using the ‘Previous’ and ‘Next’ buttons. Refer to **Section 3.9** for more information regarding the save functionality in an expandable/collapsible field set.

After the document is attached and you click the ‘OK’ button, the ‘Attach Chemical Structure’ pop-up window closes and the document information displays in a table format on the ‘Polymer Identification Information’ screen. The attachment table displays the file name of the document and provided description of the document. Click the ‘Delete’ icon (✖) located under the ‘Actions’ column to delete unwanted documents. Click the appropriate file name of the document within the ‘File Name’ column of the attachment table to access or edit previously attached documents.

Exhibit 8-14 shows a screen capture of the ‘Polymer Identification Information’ screen:

Exhibit 8-14 Polymer Identification Information Screen (Bona Fide)

Navigation: Click the ‘Next’ button to navigate to the ‘Monomers and Other Reactants’ screen. You can also access this screen by clicking the ‘Monomers and Other Reactants’ link within the navigation tree.

8.1.12 Monomers and Other Reactants

You can navigate to the ‘Monomers and Other Reactants’ screen by clicking the ‘Next’ button from the ‘Polymer Identification Information’ screen. You can also access this screen by clicking the ‘Monomers and Other Reactants’ link within the navigation tree.

The ‘Monomers and Other Reactants’ screen is used to identify the chemical measurements and monomers that make up a polymer. The ‘Monomers and Other Reactants’ screen has an ‘Add

Monomer' button that allows you to identify the monomer(s) that make up the polymer composition.

- **Add Monomer:** Click the 'Add Monomer' button to generate an expandable/collapsible field set.
- **Cancel:** Click the 'Cancel' link located in the upper right-hand corner of the expandable/collapsible field set to prevent edits from saving and to remove a field set. The 'Cancel' link displays when the expandable/collapsible field set is open for editing. A confirmation message displays to confirm the action.
- **Edit:** Click the 'Edit' link located in the upper right-hand corner of the expandable/collapsible field set to modify the information entered in the fields. The 'Edit' link displays when the expandable/collapsible field set has been saved and the data is not currently editable.
- **Delete:** Click the 'Delete' icon (✖) located in the upper right-hand corner of the expandable/collapsible field set to delete the field set. A confirmation message displays to confirm the deletion.
- **Expand All:** Click the 'Expand All' link located at the upper right-hand corner of the expandable/collapsible field sets to expand a series of field sets.
- **Collapse All:** Click the 'Collapse All' link located at the upper right-hand corner of the expandable/collapsible field sets to collapse a series of field sets.
- **Search SRS:** Click the 'Search SRS' button to generate the 'Search Substance Registry Services' pop-up window. Refer to **Section 3.10** for additional details regarding the search SRS functionality.
- **CAS Registry Number:** Displays the CASRN for the specified monomer; this field populates based on information entered on the 'Search Substance Registry Services' pop-up window. This is a required field.
- **Monomer or Other Reactant:** Displays the monomer or other reactant name; this field populates based on information entered on the 'Search Substance Registry Services' pop-up window. This is a required field.
- **Include in Identity:** Check the 'Include in Identity' checkbox to claim the value for 'Monomer or Other Reactant' as part of the monomer identification.
- **Typical Composition:** Enter the 'Typical Composition' value that a monomer contributes to a polymer; the value entered must be a positive numerical value greater than zero (0) and less than or equal to 100 with up to three decimal points. If the value entered is less than or equal to '2' a warning will be displayed in the global 'Validate' function or during the submission process indicating that the 'Typical Composition' is a value that is less than or equal to 2% and asking the user whether it should be included in the 'Chemical Identity.' This is a required field.
- **Save:** Click the button to save the information entered within the expandable/collapsible field set. You must click this button instead of the 'Save' icon (💾) located within the bottom action bar to successfully save the entered information within the field set before being able to navigate away from the screen using the 'Previous' and 'Next' buttons. Refer to **Section**

3.9 for more information regarding the save functionality in an expandable/collapsible field set.

- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window. Refer to **Section 3.6** for additional details regarding the attach document functionality.
- **File Name:** Displays the file name and file extension of the file that is uploaded on the ‘Attach Documents’ pop-up window. Click the file name link to navigate to the ‘Attach Documents’ pop-up window to make any edits.
- **Description:** Displays the description associated with a document.
- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire attached document row permanently from the system. A warning message displays to confirm the deletion of the document.

Exhibit 8-15 shows a screen capture of the ‘Monomers and Other Reactants’ screen:

Exhibit 8-15 Monomers and Other Reactants Screen (Bona Fide)

Navigation: Click the ‘Next’ button to navigate to the ‘Use Information’ screen. You can also access this screen by clicking the ‘Use Information’ link within the navigation tree.

8.1.13 Use Information

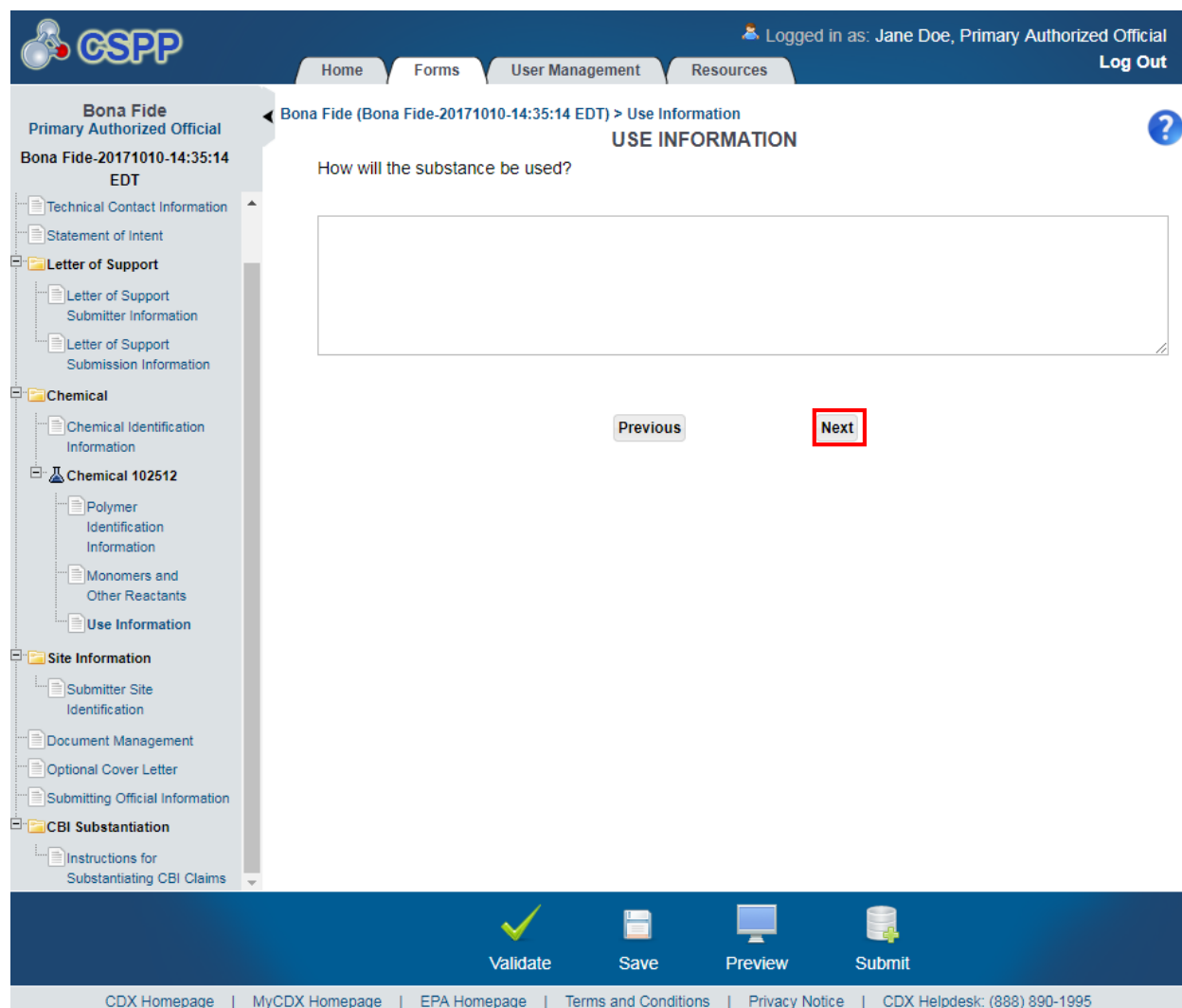
You can navigate to the ‘Use Information’ screen by clicking the ‘Next’ button from the ‘Class 1 or 2 Chemical Substances’ screen, from the ‘Class 2 Substances’ screen, or from the ‘Monomers and Other Reactants’ screen, depending on the choice made on the ‘Chemical Identification Information’ screen. You can also access this screen by clicking the ‘Use Information’ link within the navigation tree.

The ‘Use Information’ screen captures data about the chemical substance’s intended use. When you navigate to the screen, the screen contains a text box with instructional text that reads, ‘How will the substance be used?’ Enter the specific data for the chemical substance and then advance to the next screen.

- **How will the substance be used?:** Enter data regarding how the chemical substance is intended to be used. This is a required field.

Exhibit 8-16 shows a screen capture of the ‘Use Information’ screen:

Exhibit 8-16 Use Information Screen (Bona Fide)



Navigation: Click the ‘Next’ button to navigate to the ‘Submitter Site Identification’ screen. You can also access this screen by clicking the ‘Submitter Site Identification’ link within the navigation tree.

8.1.14 Submitter Site Identification

You can navigate to the ‘Submitter Site Identification’ screen by clicking the ‘Next’ button from the ‘Use Information’ screen. You can also access this screen by clicking the ‘Submitter Site Identification’ link within the navigation tree.

The ‘Submitter Site Identification’ screen captures information about the identification of the sites of manufacture and/or the port of entry. The system requires you to select from the ‘Site of Manufacture or Import’ drop-down menu when both the ‘Manufacture’ and ‘Import’ checkboxes

are checked on the ‘Statement of Intent’ screen. List all of the sites of manufacture and/or the ports of entry that are controlled by the submitter on this screen; at least one site is required.

- **Add Site:** Click the ‘Add Site’ button to display the ‘Add Site’ pop-up window. Refer to **Section 3.11** for additional details regarding the add site functionality.
- **EPA Registry ID:** Displays the EPA Registry ID of the site and/or port.
- **Site of Manufacture or Port of Entry:** Displays the site of manufacture or port of entry depending on the checkbox(es) the user checks on the ‘Statement of Intent’ screen. This is a required field if the checkboxes were checked.
- **Site Name:** Displays the site name of the site or port. This is a required field.
- **Address:** Displays the address of the site or port. This is a required field.
- **Actions:** Click the ‘Delete’ icon (✖) to delete the entire site row permanently from the system. A warning message displays to confirm the deletion of the site.

Exhibit 8-17 shows a screen capture of the ‘Submitter Site Identification’ screen:

Exhibit 8-17 Submitter Site Identification Screen (Bona Fide)

The screenshot displays the GSPP interface for a Primary Authorized Official. The main heading is "SUBMITTER SITE IDENTIFICATION". Below this, there is a section for "Site of Manufacture or Port of Entry" with an "Add Site" button. A table titled "List of Submitter Sites" is shown with columns for EPA Registry ID, Site of Manufacture or Port of Entry, Site Name, Address, and Actions. Below the table are "Previous" and "Next" navigation buttons, with the "Next" button highlighted in red. At the bottom of the screen, there are four action buttons: "Validate" (with a green checkmark), "Save", "Preview", and "Submit" (with a database icon).

Navigation: Click the ‘Next’ button to navigate to the ‘Document Management’ screen. You can also access this screen by clicking the ‘Document Management’ link within the navigation tree.

8.1.15 Document Management

You can navigate to the ‘Document Management’ screen by clicking the ‘Next’ button from the ‘Submitter Site Identification’ screen. You can also access this screen by clicking the ‘Document Management’ link within the navigation tree.

The ‘Document Management’ screen is used to attach required documents to the electronic form. The user must attach three required documents: ‘Spectrum of Substance,’ ‘Statement of Commercialization,’ and ‘Statement of Research and Development.’ The application also allows the user to attach ‘Other’ documents.

- **Attach Document:** Click the ‘Attach Document’ button to generate the ‘Attach Documents’ pop-up window to upload documents. Refer to **Section 3.6** for additional details regarding the attach document functionality.
- **Document Name:** Displays the document name and file extension of the document uploaded on the ‘Attach Documents’ pop-up window.
- **Document Type:** Displays the document type associated with the uploaded document.
- **Action:** Click the ‘Delete’ icon (✖) to delete the entire document row permanently from the system. A warning message displays to confirm the deletion of the document.

Exhibit 8-18 shows a screen capture of the ‘Document Management’ screen:

Exhibit 8-18 Document Management Screen (Bona Fide)

The screenshot shows the GSPP Document Management interface. At the top, it indicates the user is logged in as Jane Doe, Primary Authorized Official. The main content area is titled 'DOCUMENT MANAGEMENT' and lists required documents: Spectrum of Substance, Statement of Commercialization, and Statement of Research and Development. Below this is an 'Attach Document' button and a table with columns for Document Name, Document Type, and Action. The 'Next' button in the Action column is highlighted with a red box. At the bottom, there are buttons for Validate, Save, Preview, and Submit.

Navigation: Click the ‘Next’ button to navigate to the ‘Optional Cover Letter’ screen. You can also access this screen by clicking the ‘Optional Cover Letter’ link within the navigation tree.

8.1.16 Optional Cover Letter

You can navigate to the ‘Optional Cover Letter’ screen by clicking the ‘Next’ button from the ‘Document Management’ screen. You can also access this screen by clicking the ‘Optional Cover Letter’ link within the navigation tree.

The ‘Optional Cover Letter’ screen is used to communicate information with EPA that is not collected elsewhere in the form. The cover letter is used to give EPA resources and special instructions regarding the application.

- **Optional Cover Letter:** Enter any additional special instructions regarding the form.

Exhibit 8-19 shows a screen capture of the ‘Optional Cover Letter’ screen:

Exhibit 8-19 Optional Cover Letter Screen (Bona Fide)

Navigation: Click the ‘Next’ button to navigate to the ‘Submitting Official Information’ screen.

8.1.17 Submitting Official Information

You can navigate to the ‘Submitting Official Information’ screen by clicking the ‘Next’ button from the ‘Optional Cover Letter’ screen. You can also access this screen by clicking the ‘Submitting Official Information’ link within the navigation tree.

Exhibit 8-20 shows a screen capture of the ‘Submitting Official Information’ screen:

Exhibit 8-20 Submitting Official Information Screen (Bona Fide)

Navigation: Click the ‘Next’ button to proceed to the ‘Instructions for Substantiating CBI Claims’ screen if any claims of confidentiality were made in the form. If no CBI claims were made, click the ‘Submit’ button to begin the submission process. 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. Refer to **Section 12** for further information on the ‘Submitting Official Information’ screen. Refer to **Section 13** for more information on CBI substantiation.

9 Create Alternative Control Measures (ACM) Form

The Section 5 Notices and Supports application allows ACM forms to be submitted. The ACM form is used to report proposed alternative control measures for published significant new use rules (SNURs).

9.1 Create Alternative Control Measures Form

To create a new ACM form, navigate to the ‘Section 5 Notices and Supports Forms’ screen and select ‘Alternative Control Measures (ACM)’ from the ‘Form Type’ drop-down menu. Refer to **Section 3.4** for additional details regarding the ‘Section 5 Notices and Supports Forms’ screen.

Refer to **Section 3.5** for additional details regarding the create passphrase process.

9.1.1 Contact Information

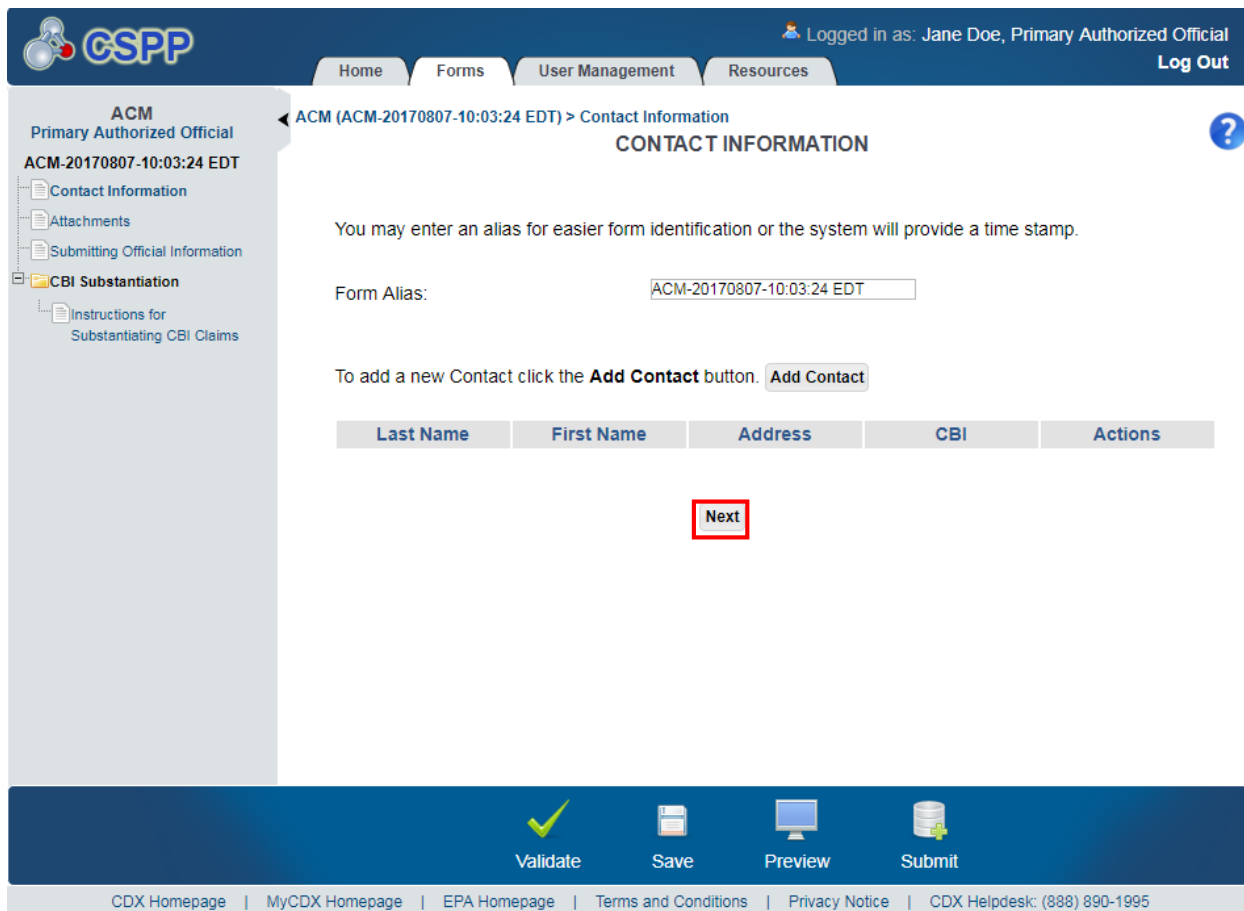
You can access the ‘Contact Information’ screen by entering the passphrase on the ‘Enter Passphrase’ screen or creating a passphrase on the ‘Create Passphrase’ screen.

The ‘Contact Information’ screen provides an ‘Add Contact’ button and a contact information table for you to identify a point of contact who is working for a U.S. based company.

- **Form Alias:** Enter a custom alias to differentiate the ACM 721.30 form, if applicable. The system auto-generates a default alias consisting of the form type and date stamp in the following format: <Form Type-YYYYMMDD-HH:MM:SS Time Zone>. The form alias is an editable field that may be changed at any time. This is a required field.
- **Add Contact:** Click the button to generate the ‘Add Contact’ window, which allows a user to enter information for a point of contact. At least one contact is required.
- **Last Name:** Displays the last name of the contact identified on the ‘Add Contact’ pop-up window.
- **First Name:** Displays the first name of the contact identified on the ‘Add Contact’ pop-up window.
- **Address:** Displays the mailing address of the contact identified on the ‘Add Contact’ pop-up window.
- **CBI:** Indicates the CBI status of a contact by displaying either a ‘Y’ or an ‘N.’
- **Actions:** Click the ‘Delete’ icon (✖) to delete a contact from the table. A warning message displays to confirm deletion of the contact.

Exhibit 9-1 shows a screen capture of the ‘Contact Information’ screen:

Exhibit 9-1 Contact Information Screen (ACM)



Navigation: Click the ‘Add Contact’ button to begin the process of adding contact information. Click the ‘Next’ button to navigate to the ‘Attachments’ screen. You can also access this screen by clicking the ‘Attachments’ link within the navigation tree.

9.1.1.1 Add Contact

You can access the ‘Add Contact’ pop-up window by clicking the ‘Add Contact’ button on the ‘Contact Information’ screen.

The ‘Add Contact’ pop-up window displays fields for you to enter information regarding the point of contact.

- **Click here to copy your information from CDX Registration:** Click the ‘Copy CDX Registration’ button to populate the fields with your contact information provided during CDX registration. A prompt will display confirming the import of CDX registration information.
- **Check here to claim this information as CBI:** Check the ‘Check here to claim this information as CBI’ checkbox to claim the contact information as confidential. If the ‘CBI’ checkbox is checked before clicking the ‘Copy CDX Registration’ button, the ‘CBI’ checkbox becomes unchecked upon navigating back to the screen after copying CDX

registration information. Check the 'CBI' checkbox after importing CDX registration information to claim a contact as confidential.

- **First Name:** Enter the contact's first name. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Last Name:** Enter the contact's last name. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Company Name:** Enter the contact's company name. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Phone Number:** Enter the contact's daytime phone number; dashes are not allowed. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Phone Extension:** Enter the contact's phone number extension, if applicable.
- **Email Address:** Enter the contact's email address. The email address must follow the standard email address format: John.Doe@abc.com. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Mailing Address 1:** Enter the first line of the contact's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Mailing Address 2:** Enter the second line of the contact's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration.
- **City:** Enter the contact's U.S. city of the mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **State:** Select the state of the contact's mailing address from the drop-down menu. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Postal Code:** Enter the postal code of the contact's mailing address. Click the 'Copy CDX Registration' button to populate the fields with information entered during CDX registration. This is a required field.
- **Country:** Displays 'United States.'

Exhibit 9-2 shows a screen capture of the ‘Add Contact’ pop-up window:

Exhibit 9-2 Add Contact Pop-Up Window (ACM)



CSPP

ADD CONTACT

Please enter the information for the contacts who will be responsible for supporting the information on the form. For multiple contacts, click the **Add Contact** button to populate a table with multiple contacts. Check to claim information as CBI or 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:

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:

Navigation: Click the ‘Cancel’ button or the ‘X’ icon to stop populating contact information. Click the ‘OK’ button to save the entered contact information and navigate back to the ‘Contact Information’ screen.

9.1.2 Attachments

You can access the ‘Attachments’ screen by clicking the ‘Next’ button from the ‘Contact Information’ screen. You can also access this screen by clicking the ‘Attachments’ link within the navigation tree.

The ‘Attachments’ screen provides an ‘Attach Document’ button for you to upload documentation that fulfills the specified requirements, and a text field to provide the 40 CFR 721 citation to which the documentation refers.

-
- **Attach Document:** Click the ‘Attach Document’ button to attach documents that fulfill the outlined requirements in the instructional text. At least one document is required. Refer to **Section 3.6** for additional information regarding the attach document functionality.
 - **File Name:** Displays the file name and file extension of a document.
 - **Description:** Displays the description of a document.
 - **Pages:** Displays the number of pages a document contains.
 - **Date:** Displays the date that a document was uploaded on the ‘Attach Documents’ pop-up window.
 - **CBI:** Indicates the CBI status of a document by displaying either a ‘Y’ or an ‘N.’
 - **Action:** Click the ‘Delete’ icon (✖) to remove the attached document row. A warning message displays to confirm deletion of the document.
 - **ACM Citation at 40 CFR 721:** Enter the ACM citation reference that the uploaded documents support. This field allows up to seven (7) numeric characters; letters or other characters are not allowed. This is a required field.

Exhibit 9-3 shows a screen capture of the ‘Attachments’ screen:

Exhibit 9-3 Attachments Screen (ACM)

CDX
GSP

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

Home Forms User Management Resources

ACM
Primary Authorized Official
ACM-20170731-12:26:39 EDT

Contact Information
Attachments
Submitting Official Information
CBI Substantiation
Instructions for Substantiating CBI Claims

ACM (ACM-20170731-12:26:39 EDT) > Attachments

ATTACHMENTS

Please remember to upload documentation that fulfills the following requirements under 721.33:

- 1) The specific chemical identity of the substance.
- 2) A detailed description of the activities involved.
- 3) The specifications of the alternative worker exposure control measures or environmental release control measures.
- 4) An analysis justifying why such alternative control measures provide substantially the same degree of protection as the specific control measures identified which pertain to the substance for which the request is being submitted.
- 5) The data and information described in 720.50 (a) and (b) of this chapter unless such data and information have already been submitted to the Office of Pollution Prevention and Toxics, EPA.

Attach Document

File Name	Description	Pages	Date	CBI	Action
Please provide the specific section in subpart E to which the proposed Alternative Control Measure refers. ACM Citation at 40 CFR 721: <input type="text"/>					

Previous **Next**

Validate Save Preview Submit

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

Navigation: Click the ‘Next’ button to navigate to the ‘Submitting Official Information’ screen.

9.1.3 Submitting Official Information

You can navigate to the ‘Submitting Official Information’ screen by clicking the ‘Next’ button from the ‘Attachments’ screen. You can also access this screen by clicking the ‘Submitting Official Information’ link within the navigation tree.

Exhibit 9-4 shows a screen capture of the ‘Submitting Official Information’ screen:

Exhibit 9-4 Submitting Official Information Screen (ACM)

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

Home Forms User Management Resources

ACM
Primary Authorized Official
ACM-20170720-14:53:35 EDT

- Contact Information
- Attachments
- 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.

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: TEST

Phone Number:

Email Address:

Mailing Address 1: TEST

Mailing Address 2:

City: TEST

State: VA

Postal Code: 22201

Country: US

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

Navigation: Click the ‘Next’ button to proceed to the ‘Instructions for Substantiating CBI Claims’ screen if any claims of confidentiality were made in the form. If no CBI claims were made, click the ‘Submit’ button to begin the submission process. Click the ‘Validate’ icon (✓) in the bottom action bar to validate the form. Click the ‘Save’ icon (💾) in the bottom action bar to save the overall form. Click the ‘Preview’ icon (🖨️) to generate a PDF preview of the form. Refer to **Section 12** for further information on the ‘Submitting Official Information’ screen. Refer to **Section 13** for more information on CBI substantiation.

10 Preview

The system provides the option to preview a form at any point during the submission process. Click the ‘Preview’ icon (🖨️), located within the bottom action bar, to see a PDF version of the form. A screen will display for you to view either the ‘Full’ or the ‘Sanitized’ version of the PDF differentiated by buttons. After you choose either the ‘Full’ or ‘Sanitized’ PDF, the application generates a draft, watermarked PDF version of the form.

The watermark reads ‘Not for Submission’ and displays across each page in the background. The form preview displays the entire form in a printable format. The preview functionality provides the flexibility to track the status of the form and see the entire form in a single viewpoint.

Exhibit 10-1 shows a screen capture of the ‘Preview EPMN Form’ screen:

Exhibit 10-1 Preview EPMN Form Screen (ACM)

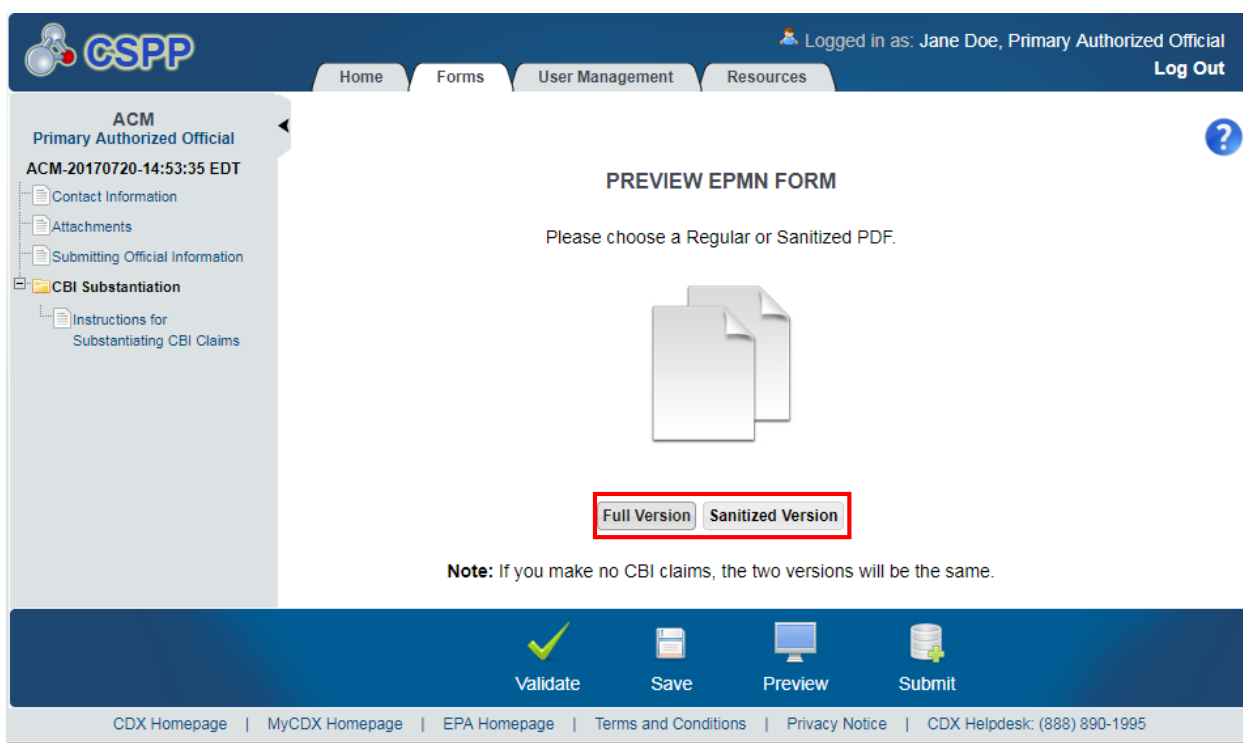




Exhibit 10-2 shows a screen capture for the 'Preview' of the Biotechnology form:

Exhibit 10-2 Preview Biotechnology Form PDF


		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 <input type="checkbox"/>	
<p>I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.</p> <p>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:</p> <ul style="list-style-type: none"> (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. <p>Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.</p>			
I. SUBMITTER IDENTIFICATION INFORMATION			CBI <input type="checkbox"/>
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) <input type="checkbox"/>			CBI <input type="checkbox"/>
First Name		Last Name	
Position		Company	
Mailing Address (Number & Street)			
City	State	Postal Code	


Exhibit 10-3 shows a screen capture for the 'Preview' of the NOC form:

Exhibit 10-3 Preview NOC Form PDF

		Form Approved. O.M.B. No. 2070-0012		CBI SUBMISSION	
NOC2014P1		U.S. Environmental Protection Agency EPA		Report Number	
U.S. Environmental Protection Agency NOTICE OF COMMENCEMENT OF MANUFACTURE OR IMPORT <small>(40CFR§720.102)</small>					
Part I - SUBMITTER IDENTIFICATION			Document Control #:		
Manu- facturer/ Importer (in U.S.)	Name of Authorized Official (first) (last)		Mailing Address (number and street)		
	Company Name		City	State	Zip
Technical Contact (in U.S.)	Name (first) (last)		Telephone Number		
Part II - Premanufacture Notice (PMN) "P" Case Number:					
Part III - Check the appropriate box and provide the exact date of manufacture or importation:					
First Commercial Manufacture**			First Commercial Importation***		
Date:			Date:		
<small>**Date of commencement is the date of completion of non-exempt manufacture of the first amount (batch/drum, etc.) ***For importees, the date of commencement is the date that the new chemical substance clears U.S. customs.</small>					
Part IV - Manufacturing Plant Site(s) or Importing Site(s): (Importers, provide street address of destination)					
[Empty field for site information]					
Part V - Specific Chemical Identity: (For Consolidated submissions, each substance must have a separate NOC form with the specific identity of each chemical substance.)					
[Empty field for chemical identity]					
Part VI - Generic Chemical Name (if chemical identity is claimed CBI*):					
[Empty field for generic name]					
Part VII - Substance Identity Confidentiality Status:					
<input type="checkbox"/> I wish to continue to claim the substance identity confidential and the substantiation to support this claim is attached. Failure to submit the required substantiation in accordance with 40 CFR 720.85(b) will result in a waiver of your claim.					
<input type="checkbox"/> I previously claimed the substance identity as confidential and hereby relinquish that claim.					
<input type="checkbox"/> I did not claim the substance identity as confidential in my original PMN submission.					
The public reporting and recordkeeping burden for this collection of information 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 7710-56 to this address. You must submit your completed notice no later than 30 calendar days after the first date of commercial manufacture/importation to the address shown below: U.S. Environmental Protection Agency OPPT Document Control Office (7407M) 1200 Pennsylvania Ave., NW Washington, D.C. 20460 ATTN: Notice of Commencement					
Signature of authorized official				Date	
<small>Note: CBI* - refers to the term "Confidential Business Information". Mark (X) in the box if the information is to be held Confidential.</small>					
EPA Form 7710-56 (6-09)					

Exhibit 10-4 shows a screen capture for the 'Preview' of the Support form:

Exhibit 10-4 Preview Support Form PDF

 SUP2014P1		NON-CBI SUBMISSION Form Approved. O.M.B. No. 2070-0173.	
EPA Support Form			
Support Form Report Number		Mark (X) if anything is CBI <input type="checkbox"/>	
I. ORIGINAL NOTICE SUBMISSION IDENTIFICATION			
Report Number	TS Number	Case Number	
Original Submission Date			
Original Submission Media Type			
II. ORIGINAL NOTICE SUBMITTER IDENTIFICATION			CBI <input type="checkbox"/>
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			CBI <input type="checkbox"/>
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)			
<input type="checkbox"/>	Transfer of Ownership		
<input type="checkbox"/>	Suspension Request		
<input type="checkbox"/>	Withdrawal Request		
<input type="checkbox"/>	Other Correspondence		
<input type="checkbox"/>	TEST DATA (Health/Eco/Fate)		
<input type="checkbox"/>	Amendment (Changes made to PMN pages 1-13, MSDS or Physical/Chemical properties)		
Check if requested by EPA/ contractor			<input type="checkbox"/>
EPA person/ contractor			
Submitter Signature			

11 Validate

You can click the ‘Validate’ icon (✓) at any stage of completing a Section 5 Notices and Supports form. The ‘Section 5 Notices and Supports Validation’ pop-up window displays when you click the ‘Validate’ icon (✓). Disable the pop-up blocker within your internet browser so that the ‘Section 5 Notices and Supports Validation’ pop-up window displays correctly. The ‘Section 5 Notices and Supports Validation’ pop-up window displays a report of all validation errors and warning messages. During the validation process, the application validates each screen of the Section 5 Notices and Supports form to find missing and invalid data.

Validation Errors: Errors are denoted by an ‘Error’ icon (⚠) and can be fixed by clicking the error link. The links will display the *Screen Title Name* (e.g., Chemical Identification) and the associated error. After you click a link, the main application screen will display the section where the error occurred so you can easily fix the error. Once you have fixed the error(s), click the ‘Validate’ icon (✓) again to refresh the ‘Section 5 Notices and Supports Validation’ pop-up window. If the information you fixed passes validation, the error will be removed from the ‘Section 5 Notices and Supports Validation’ pop-up window. You must fix all validation errors to submit the form to CDX successfully.

Warning Messages: Warnings are denoted by a ‘Warning’ icon (⚠) and can be fixed by clicking the warning link. The links will display the *Screen Title* and the associated warning. After you click a link, the main application screen will display the section where the warning occurred so you can easily fix the warning. Once you have fixed the warning(s), click the ‘Validate’ icon (✓) again to refresh the ‘Section 5 Notices and Supports Validation’ pop-up window. If the information you fixed passes validation, the warning will be removed from the ‘Section 5 Notices and Supports Validation’ pop-up window. You can pass validation and continue to submit a form to CDX with active warning messages.

You can close the ‘Section 5 Notices and Supports Validation’ pop-up window by clicking the ‘X’ button located at the upper right-hand corner of the window.

Exhibit 11-1 shows a screen capture for the ‘Section 5 Notices and Supports Validation’ pop-up window (Scroll 1):

Exhibit 11-1 Section 5 Notices and Supports Validation Pop-Up Window (Scroll 1)



 **CSPP** 

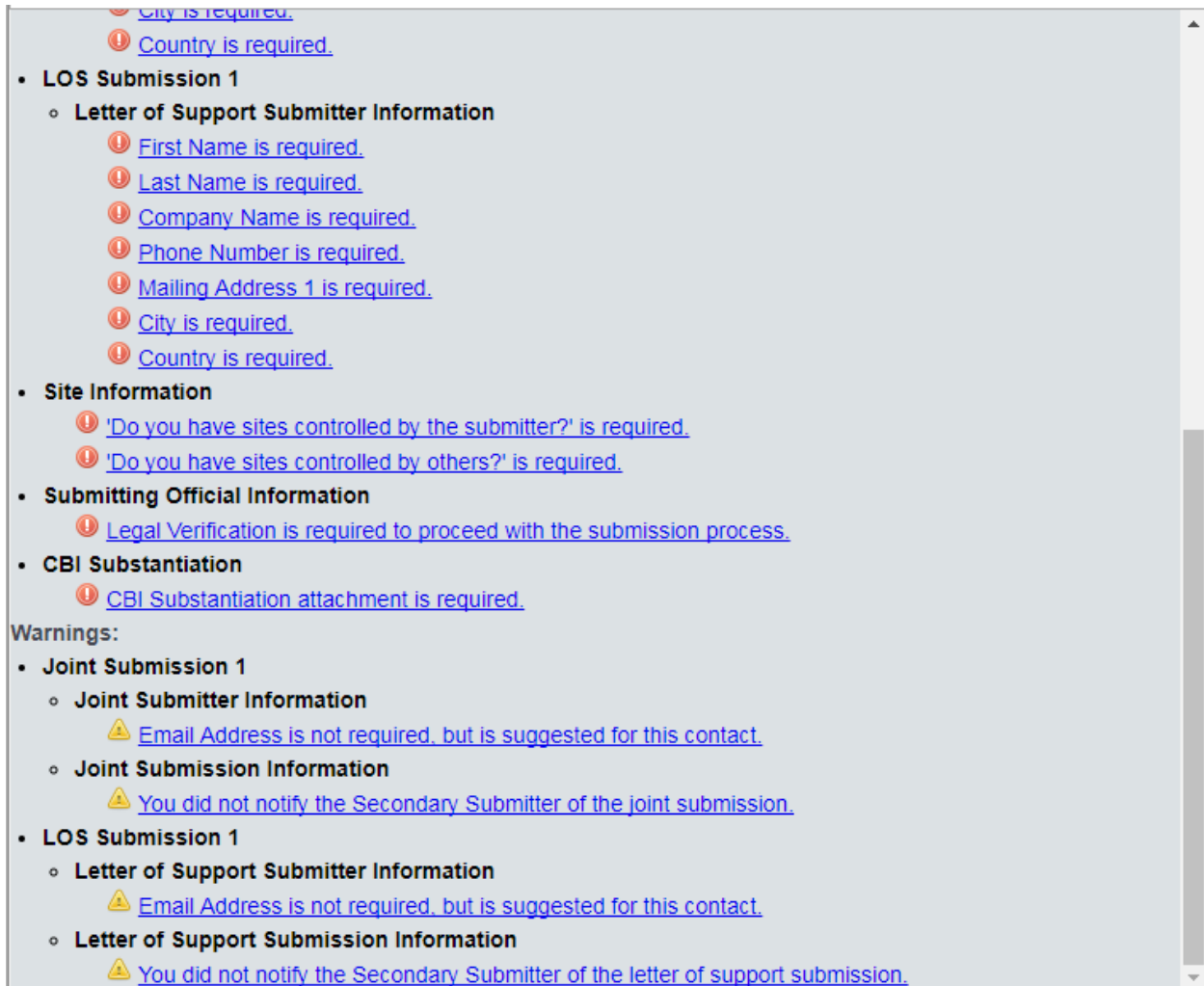
SECTION 5 NOTICES AND SUPPORTS VALIDATION

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.](#)

Exhibit 11-2 shows a screen capture for the ‘Section 5 Notices and Supports Validation’ pop-up window (Scroll 2):

Exhibit 11-2 Section 5 Notices and Supports Validation Pop-Up Window (Scroll 2)



The screenshot displays a validation window with the following content:

- [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.](#)

12 Submitting Official Information

On the ‘Submitting Official Information’ page, the system requires you to review your contact information provided during CDX registration. If you do not identify your job title, ‘Not Applicable’ fills the value by default.

The following statement which displays to the Primary AO must be confirmed before the system will allow you to move forward: “Please confirm that you are the legally responsible party from the submitting company.” If you check this checkbox associated with the statement, the application navigates to the ‘CBI Substantiation’ screen if there are CBI claims made within a form, the appropriate certification screen, or the ‘Cross-Media Electronic Reporting Regulation (CROMERR)’ screen. If you do not check the checkbox associated with this statement, the application will remain on the same screen with a warning box at the top stating. “Legal verification is required to proceed with the submission process.”

- **CBI:** Check the ‘CBI’ checkbox to claim the submitting official’s information as confidential.
- **Please confirm that you are the legally responsible party from the submitting company:** Check the checkbox to confirm that the individual submitting the form has permission to do so.
- **First Name:** Displays the first name of the submitting official, which has been pre-populated from CDX registration information.
- **Middle Initial:** Displays the middle initial of the submitting official, which has been pre-populated from CDX registration information.
- **Last Name:** Displays the last name of the submitting official, which has been pre-populated from CDX registration information.
- **Job Title:** Displays ‘Not Applicable.’
- **Company Name:** Displays the company name of the submitting official, which has been pre-populated from CDX registration information.
- **Phone Number:** Displays the phone number of the submitting official, which has been pre-populated from CDX registration information.
- **Email Address:** Displays the email address of the submitting official, which has been pre-populated from CDX registration information.
- **Mailing Address 1:** Displays the first line of the mailing address from CDX registration information.
- **Mailing Address 2:** Displays the second line of the submitting official’s mailing address, which has been pre-populated from CDX registration information.
- **City:** Displays the city of the submitting official’s mailing address, which has been pre-populated from CDX registration information.
- **State:** Displays the state of the submitting official’s mailing address, which has been pre-populated from CDX registration information.
- **Postal Code:** Displays the postal code of the submitting official’s mailing address, which has been pre-populated from CDX registration information.

- **Country:** Displays the country of the submitting official’s mailing address, which has been pre-populated from CDX registration information.

Exhibit 12-1 shows a screen capture of the ‘Submitting Official Information’ (PMN) screen:

Exhibit 12-1 Submitting Official Information Screen (PMN)

Navigation: Click the ‘Submit’ button to initiate the submission process. Click the ‘Next’ button to proceed to the CBI Substantiation process if a CBI claim was made within the form. Refer to **Section 14** for information on the submission process. Refer to **Section 13** for more information on CBI substantiation.

13 CBI Substantiation

EPA modified the electronic reporting applications for TSCA submissions to accept CBI substantiations for CBI claims made during the creation of electronic submissions. Other than information exempt from substantiation under TSCA Section 14(c)(2), users who wish to assert CBI claims for data within a submission must substantiate those claims at the time of submission as required by TSCA Section 14(c)(3).

13.1 Instructions for Substantiating Confidential Business Information (CBI) Claims

You can access the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen by claiming information as CBI within a form and clicking the ‘Instructions for Substantiating CBI Claims’ link within the navigation tree under the ‘CBI Substantiation’ folder. The ‘CBI Substantiation’ folder and the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen will not generate until a CBI claim is made within a submission. Information claimed CBI must either be substantiated or claimed exempt pursuant to TSCA Section 14(c)(2) at the time of submission.

To substantiate a CBI claim, upload documentation asserting your claim(s). You may also opt-out of substantiation if, for example, you believe your CBI claim is exempt under TSCA Section 14(c)(2). Common exemption reasons can be found at <https://www.epa.gov/tsc-cbi/what-information-include-cbi-substantiations>. To opt-out of substantiation at the time of submission, all CBI claims within a submission must be exempt.

- **Substantiation Opt-Out:** Certain data claimed CBI may be exempt from substantiation at the time of submission. If all information contained within the submission was previously substantiated or you believe it to be exempt pursuant to TSCA Section 14(c)(2), check the ‘Substantiation Opt-Out’ checkbox to generate the ‘Substantiation Opt-Out Reason’ text box and hide the ‘File Upload’ button. If a substantiation document is uploaded, checking the ‘Substantiation Opt-Out’ checkbox clears the uploaded attachments. Either a substantiation opt-out reason or CBI substantiation document must be provided if a CBI claim is made in a submission.
- **Substantiation Opt-Out Reason:** Enter information explaining why you believe your CBI claim(s) to be exempt from substantiation. Either a substantiation opt-out reason within the text box or CBI substantiation document must be provided if a CBI claim is made in a submission.
- **File Upload:** Click the ‘File Upload’ button to search your local machine and upload a file that contains your CBI substantiation. To overwrite an uploaded file, click the ‘File Upload’ button again to search for and upload a new file. If the ‘Substantiation Opt-Out’ checkbox is checked after you upload a file, the application will delete the uploaded file. Either a substantiation opt-out reason or CBI substantiation document must be provided if a CBI claim is made in a submission.
- **Check if the Substantiation Document is CBI:** If the uploaded substantiation document contains CBI, check the ‘Check if the Substantiation Document is CBI’ checkbox to generate the ‘Sanitized Upload’ button. A sanitized CBI substantiation document must be provided if the original substantiation document is claimed CBI.

-
- **Sanitized Upload:** Click the ‘Sanitized Upload’ button to search your local machine and upload a file that contains your sanitized CBI substantiation. To overwrite an uploaded file, click the ‘Sanitized Upload’ button again to search for and upload a new file. If the ‘Substantiation Opt-Out’ checkbox is checked after you upload a file, the application will delete the uploaded sanitized file. A substantiation attachment must be provided if the original substantiation document is claimed CBI.

If you are unfamiliar with substantiating CBI claims or require assistance preparing substantiation documents, EPA offers a link to templates and other information for substantiating CBI claims on the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen. It is suggested that you right-click the link and open in a new tab or new window so you do not leave your submission as this may affect your saved data.

Exhibit 13-1 shows a screen capture of the ‘Instructions for Substantiating CBI Claims’ screen (Scroll 1):

Exhibit 13-1 Instructions for Substantiating Confidential Business Information (CBI) Claims Screen (PMN) (Scroll 1)

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

Home Forms User Management Resources

Premanufacture Notice Primary Authorized Official
Primary PMN-20170731-11:45:56 EDT

form (Primary PMN-20170731-11:45:56 EDT) > Instructions for Substantiating CBI Claims

INSTRUCTIONS FOR SUBSTANTIATING CONFIDENTIAL BUSINESS INFORMATION (CBI) CLAIMS

The Frank R. Lautenberg Chemical Safety for the 21st Century Act created a number of new requirements for those making confidential business information (CBI) claims in TSCA submissions. Among these requirements is an obligation to substantiate most CBI claims at the time of submission.

Information which may be claimed as CBI without substantiation is identified at TSCA 14(c)(2). This information includes:

1. Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article;
2. Marketing and sales information;
3. Information identifying a supplier or customer;
4. In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents;
5. Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article;
6. Specific production or import volumes of the manufacturer or processor; and
7. Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under TSCA 5.

Upload XML

Validate Save Preview Submit

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

Exhibit 13-2 shows a screen capture of the ‘Instructions for Substantiating CBI Claims’ screen (Scroll 2) (Substantiation Upload Example):

Exhibit 13-2 Instructions for Substantiating Confidential Business Information (CBI) Claims Screen (PMN) (Scroll 2) (Substantiation Upload Example)

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

Home Forms User Management Resources

Premanufacture Notice
Primary Authorized Official

Primary PMN-20171003-15:12:28 EDT

- Exposures/Releases
- Byproduct Information
- Remove
- Add Operation
- Optional Pollution Prevention
- Additional Attachments
- Attachment Summary
- Optional Cover Letter
- 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
- Submitting Official Information
- CBI Substantiation
 - Instructions for

For other submissions where the submitter has claimed information as CBI, the submitter will be required to upload a document substantiating those CBI claims at the time of submission. The substantiation document should provide EPA any information believed to support the validity of the CBI claims. In order to assist submitters in substantiating their CBI claims, EPA has developed substantiation templates that may be used as a starting point in preparing their CBI substantiations. Submitters are encouraged to use these substantiation template documents, but are not required to do so. The templates and other information relating to substantiating CBI claims can be found at <https://www.epa.gov/tsc-cbi/what-information-include-cbi-substantiations>.

The Agency is required to review and make a determination on the validity of many CBI claims. Failure to substantiate a CBI claim or a substantiation that does not adequately justify the claim may result in a denial of claims and subsequent public release of information. If you have any questions concerning the options or the substantiation process, please contact:

- Scott Sherlock, 202-564-8257, sherlock.scott@epa.gov
- Jessica Barkas, 202-250-8880, barkas.jessica@epa.gov

If you believe all of the information you have claimed as CBI is exempt from substantiation under TSCA section 14(c) (2) or has been previously substantiated, select the following “Substantiation Opt Out” checkbox and provide a detailed explanation why you believe substantiation is not required.

Substantiation Opt-Out:

Select a file to attach (will write over previously attached file if present):

Original Substantiation Document: **test1.docx**

Check if the Substantiation Document is CBI:

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

Exhibit 13-3 shows a screen capture of the ‘Instructions for Substantiating CBI Claims’ screen (Scroll 3) (Sanitized Substantiation Upload Example):

Exhibit 13-3 Instructions for Substantiating Confidential Business Information (CBI) Claims Screen (PMN) (Scroll 3) (Sanitized Substantiation Upload Example)

The screenshot shows the GSPP (Global Substantiation Portal) interface. At the top, it indicates the user is logged in as Jane Doe, Primary Authorized Official. The navigation menu on the left includes options like 'Premanufacture Notice', 'Joint Submission', 'Letter of Support', and 'CBI Substantiation'. The main content area contains the following text:

their CBI claims, EPA has developed substantiation templates that may be used as a starting point in preparing their CBI substantiations. Submitters are encouraged to use these substantiation template documents, but are not required to do so. The templates and other information relating to substantiating CBI claims can be found at <https://www.epa.gov/tsc-cbi/what-information-include-cbi-substantiations>.

The Agency is required to review and make a determination on the validity of many CBI claims. Failure to substantiate a CBI claim or a substantiation that does not adequately justify the claim may result in a denial of claims and subsequent public release of information. If you have any questions concerning the options or the substantiation process, please contact:

- Scott Sherlock, 202-564-8257, sherlock.scott@epa.gov
- Jessica Barkas, 202-250-8880, barkas.jessica@epa.gov

If you believe all of the information you have claimed as CBI is exempt from substantiation under TSCA section 14(c) (2) or has been previously substantiated, select the following “Substantiation Opt Out” checkbox and provide a detailed explanation why you believe substantiation is not required.

The form area, highlighted with a red box, contains the following elements:

- Substantiation Opt-Out:
- Select a file to attach (will write over previously attached file if present):
- Original Substantiation Document: **test1.docx**
- Check if the Substantiation Document is CBI:
- Select a Sanitized file to attach (will write over previously attached Sanitized file if present):
- Sanitized Substantiation Document: **test2.docx**

At the bottom of the form area are 'Previous' and 'Submit' buttons. The footer of the application includes an 'Upload XML' button, utility icons for 'Validate', 'Save', 'Preview', and 'Submit', and a list of links: CDX Homepage, MyCDX Homepage, EPA Homepage, Terms and Conditions, Privacy Notice, and CDX Helpdesk: (888) 890-1995.

Exhibit 13-4 shows a screen capture of the ‘Instructions for Substantiating CBI Claims’ screen (Scroll 4) (Substantiation Opt-Out Example):

Exhibit 13-4 Instructions for Substantiating Confidential Business Information (CBI) Claims Screen (PMN) (Scroll 4) (Substantiation Opt-Out Example)

5.

For other submissions where the submitter has claimed information as CBI, the submitter will be required to upload a document substantiating those CBI claims at the time of submission. The substantiation document should provide EPA any information believed to support the validity of the CBI claims. In order to assist submitters in substantiating their CBI claims, EPA has developed substantiation templates that may be used as a starting point in preparing their CBI substantiations. Submitters are encouraged to use these substantiation template documents, but are not required to do so. The templates and other information relating to substantiating CBI claims can be found at <https://www.epa.gov/tsca-cbi/what-information-include-cbi-substantiations>.

The Agency is required to review and make a determination on the validity of many CBI claims. Failure to substantiate a CBI claim or a substantiation that does not adequately justify the claim may result in a denial of claims and subsequent public release of information. If you have any questions concerning the options or the substantiation process, please contact:

- Scott Sherlock, 202-564-8257, sherlock.scott@epa.gov
- Jessica Barkas, 202-250-8880, barkas.jessica@epa.gov

If you believe all of the information you have claimed as CBI is exempt from substantiation under TSCA section 14(c) (2) or has been previously substantiated, select the following “Substantiation Opt Out” checkbox and provide a detailed explanation why you believe substantiation is not required.

Substantiation Opt-Out:

Substantiation Opt-Out Reason:

Previous Submit

Upload XML Validate Save Preview Submit

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

14 Submit to EPA via CDX

As a Primary AO, you have the ability to sign and submit a Section 5 Notices and Supports form to EPA via CDX. You can save your form at any point during the data entry process. Any assigned Supports for your form cannot submit the Section 5 Notices and Supports form. The save functionality will allow you to return to that same form at any point in the future.

Once you complete all required information and correct all items failing validation, the system will allow the Section 5 Notices and Supports form to be successfully submitted.

14.1 LVE Certification

Click the ‘Submit’ icon () located in the bottom action bar to access the ‘LVE Certification’ screen. This screen displays when ‘LVE’ or ‘LVE Modification’ is selected from the ‘Type of Notice’ drop-down menu on the ‘General Form Information’ screen for a PMN form. If the notice type is not ‘LVE’ or ‘LVE Modification,’ click the ‘Next’ button to navigate to the ‘Submission Process: Validation’ screen or a different certification screen.

Exhibit 14-1 shows a screen capture of the ‘LVE Certification’ screen:

Exhibit 14-1 LVE Certification Screen

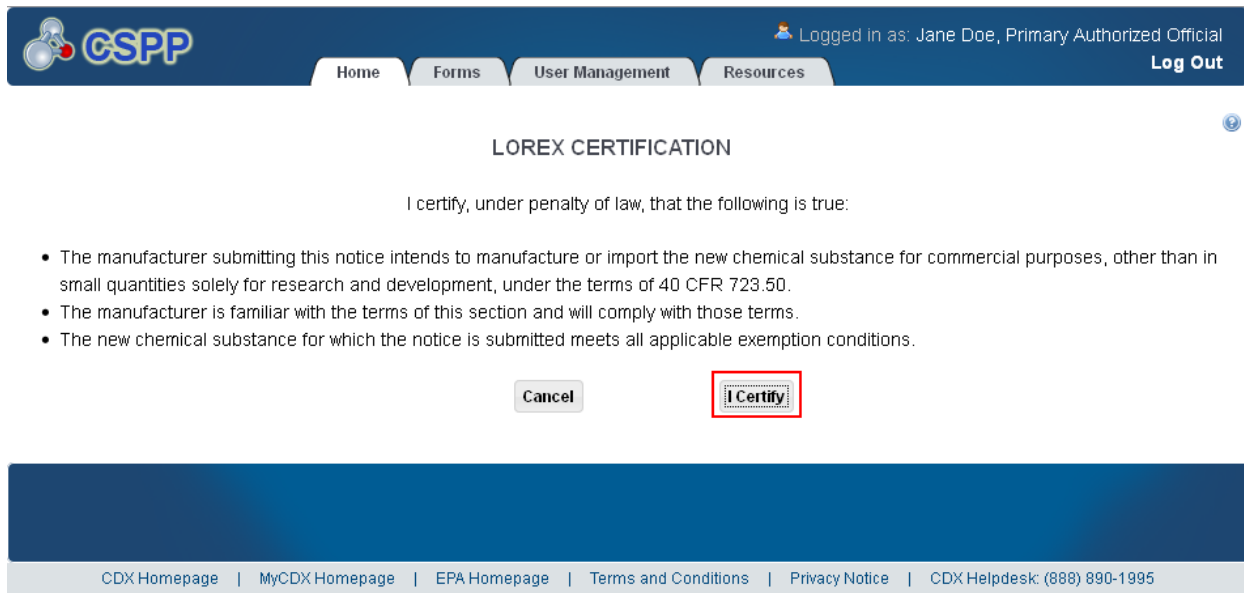
Navigation: Click the ‘I Certify’ button to continue with submitting the form and navigate to the ‘Submission Process: Validation’ screen. Click the ‘Cancel’ button to stop the submission process.

14.2 LOREX Certification

Click the ‘Submit’ icon () located in the bottom action bar to access the ‘LOREX Certification’ screen. This screen displays when ‘LOREX’ or ‘LOREX Modification’ is selected from the ‘Type of Notice’ drop-down menu on the ‘General Form Information’ screen for a PMN form.

Exhibit 14-2 shows a screen capture of the ‘LOREX Certification’ screen:

Exhibit 14-2 LOREX Certification Screen



Navigation: Click the ‘I Certify’ button to continue with submitting the form and proceed to the ‘Submission Process: Validation’ screen.

14.3 Biotech Certification



Click the ‘Submit’ icon () located in the bottom action bar to access the ‘Biotech Certification’ screen. This screen displays when ‘Biotechnology’ is selected from the ‘Form Type’ drop-down menu on the ‘Section 5 Notices and Supports’ page.

Exhibit 14-3 shows a screen capture of the ‘Biotech Certification’ screen:

Exhibit 14-3 Biotech Certification Screen

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.

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

Navigation: Click the ‘I Certify’ button to continue with submitting the form and proceed to the ‘Submission Process: Validation’ screen.

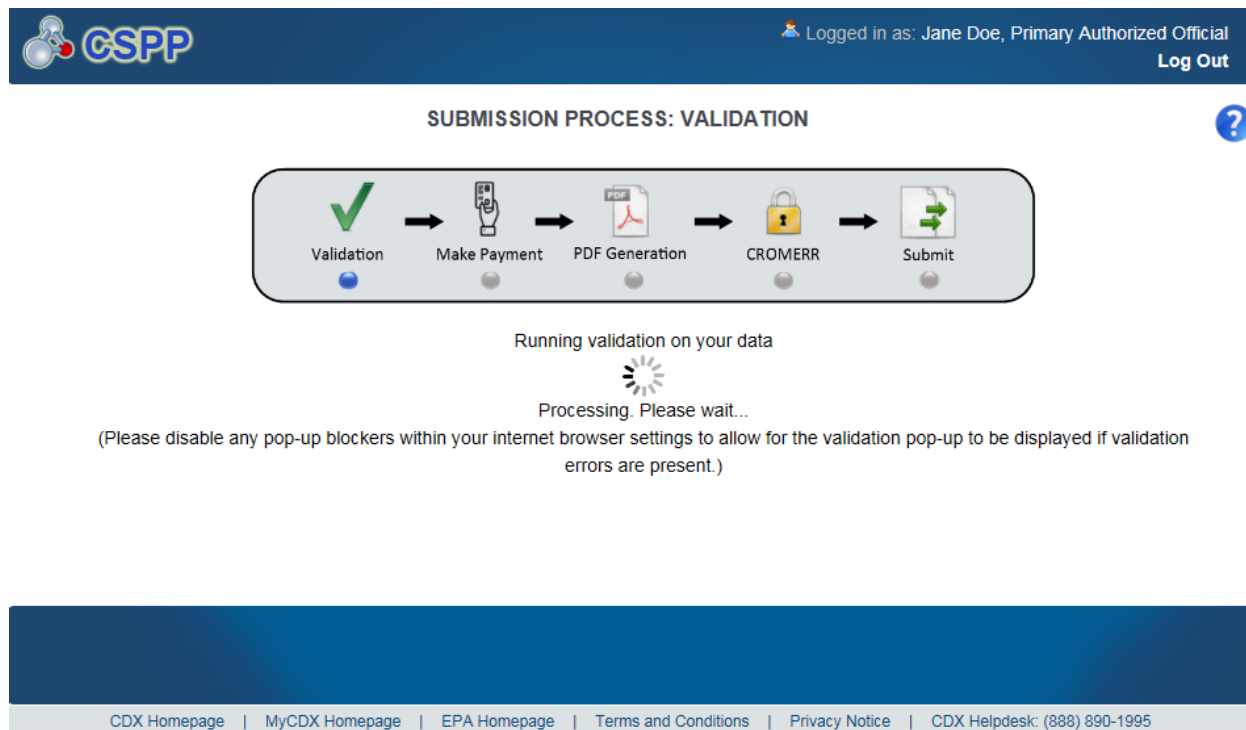
14.4 Submission Process: Validation

Click the ‘Submit’ icon () that is located in the bottom action bar of the Section 5 Notices and Supports form to begin the submission process and access the ‘Submission Process: Validation’ screen. You can also navigate to the validation step upon certifying applicable PMN forms by clicking the ‘I Certify’ button.

The first step in the submission process will validate the information entered within the Section 5 Notices and Supports form. After a form is validated, the system generates a PDF.

Exhibit 14-4 shows a screen capture of the ‘Submission Process: Validation’ screen:

Exhibit 14-4 Submission Process: Validation Screen



Navigation: The ‘Make A Payment’ page automatically displays for PMN forms with a ‘PMN,’ ‘SNUN,’ ‘LoREX,’ ‘LVE,’ or ‘TMEA’ subtype. The ‘Make A Payment’ page automatically displays for Biotechnology forms with a ‘MCAN,’ ‘TME,’ ‘Tier II Exemption,’ or ‘TERA’ subtype. The ‘Submission Process: PDF Generation’ page displays for all other form type/subtype combinations.

14.5 Submission Process: Make a Payment

After the application successfully validates a form, the ‘Make a Payment’ page displays for PMN forms with a ‘PMN,’ ‘SNUN,’ ‘LoREX,’ ‘LVE,’ ‘LoREX Modification,’ ‘LVE Modification,’ or ‘TMEA’ subtype, or for Biotech forms with a ‘MCAN,’ ‘TME,’ ‘Tier II Exemption,’ or ‘TERA’ subtype. If (a) secondary submitter(s) is/are identified, the ‘Payment Amount’ field is editable and the primary user can adjust the amount that he/she is responsible for, with the remaining balance being the responsibility of the joint submitter(s).

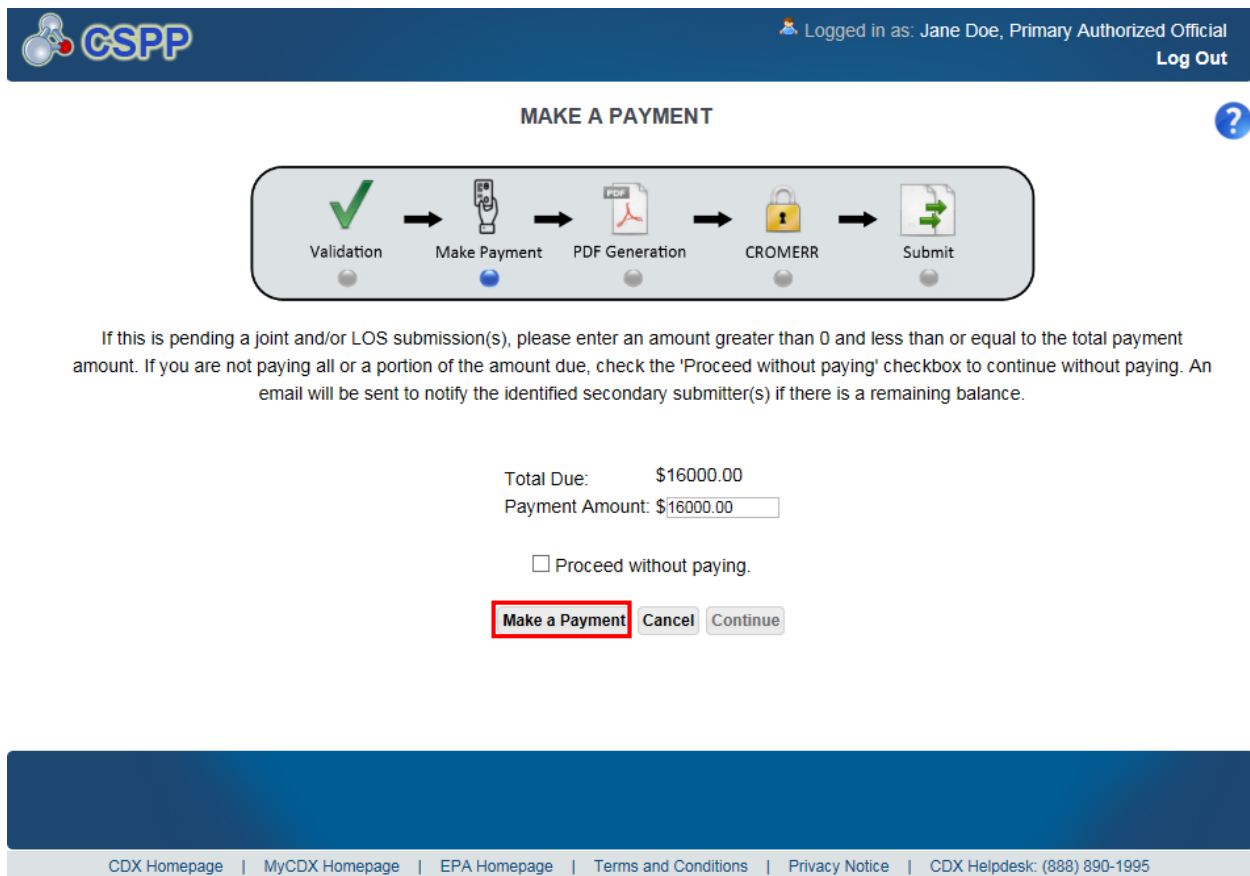
A primary user also has the option to continue without making a payment, in which case the secondary submitter(s) is/are responsible for the full payment amount.

- **Total Due:** This is a display-only field that reflects the total amount due for a primary and joint submitter(s) (if applicable).
- **Payment Amount:** If a joint submitter is not identified, this is a non-editable field. If (a) joint submitter(s) is/are identified, the value in this field can be modified. Enter an amount greater than zero (0) and less than or equal to the total displayed amount.

- **Proceed without paying:** Check the ‘Proceed without paying’ checkbox to hide the ‘Total Due’ and ‘Payment Amount’ fields and enable the ‘Continue’ button without paying any of the fee.
- **Make a Payment:** Click the ‘Make a Payment’ button to generate the ‘CSPP Payment Processor’ window with a payment amount equal to what is entered in the ‘Payment Amount’ field.
- **Cancel:** Click the ‘Cancel’ button to stop the payment process and exit the submission process.
- **Continue:** Click the ‘Continue’ button to proceed with the submission process without making a payment.

Exhibit 14-5 shows a screen capture of the ‘Make a Payment’ screen:

Exhibit 14-5 Make a Payment Screen



Navigation: Click the ‘Make a Payment’ button to generate the ‘CSPP Payment Processor’ window and pay the fee. Check the ‘Proceed without paying’ checkbox to enable the ‘Continue’ button to proceed with no payment and navigate to the ‘Submission Process: PDF Generation’ screen. Click the ‘Cancel’ button to stop the submission process.

14.6 CSPP Payment Processor

The 'CSPP Payment Processor' window provides functionality for you to remit your fee via debit/credit card or Automatic Clearing House (ACH) payment.

- **Credit/Debit Card:** Select the radio button to display the credit/debit card fields. This option is only available for payment amounts less than or equal to \$24,999.99.
- **Payment Amount:** Displays the fee amount the user will be paying.
- **Card Number:** Enter the credit/debit card number. This is a required field.
- **Expiration Date:** Select the month and date of the expiration date of the credit/debit card. This is a required field.
- **Security Code:** Enter the security code/CCV of the credit/debit card. This is a required field.
- **First Name:** Enter the first name of the cardholder. This is a required field.
- **Last Name:** Enter the last name of the cardholder. This is a required field.
- **Billing Address 1:** Enter line 1 of the billing address. This is a required field.
- **Billing Address 2:** Enter line 2 of the billing address, if applicable.
- **City:** Enter the city of the billing address. This is a required field.
- **State:** Select the state of the billing address from the drop-down menu. This is a required field.
- **Zip:** Enter the zip code of the billing address. This is a required field.
- **ACH Payment:** Select the radio button to display the ACH fields.
- **Account Type:** Select 'Business Checking,' 'Business Savings,' 'Personal Checking,' or 'Personal Savings' to indicate the account type that will be used to remit the fee. This is a required field.
- **Check Number:** Enter the check number.
- **Use a Company Name:** Check the check box to generate a 'Company Name' field and pay on behalf of the reporting company's name.
- **Company Name:** Enter the name of the company that is submitting the payment. This is a required field.
- **Routing Number:** Enter the routing number of the bank account. This is a required field.
- **Account Number:** Enter the account number of the bank account. This is a required field.
- **Confirm Account Number:** Re-enter the account number of the bank account. This is a required field.
- **Submit Payment:** Click the button to submit the payment credentials.

Exhibit 14-6 shows a screen capture of the 'CSPP Payment Processor' window (Credit/Debit Card):

Exhibit 14-6 CSPP Payment Processor (Credit/Debit Card)

CSPP PAYMENT PROCESSOR ✕

Payment Method

Credit/Debit Card ACH Payment

Payer Information

Payment Amount \$8000.00	Account Holder Name *
Card Number *	First Name
	Last Name
Expiration Date *	<input type="checkbox"/> Use a company name
01 / 2018	Billing Address *
Security Code *	Address 1*
	Address 2
	City/State/Zip Code *
	City
	AK Zip

Submit Payment

Exhibit 14-7 shows a screen capture of the 'CSPP Payment Processor' window (ACH Payment):

Exhibit 14-7 CSPP Payment Processor (ACH Payment)

CSPP PAYMENT PROCESSOR ✕

Payment Method

Credit/Debit Card ACH Payment

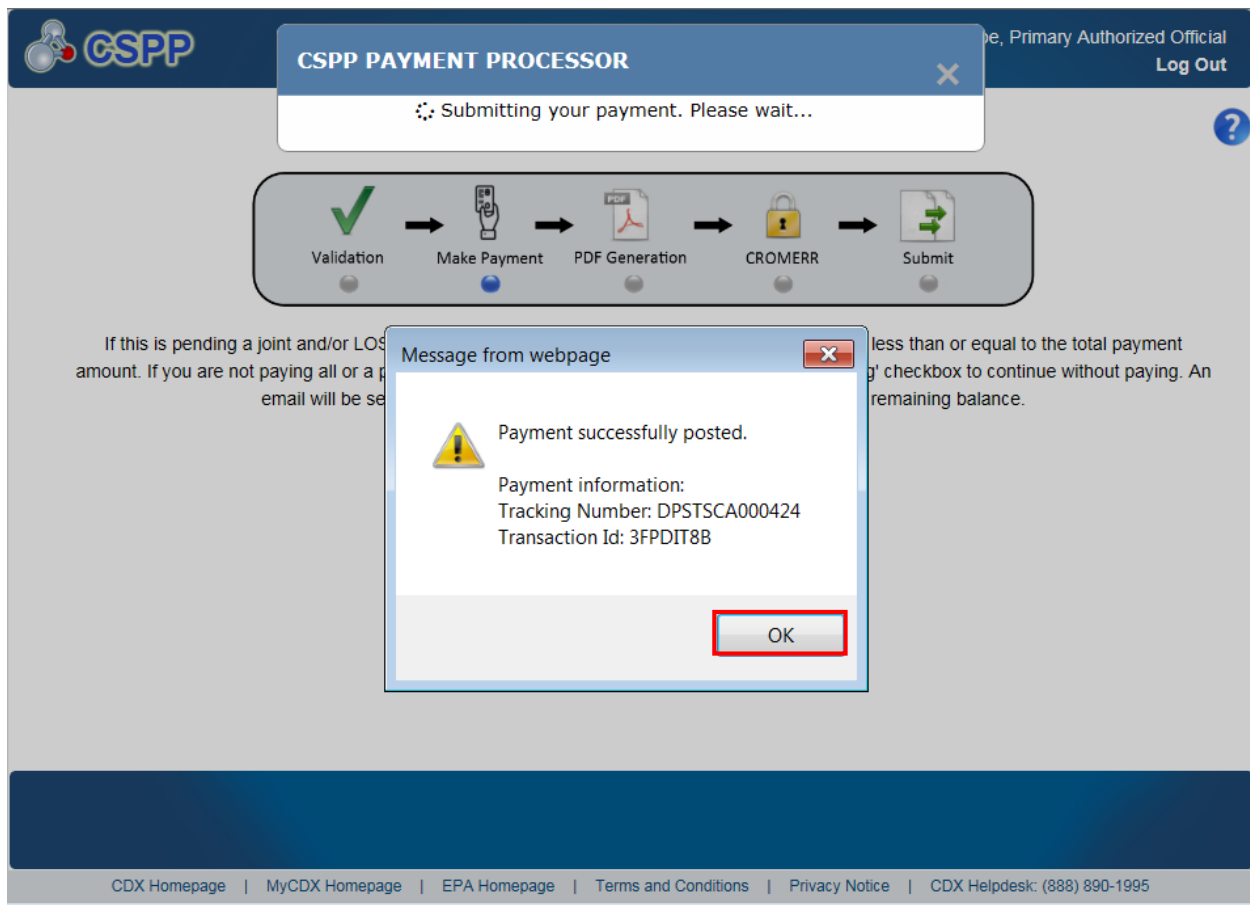
Bank Account Transaction

Payment Amount \$8000.00	Account Holder Name *
Account Type * Business Checking ▼	First Name <input type="text"/>
Check Number <input type="text"/>	Last Name <input type="text"/>
	<input type="checkbox"/> Use a company name
	Routing Number * <input type="text"/>
	Account Number * <input type="text"/>
	Confirm Account Number * <input type="text"/>

Submit Payment

Exhibit 14-8 shows a screen capture of the payment successful message:

Exhibit 14-8 Successful Payment






Navigation: Click the ‘Submit Payment’ button to submit the payment. The application displays a payment successful message and sends a payment receipt to the submitter. Click the ‘OK’ button on the payment successful message to return to the ‘Make A Payment’ screen.

14.7 Make a Payment

The ‘Make a Payment’ screen displays after a user has made a payment, or during the amendment process if a payment does not need to be made. If a user has made a payment, a payment receipt is emailed and sent to the submitter’s CDX inbox. If the submission is pending a secondary form, email(s) will be sent to the identified Joint/LOS submitter(s) reminding the secondary submitters of the payment responsibility once the submission process is completed.

Exhibit 14-9 shows a screen capture of the 'Payment Receipt' email:

Exhibit 14-9 Payment Receipt Email

 Reply  Reply All  Forward



Thu 9/13/2018 1:06 PM

noreply-dev <noreply-dev@epacdx.net>

Payment Receipt

To

Payment Receipt

Payee Information

- Jane Doe

Receipt Details

Your payment has been submitted.

- Date: 09/13/2018 1:05 PM
- Tracking Number: DPSTSCA000424

Total: \$8,000.00

Exhibit 14-10 shows a screen capture of the joint fee notification email:

Exhibit 14-10 Joint Fee Notification Email

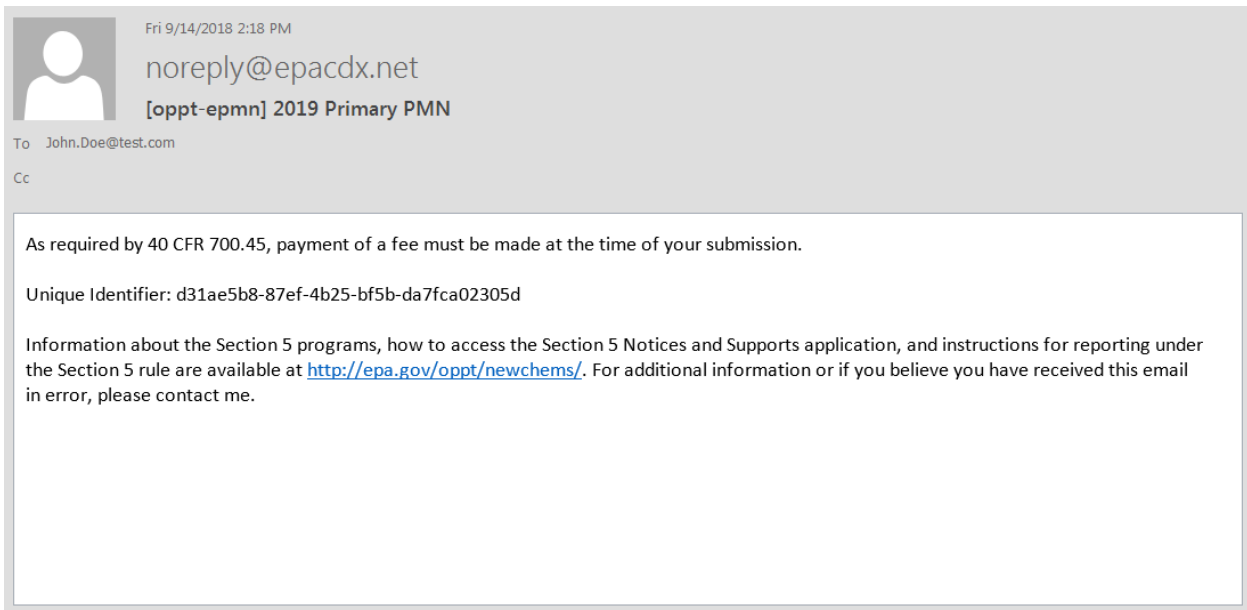


Exhibit 14-11 shows a screen capture of the ‘Make a Payment’ screen (Original after Paying):

Exhibit 14-11 Make a Payment Screen (Original after Paying)

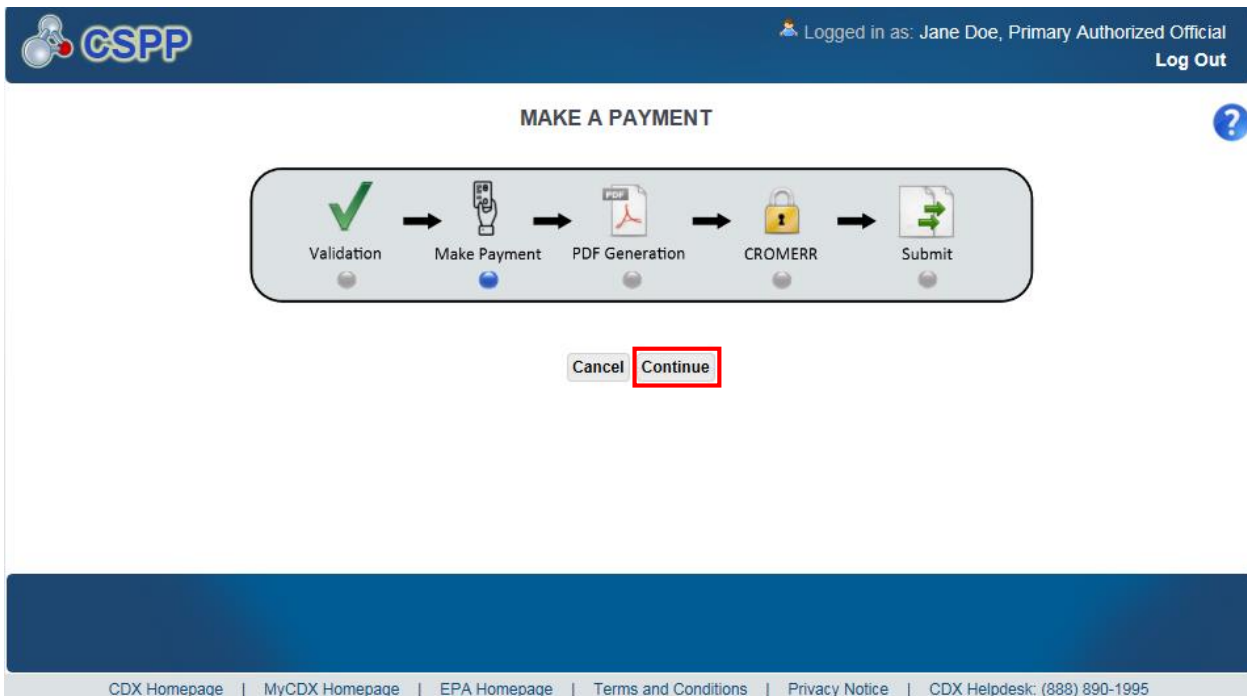
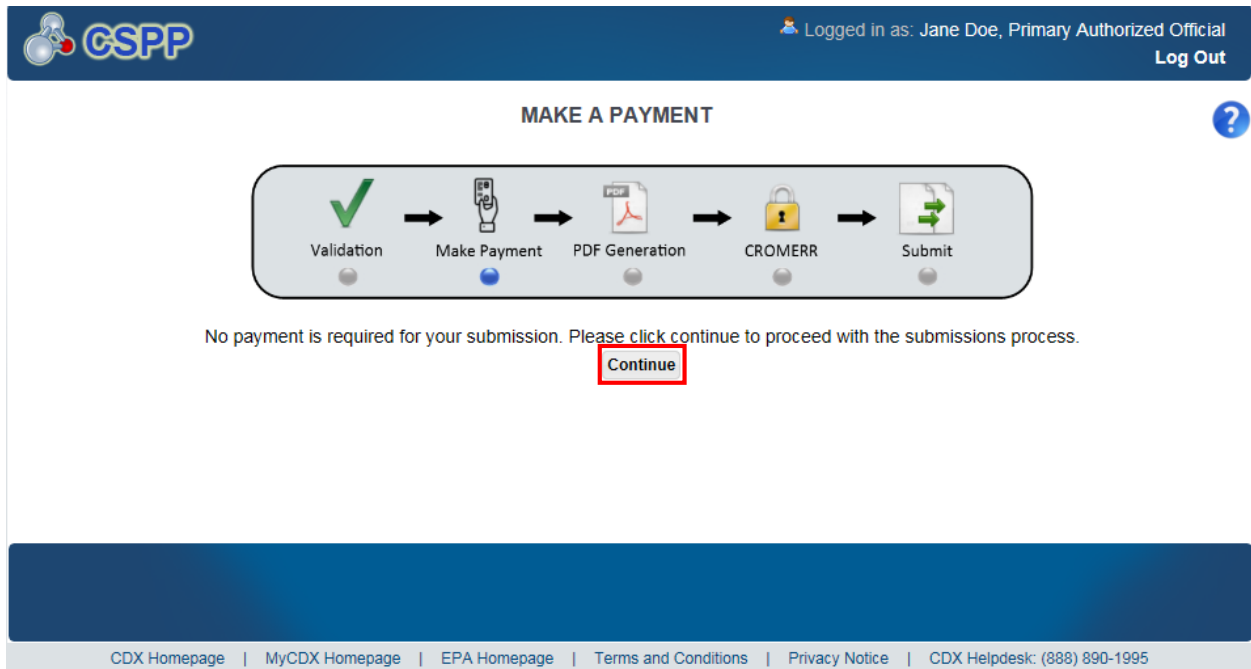


Exhibit 14-12 shows a screen capture of the ‘Make a Payment’ screen (Amendment):

Exhibit 14-12 Make a Payment Screen (Amendment)



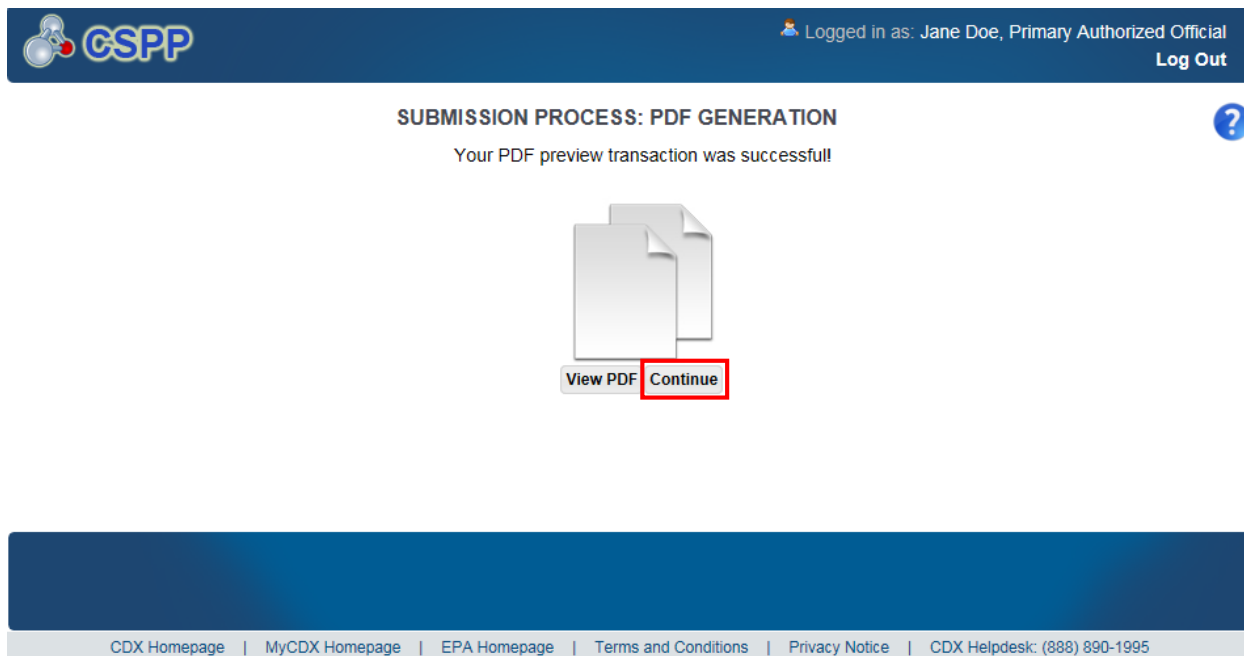
Navigation: Click the ‘Continue’ button to navigate to the ‘Submission Process: PDF Generation’ screen.

14.8 Cross-Media Electronic Reporting Regulation (CROMERR) Certification

The application generates the PDF after successfully validating a form or making a payment.

Exhibit 14-13 shows a screen capture of the ‘Submission Process: PDF Generation’ screen:

Exhibit 14-13 Submission Process: PDF Generation Screen



Navigation: Click the ‘Continue’ button to navigate to the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Certification’ screen.

14.9 Cross-Media Electronic Reporting Regulation (CROMERR) Certification

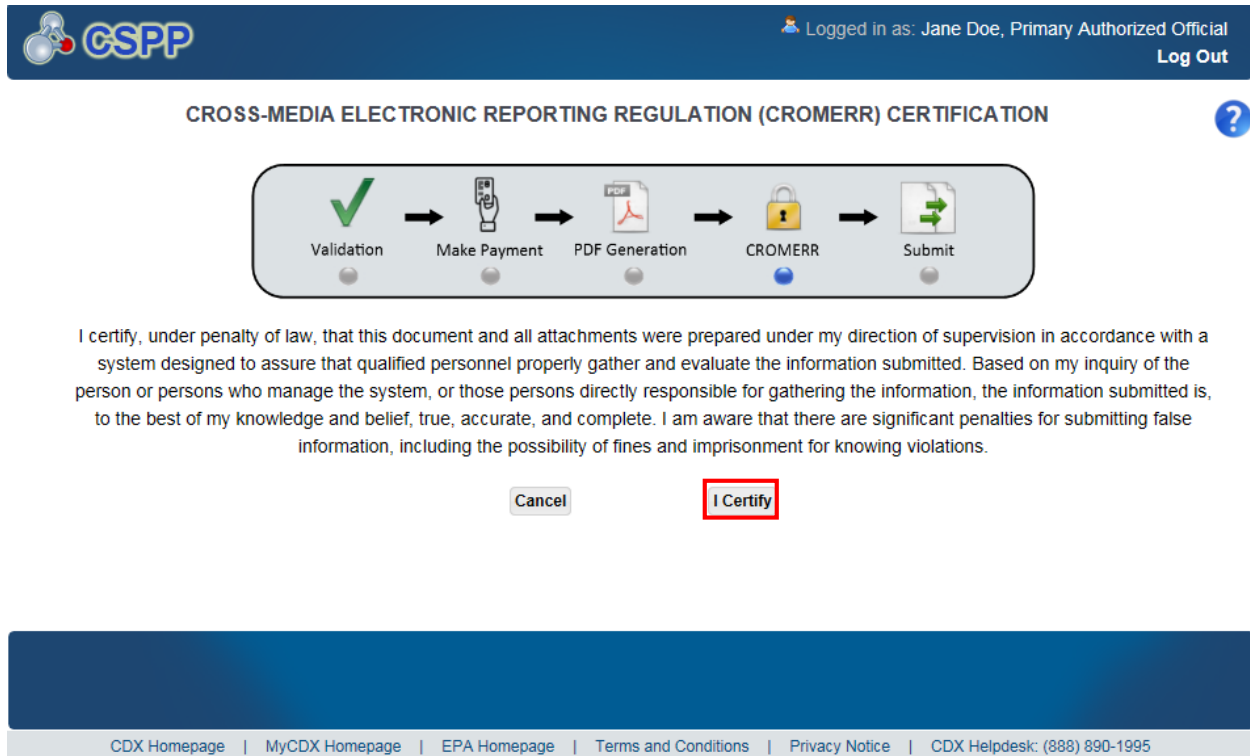
Click the ‘Continue’ button on the ‘Submission Process: PDF Generation’ screen to access the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Certification’ screen.

CROMERR provides the legal framework for electronic reporting under all of EPA’s environmental regulations.

After clicking the ‘Continue’ button, the system requires you to certify that the form is CROMERR compliant. By clicking the ‘I Certify’ button on the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Certification’ screen, you authenticate all of the information entered in the form. Click the ‘Cancel’ button to navigate back to the Section 5 Notices and Supports application.

Exhibit 14-14 shows a screen capture for the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Certification’ screen:

Exhibit 14-14 Cross-Media Electronic Reporting Regulation (CROMERR) Certification Screen



Navigation: Click the ‘I Certify’ button to continue with submitting the form and proceed to the ‘CROMERR Login’ screen.

14.10 Cross-Media Electronic Reporting Regulation (CROMERR) Login

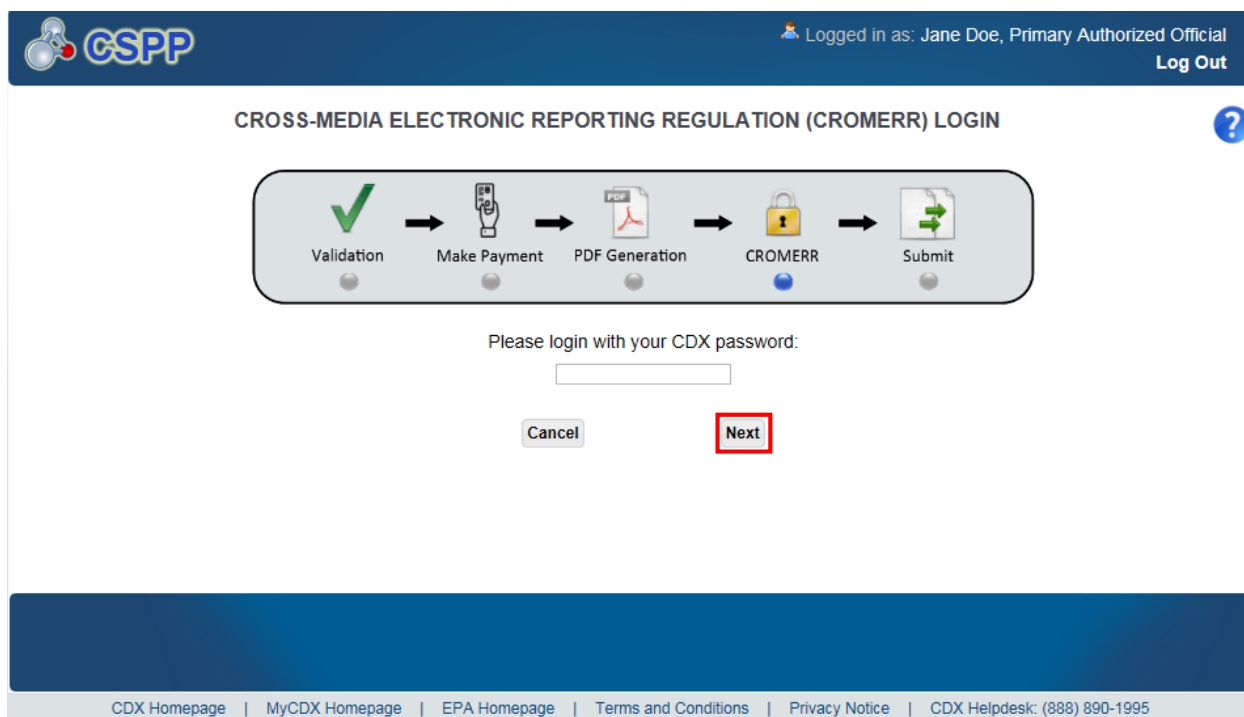
You can access the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Login’ screen by clicking the ‘I Certify’ button on the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Certification’ screen.

To proceed with the submission, log into CDX using the credentials you provided during CDX registration:

- **Please login with your CDX password:** Enter your CDX registration password.

Exhibit 14-15 shows a screen capture of the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Login’ screen:

Exhibit 14-15 Cross-Media Electronic Reporting Regulation (CROMERR) Login Screen



Navigation: Enter your CDX registration password and click the ‘Next’ button to navigate to the ‘CROMERR Security Question’ screen.

14.11 Cross-Media Electronic Reporting Regulation (CROMERR) Security Question

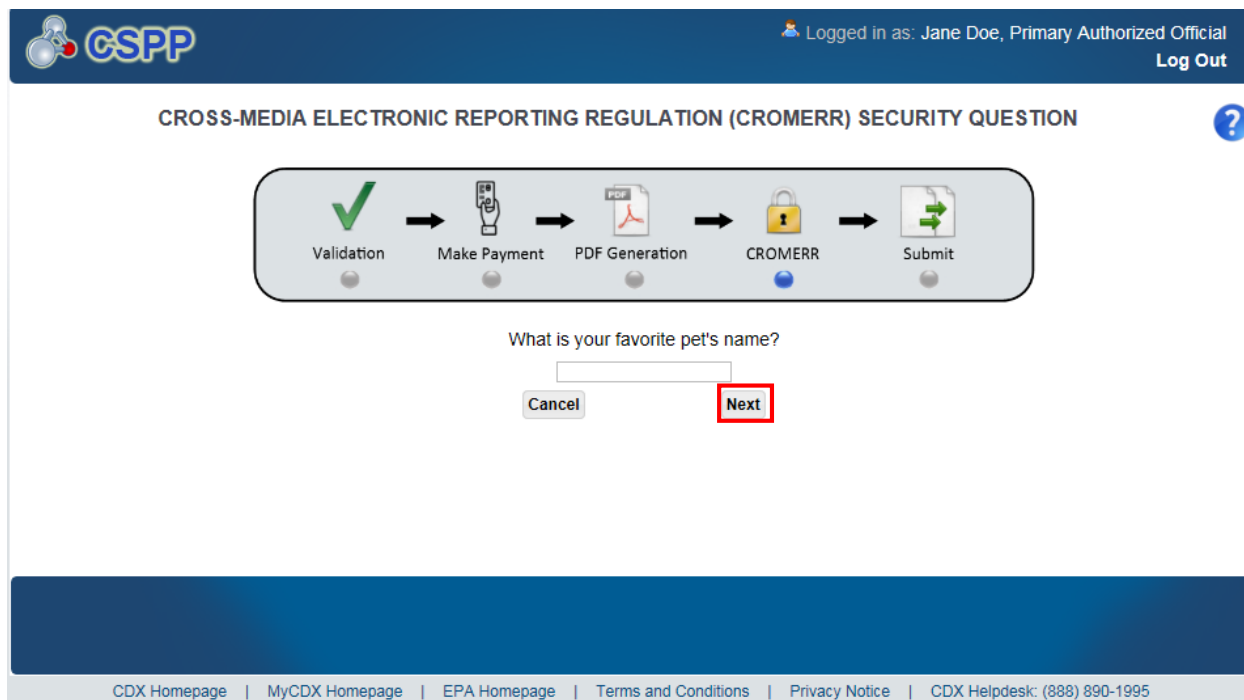
You can access the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen by entering your CDX registration password on the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Login’ screen and clicking the ‘Next’ button.

The ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen randomly selects and displays one of the five CROMERR eSIG-PIN questions you answered on the ‘20-5-1 Question’ screen during the initial login to CDX.

eSIG-PIN Authorization Code: Provide one of the five secret answers to the questions that were pulled from the list of 20 CDX security questions.

Exhibit 14-16 shows a screen capture of the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen:

Exhibit 14-16 Cross-Media Electronic Reporting Regulation (CROMERR) Security Question Screen



Navigation: Answer the security question and click the ‘Next’ button to navigate to the ‘Submit to CDX’ screen.

14.12 Submit to CDX

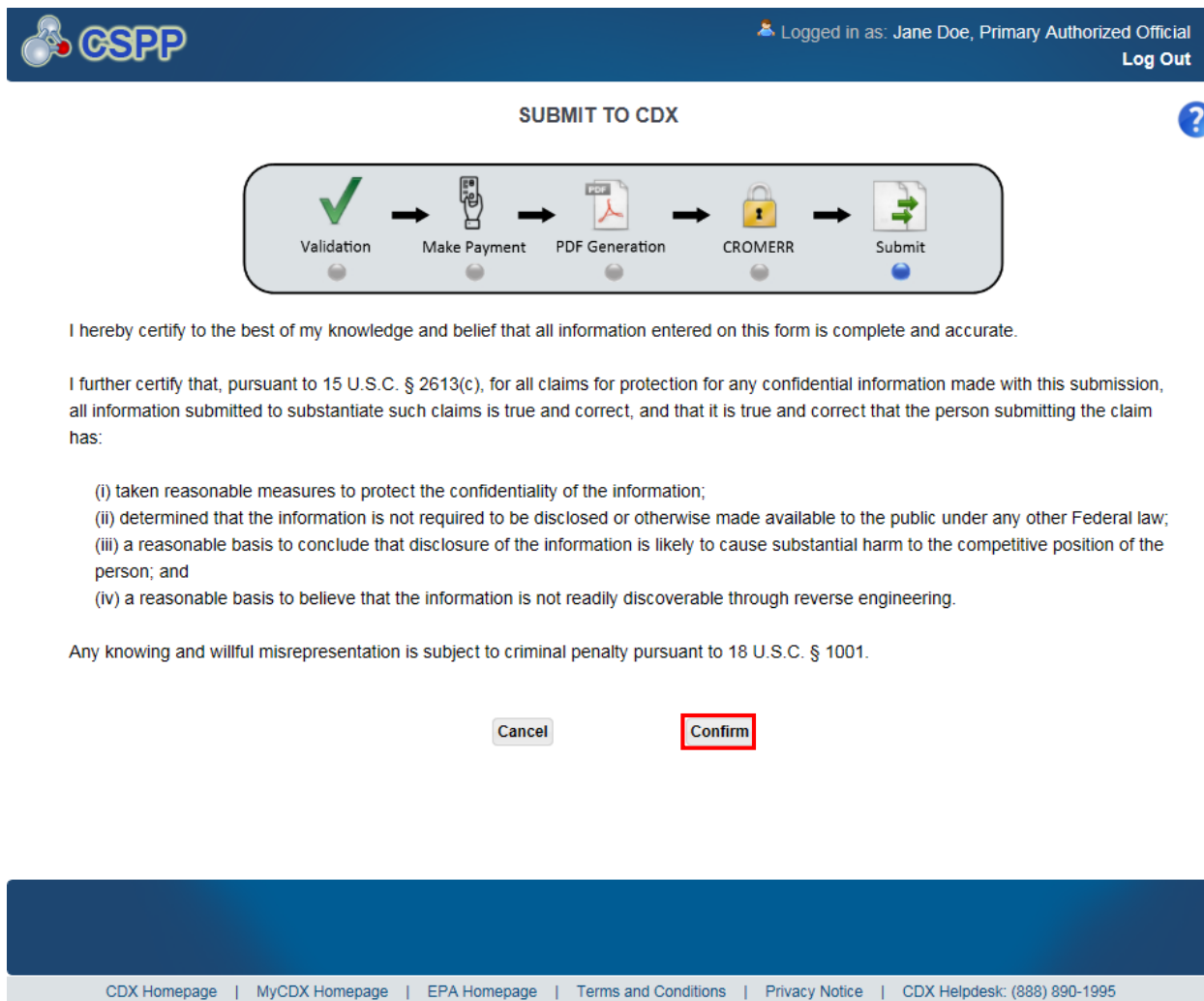
You can access the ‘Submit to CDX’ screen after answering the 20-5-1 security question on the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen and clicking the ‘Next’ button.

On the ‘Submit to CDX’ screen, you will see a certification message. Read the message and acknowledge by clicking the ‘Confirm’ button. Once you have clicked the ‘Confirm’ button, your form will be submitted to CDX.

This screen is only applicable to the original forms (PMN, NOC, Biotechnology, Bona Fide, and ACM). This screen will display during the submission process for joint submissions and Letters of Support. This screen is not applicable to Support forms and amendments to original submissions (with the exception of Biotechnology amendments).

Exhibit 14-17 shows a screen capture of the ‘Submit to CDX’ screen:

Exhibit 14-17 Submit to CDX Screen



Navigation: Click the ‘Confirm’ button to navigate to the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Submission’ screen.

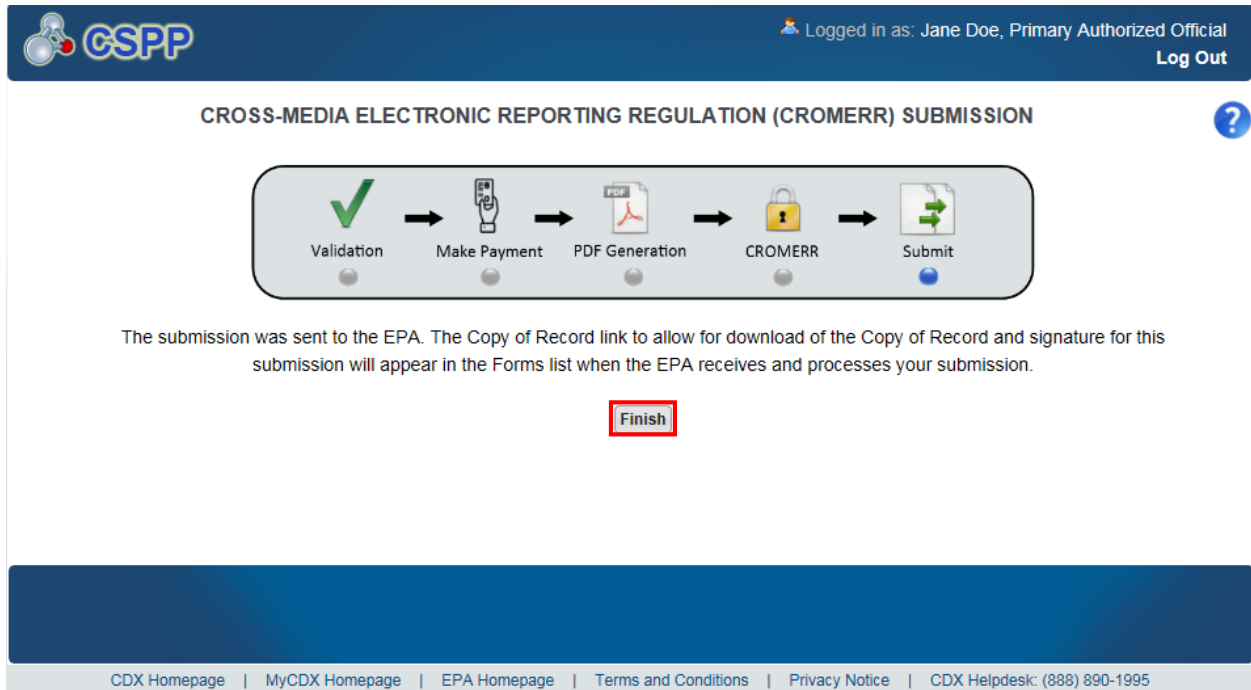
14.13 Cross-Media Electronic Reporting Regulation (CROMERR) Submission

You can access the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Submission’ screen by acknowledging the certification to submit to CDX by clicking the ‘Confirm’ button on the ‘Submit to CDX’ screen.

On the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Submission’ screen, you will see a message indicating the form has been successfully submitted to CDX.

Exhibit 14-18 shows a screen capture of the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Submission’ screen:

Exhibit 14-18 Cross-Media Electronic Reporting Regulation (CROMERR) Submission Screen



Navigation: Click the ‘Finish’ button to navigate back to the Section 5 Notices and Supports ‘Home’ screen. Click the ‘Forms’ link or tab to find your locked submission. The ‘Section 5 Notices and Supports Forms’ screen will display the submission with a ‘Lock’ icon (🔒) under the ‘Action’ column and will display a status of ‘Submitted.’

15 Download Copy of Record

To download a Copy of Record, navigate to the ‘Section 5 Notices and Supports Forms’ screen and locate a form alias for which you have successfully completed a submission and which has a status of ‘Submitted.’


Click the ‘Copy of Record’ icon () from the ‘Section 5 Notices and Supports Forms’ screen to navigate to the ‘Enter Passphrase’ screen to login into CDX. The ‘Enter Passphrase’ screen requires you to enter the passphrase originally associated with the form. If your passphrase is entered correctly, you will access the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Login’ screen where you are required to enter the credentials you provided during CDX registration. Once you have provided the correct CDX password, click the ‘Next’ button to navigate to the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen. The ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen randomly selects and displays one of the five CROMERR eSIG-PIN questions that you answered on the 20-5-1 Question screen during CDX registration. Answer the CROMERR security question and click the ‘OK’ button. If your answer was successful, you will be taken to the ‘Download Copy of Record’ screen.

Exhibit 15-1 shows a screen capture of the ‘Download Copy of Record’ screen:

Exhibit 15-1 Download Copy of Record Screen

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

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	<div style="border: 2px solid red; padding: 2px; display: inline-block;">Pay Your Invoice Now</div>

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The ‘Download Copy of Record’ screen displays the ‘File Name’ and ‘Action’ columns in a table format. Click the ‘Copy of Record’ icon () to download the individual files uploaded during the submission process, a PDF version of the submission, and the XML version of the Section 5 Notices and Supports form. When you click the ‘Copy of Record’ icon () , the system will allow you to view or download the individual files that were uploaded during the submission process.

After you click the 'Copy of Record' icon () , enter the passphrase associated with the case number, and click the 'Next' button. If the passphrase was correctly entered, the application will take you to the 'CROMERR Login' screen to enter the CDX password. If your login was successful, you will access the 'CROMERR Security Question' screen. The 'CROMERR Security Question' screen randomly selects and displays one of the five CROMERR eSIG-PIN questions that you answered on the 20-5-1 Question screen during the initial login to CDX. Answer the CROMERR security question and click the 'OK' button. If your answer was successful, you will navigate to the 'Download Copy of Record' screen.

The 'Fee Payment' table displays 'Payment Amount,' 'Payment Date,' 'Status,' 'Transaction ID,' and 'Tracking Number' columns.

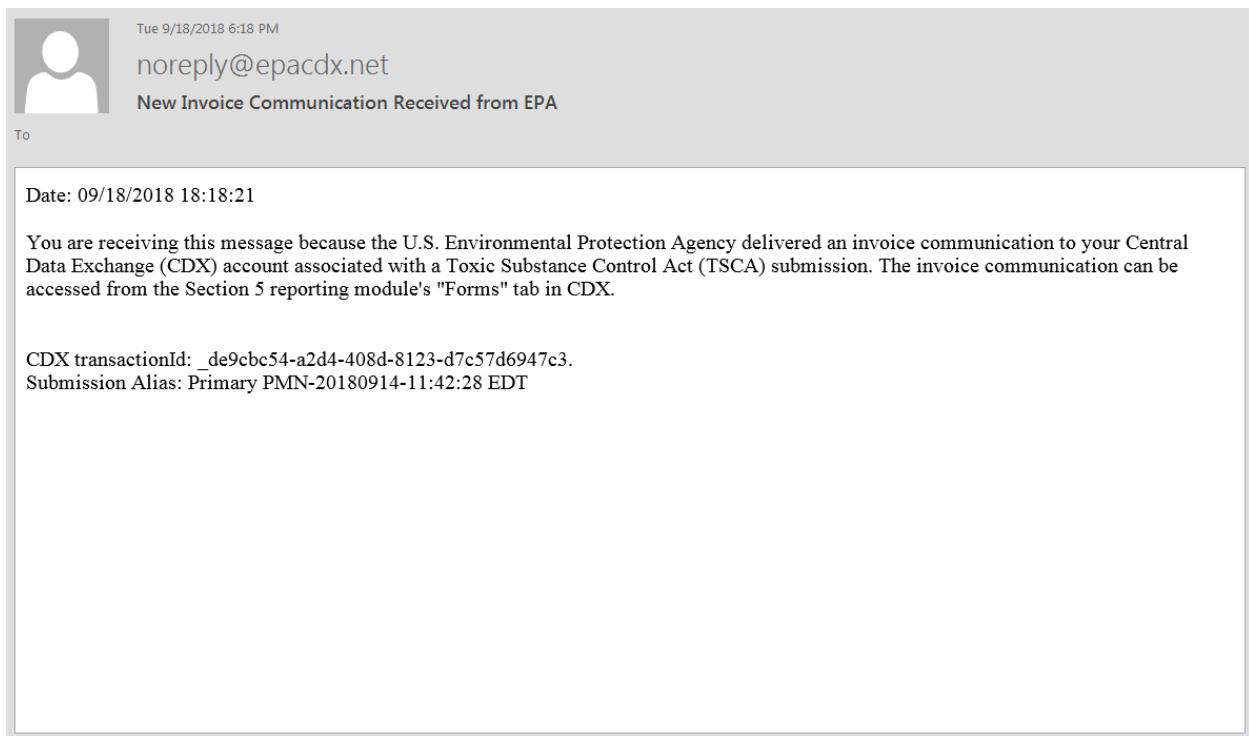
- **Payment Amount:** Displays the amount that a user paid for the PMN/Biotech fee.
- **Payment Date:** Displays the date that a payment is made.
- **Status:** Displays the status of the payment; can display a status of 'Paid.'
- **Transaction ID:** Displays the transaction ID of the payment that was made.
- **Tracking Number:** Displays the tracking number of the payment.

The 'Invoice Payment Documents' table displays 'Payment Communication Type,' 'File Name,' 'File Status,' 'Download,' 'Payment Amount,' 'Due Date,' 'Payment Status,' 'Payment Received Date,' and 'Make a Payment' columns.

- **Payment Communication Type:** Displays 'Invoice' or 'Cancelled Invoice.'
- **File Name:** Displays the file name of the fee invoice PDF.
- **File Status:** Displays an icon that indicates the status of the invoice; a closed envelope icon displays with a status of 'New Document' when a user initially accesses the 'Download Copy of Record' page.
- **Download:** Displays a green arrow for a user to download the invoice PDF.
- **Payment Amount:** Displays the amount of the invoice.
- **Due Date:** Displays the invoice due date.
- **Payment Status:** Displays the status of the payment; i.e. 'Unpaid,' 'Payment Received,' or 'Invoice Cancelled.' If the invoice has been cancelled by EPA personnel, the status displays 'Invoice Cancelled.'
- **Payment Received Date:** Displays the date of payment, if the invoice has been paid.
- **Make a Payment:** Displays a 'Pay Your Invoice Now' button; click the 'Pay Your Invoice Now' button to generate the 'CSPP Payment Processor' window to remit a payment to the invoice. The 'Pay Your Invoice Now' button is not displayed if a user has paid the invoice or the invoice was cancelled.

Exhibit 15-2 shows a screen capture of the Invoice Communication email:

Exhibit 15-2 Invoice Communication Email



The screenshot shows an email notification interface. At the top left is a grey square icon of a person. To its right, the text reads: "Tue 9/18/2018 6:18 PM", "noreply@epacdx.net", and "New Invoice Communication Received from EPA". Below this is a "To" label. The main body of the email is enclosed in a white box with a grey border. It starts with "Date: 09/18/2018 18:18:21". The main text says: "You are receiving this message because the U.S. Environmental Protection Agency delivered an invoice communication to your Central Data Exchange (CDX) account associated with a Toxic Substance Control Act (TSCA) submission. The invoice communication can be accessed from the Section 5 reporting module's 'Forms' tab in CDX." Below this, it lists: "CDX transactionId: _de9cbc54-a2d4-408d-8123-d7c57d6947c3." and "Submission Alias: Primary PMN-20180914-11:42:28 EDT".

Exhibit 15-3 shows a screen capture of the Fee Invoice:

Exhibit 15-3 Fee Invoice PDF



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON D.C. 20460

September 29, 2018

Office of
Chemical Safety and
Pollution Prevention

Fee Invoice

Jane Doe
TEST ORGANIZATION LLC
1025 LEESBURG PIKE
FALLS CHURCH, VA 22033 US

Subject: Fee Invoice Notice

Dear Submitter,

As required by 40 CFR 700.45, your organization is subject to a fee in the amount of \$5,000.00 for your Section 5 submission. Payment in full is due by December 28, 2018.

You may make a payment by clicking the Pay Your Invoice Now button on the Copy of Record screen within the TSCA Section 5 application. To access the Copy of Record screen, click the payment communication icon associated with your submission within the TSCA Section 5 application in CDX.

CBI	Case Number	Chemical ID
N	P-18-0006	70248-10-1 - Silicate(2-), hexafluoro-, ammonium (1:2), reaction products with silica

Exhibit 15-4 shows a screen capture of the CSPP Payment Processor (Credit/Debit Card):

Exhibit 15-4 CSPP Payment Processor (Credit/Debit Card)

CSPP Payment Processor

Payment Method

Credit/Debit Card ACH Payment

Payer Information

Payment Amount \$10000	Account Holder Name * First Name Last Name <input type="checkbox"/> Use a company name
Card Number * <input type="text"/>	Billing Address * Address 1* Address 2
Expiration Date * 01 / 2018	City/State/Zip Code * City AK Zip
Security Code * <input type="text"/>	

Submit Payment

Exhibit 15-5 shows a screen capture of the CSPP Payment Processor (ACH Payment):

Exhibit 15-5 CSPP Payment Processor (ACH Payment)

CSPP Payment Processor ✕

Payment Method

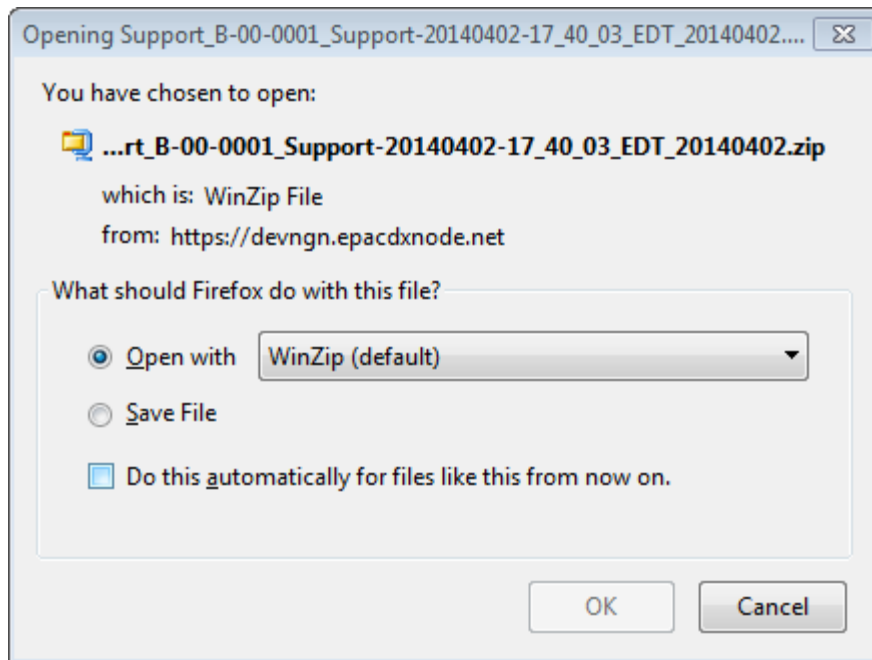
Credit/Debit Card ACH Payment

Bank Account Transaction

Payment Amount \$10000	Account Holder Name * <input type="text" value="First Name"/>
Account Type * <input type="text" value="Business Checking"/> ▼	<input type="text" value="Last Name"/>
Check Number <input type="text"/>	<input type="checkbox"/> Use a company name
	Routing Number * <input type="text"/>
	Account Number * <input type="text"/>
	Confirm Account Number * <input type="text"/>

Exhibit 15-6 shows a screen capture of the ‘Download Prompt’ window (this may appear differently depending on the browser used):

Exhibit 15-6 Download Prompt Window



If you click the ‘Copy of Record’ icon (↓) you will download:


- A PDF version of the Section 5 Notices and Supports form
- An XML version of the Section 5 Notices and Supports form
- The documents attached to a Section 5 Notices and Supports form

16 EPA Communications

EPA may send electronic communications related to specific CDX submissions. In the event EPA sends an electronic communication, the original submitter will receive a notification to both their registered email address and inbox within CDX. The notification will inform the user that there is a new, submission-specific communication available from EPA.

Exhibit 16-1 shows a screen capture of a sample Notice of Deficiency (Email Notification) from CDX:

Exhibit 16-1 New EPA Communication Email Notification



Thu 10/4/2018 11:22 AM

noreply@epacdx.net

Notice of Deficiency for CBI Claims or a Generic Chemical Name in a TSCA Submission from U.S. EPA

To

Date: 10/04/2018 11:22:03

You have received a new Notice of Deficiency Concerning CBI Claims or a Generic Chemical Name in a TSCA Submission communication in your CDX account from the U.S. EPA related to CDX transactionId: _5fdb17a4-a340-48a6-bf96-f5d7f59f7966.

If you can identify your TSCA submission using this CDX transaction ID, originally provided with the 'Copy of Record' XML file, you can use this identifier to quickly access the communication by following these steps:

1. Log into CDX.
2. Navigate to the appropriate CSPP module for the submission related to CDX transactionId: _5fdb17a4-a340-48a6-bf96-f5d7f59f7966. You will need to know the submission type related to previously referenced transactionID before selecting the CSPP module.
3. Select the Forms/Submissions tab or link to view the table of submissions.
4. Locate the submission related to CDX transactionId: _5fdb17a4-a340-48a6-bf96-f5d7f59f7966. Performing a 'Find' operation by clicking 'Ctrl+F' and entering either the related case number or submission alias is an easy way to locate the submission if you have many in your table.
5. After you locate the related submission, click on the envelope icon found in the Action column at the end of the submission row.
6. Follow the steps to access the Copy of Record.
7. Click on the green download arrow for the desired communication within the 'Download EPA Communications' section.

If you cannot identify your submission using this CDX transaction ID, you can obtain more information about how to access this communication by following these steps:

1. Log into CDX.
2. Click on the 'Inbox' tab from your 'My CDX Screen' from your 'My CDX Screen'.
3. Search your CDX inbox for a message with the same subject line as this email. This message will provide additional instructions for accessing the Notice of Deficiency communication.

Exhibit 16-2 shows a screen capture of a sample CDX Inbox Notification:

Exhibit 16-2 New EPA Communication CDX Inbox Notification

Home
About
Recent Announcements
Terms and Conditions
FAQ
Help

Central Data Exchange

[Contact Us](#)
 Logged in as JANEDOEOPPT ([Log out](#))

MyCDX
Inbox
My Profile
Role Sponsorship
Submission History
Payment History
E-Enterprise Portal

Notice of Deficiency for CBI Claims or a Generic Chemical Name in a TSCA Submission from U.S. EPA

From noreply@epacdx.net

Date 10/4/2018 11:22:03 AM

Date: 10/04/2018 11:22:03

You have received a Notice of Deficiency communication from the EPA regarding your TSCA Section 5 submission. You can retrieve this communication by following these steps:

1. Copy the submission alias identified below.
2. Navigate to the appropriate CSPP module for the TSCA section indicated.
3. Select the Forms/Submissions tab or link to view the table of submissions.
4. Perform a 'Find' operation by clicking 'Ctrl+F'.
5. Paste Submission Alias 'Joint PMN-20180930-12:06:52 EDT' into the navigation box and click return. The submission alias will be highlighted.
6. Click on the envelope icon found in the Action column at the end of the submission row.
7. Follow the steps to access the Copy of Record.
8. Click on the green download arrow for the desired communication within the 'Download EPA Communications' section.

If you have any difficulty locating the communication, please refer to the 'EPA Communications' section of the application user guides found in the 'Resources' tabs provided in each CSPP module or contact the CDX helpdesk between 8:00 am to 6:00 pm (EST/EDT) at 888-890-1995 (Domestic) or (970) 494-5500 (International callers).

Back to Inbox
Print
Delete

Users can access EPA communications by logging into CDX and navigating to the CSPP application to which a communication applies. Within the Section 5 Notices and Supports application, users should navigate to the 'Section 5 Notices and Supports Forms' screen, to access EPA communications. A 'Closed Envelope' icon () appears under the 'Action' column for a submission that contains a new EPA communication, and an 'Open Envelope' icon () displays for a submission that contains a previously downloaded EPA communication. To access a communication, click either the 'Closed Envelope,' 'Open Envelope,' or 'Copy of Record' icon. To ensure EPA communications are not improperly viewed, access to EPA communications is restricted to users who may access the copy of record for a submission. Additionally, EPA captures and stores CDX user and timestamp data each time an EPA communication is accessed.

Exhibit 16-3 shows a screen capture of the ‘Section 5 Notices and Supports Forms’ screen:

Exhibit 16-3 Section 5 Notices and Supports Forms Screen

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 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

Navigation: Click the ‘Closed Envelope,’ ‘Open Envelope,’ or ‘Copy of Record’ icon to navigate to the ‘Enter Passphrase’ screen.

Exhibit 16-4 shows a screen capture of the ‘Enter Passphrase’ screen:

Exhibit 16-4 Enter Passphrase Screen

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](#)

Navigation: Enter the passphrase associated to this submission and click the ‘Next’ button to navigate to the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Login’ screen.

Exhibit 16-5 shows a screen capture of the ‘CROMERR Login’ screen:

Exhibit 16-5 Cross-Media Electronic Reporting Regulation (CROMERR) Login Screen



CDXweb logo

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

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Navigation: Enter your CDXweb password and click the ‘OK’ button to navigate to the ‘CROMERR Security Question’ screen.

Exhibit 16-6 shows a screen capture of the ‘CROMERR Security Question’ screen:

Exhibit 16-6 Cross-Media Electronic Reporting Regulation (CROMERR) Security Question Screen



Navigation: The ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen randomly selects and displays one of the five CROMERR eSIG-PIN questions that you answered on the 20-5-1 question screen during CDX registration. Answer the CROMERR security question and click the ‘OK’ button to navigate to the ‘Download Copy of Record’ screen.

The ‘Download Communication Documents’ table is located at the bottom of the ‘Download Copy of Record’ screen and displays EPA communications associated with all versions of the selected submission. The ‘Download Communication Documents’ table includes the following columns of information:

- **Communication Type:** Displays the type of EPA communication.
- **File Name:** Displays the file name of the EPA communication.
- **File Size:** Displays the file size of the EPA communication.

- **Status:** Displays the status of the EPA communication. The ‘Closed Envelope’ icon (📁) indicates an un-accessed EPA communication, and the ‘Open Envelope’ icon (📧) indicates an accessed EPA communication.

- **Download:** Click the ‘Download’ icon (⬇️) to download an EPA communication. The communication file downloads as a PDF.

Exhibit 16-7 shows a screen capture of the ‘Download Copy of Record’ screen:

Exhibit 16-7 Download Copy of Record Screen

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

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
Deficiency or Notice to Comment (Substantiation)	CdxCommunication5a49fba-47ab-4d77-a903-805778ee76ac.pdf	104522	📁	⬇️

Fee Payment:

Payment Amount	Payment Date	Status	Transaction ID	Tracking Number
\$8,000.00	2018-09-13	Paid	3FPDIT8B	DPSTSCA000424

Invoice Payment Documents:

Payment Communication Type	File Name	File Status	Download	Payment Amount	Due Date	Payment Status	Payment Received Date	Make a Payment

[Home](#)

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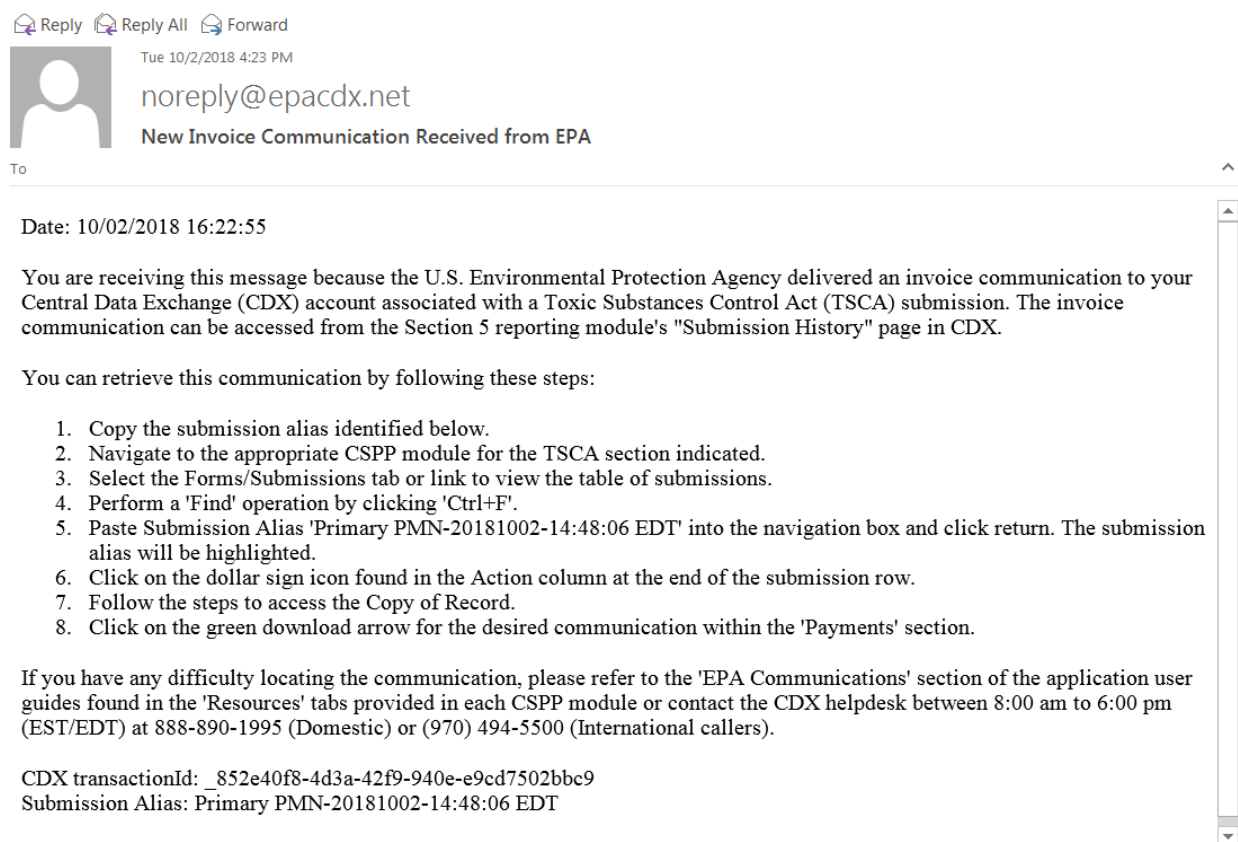
Navigation: Click the ‘Download’ icon (↓) under the ‘Download Communication Documents’ table to download an EPA communication file. Click the ‘Home’ button to return to the Section 5 Notices and Supports ‘Home’ screen.




16.1 Invoice Communications


EPA may send an invoice communication related to a specific CDX submission. In the event EPA sends an electronic communication, the original submitter will receive a notification to both their registered email address and inbox within CDX. The notification will inform the user that there is a new, submission-specific invoice communication sent from EPA.

Exhibit 16-8 shows a screen capture of the email for EPMN Invoices:

Exhibit 16-8 Invoice Communication Email



 Reply
  Reply All
  Forward


 Tue 10/2/2018 4:23 PM
 noreply@epacdx.net
New Invoice Communication Received from EPA

To

Date: 10/02/2018 16:22:55

You are receiving this message because the U.S. Environmental Protection Agency delivered an invoice communication to your Central Data Exchange (CDX) account associated with a Toxic Substances Control Act (TSCA) submission. The invoice communication can be accessed from the Section 5 reporting module's "Submission History" page in CDX.

You can retrieve this communication by following these steps:

1. Copy the submission alias identified below.
2. Navigate to the appropriate CSPP module for the TSCA section indicated.
3. Select the Forms/Submissions tab or link to view the table of submissions.
4. Perform a 'Find' operation by clicking 'Ctrl+F'.
5. Paste Submission Alias 'Primary PMN-20181002-14:48:06 EDT' into the navigation box and click return. The submission alias will be highlighted.
6. Click on the dollar sign icon found in the Action column at the end of the submission row.
7. Follow the steps to access the Copy of Record.
8. Click on the green download arrow for the desired communication within the 'Payments' section.

If you have any difficulty locating the communication, please refer to the 'EPA Communications' section of the application user guides found in the 'Resources' tabs provided in each CSPP module or contact the CDX helpdesk between 8:00 am to 6:00 pm (EST/EDT) at 888-890-1995 (Domestic) or (970) 494-5500 (International callers).

CDX transactionId: _852e40f8-4d3a-42f9-940e-e9cd7502bbc9
 Submission Alias: Primary PMN-20181002-14:48:06 EDT

Exhibit 16-9 shows a screen capture of the CDX Inbox text for EPMN Invoices:

Exhibit 16-9 CDX Inbox Invoice Communication

logged in as [username] | [logout](#)

[MyCDX](#) | **[Inbox](#)** | [My Profile](#) | [Role Sponsorship](#) | [Submission History](#) | [Payment History](#) | [E-Enterprise Portal](#)

New Invoice Communication Received from EPA

From noreply@epacdx.net

Date 10/3/2018 3:20:01 PM

Date: 10/03/2018 15:20:01

You are receiving this message because the U.S. Environmental Protection Agency delivered an invoice communication to your Central Data Exchange (CDX) account associated with a Toxic Substances Control Act (TSCA) submission. The invoice communication can be accessed within the Section 5 reporting module. You can retrieve this communication by following these steps:

1. Copy the submission alias identified below.
2. Navigate to the appropriate CSPP module for the TSCA section indicated.
3. Select the Forms/Submissions tab or link to view the table of submissions.
4. Perform a 'Find' operation by clicking 'Ctrl+F'.
5. Paste Submission Alias 'Primary PMN-20180930-10:51:56 EDTPMN' into the navigation box and click return. The submission alias will be highlighted.
6. Click on the dollar sign icon found in the Action column at the end of the submission row.
7. Follow the steps to access the Copy of Record.
8. Click on the green download arrow for the desired communication within the 'Payments' section.

If you have any difficulty locating the communication, please refer to the 'EPA Communications' section of the application user guides found in the 'Resources' tabs provided in each CSPP module or contact the CDX helpdesk between 8:00 am to 6:00 pm (EST/EDT) at 888-890-1995 (Domestic) or (970) 494-5500 (International callers).

CDX transactionId: _e918a99f-1706-499d-bc89-741945c2ebbe
Submission Alias: Primary PMN-20180930-10:51:56 EDTPMN

[Back to Inbox](#) | [Print](#) | [Delete](#)

17 Create An Amendment

To amend a submitted Section 5 Notices and Supports form, navigate to the ‘Section 5 Notices and Supports Forms’ screen and locate a submission that you previously submitted with a status of ‘Submitted.’ In addition to displaying a status of ‘Submitted’ under the ‘Status’ column, the ‘Lock’ icon (🔒) will be displayed under the ‘Action’ column. Click the ‘Lock’ icon (🔒) under the ‘Action’ column to start an amendment.

Exhibit 17-1 shows a screen capture of the ‘Section 5 Notices and Supports Forms’ screen:

Exhibit 17-1 Section 5 Notices and Supports Forms Screen - Amendment

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.

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

Items Per Page: 25

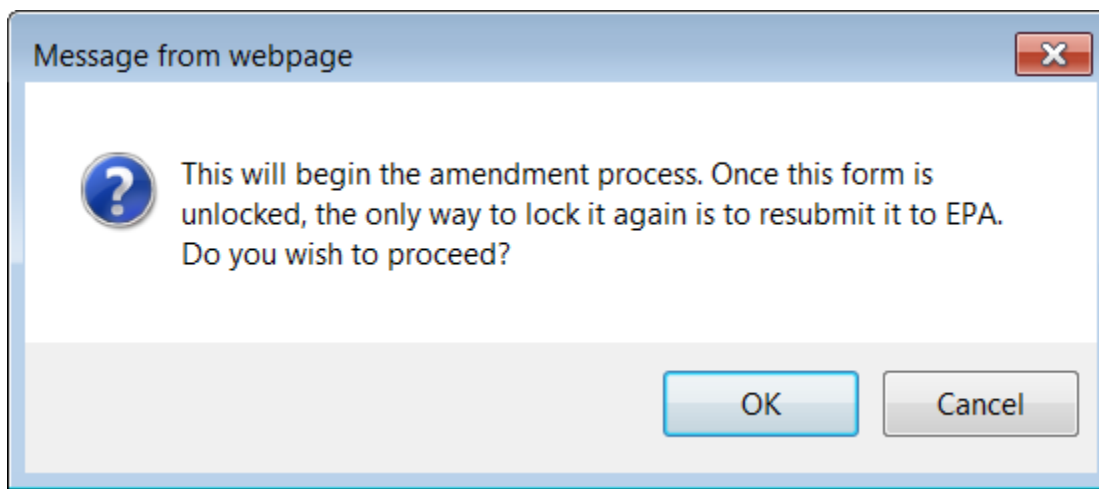
Alias	Type	Subtype	Case Number	Status	Modify Date	Submission Date	Action
Primary PMN-20180907-13:44:14 EDT	Primary PMN	PMN	P-18-0342	Submitted	09/07/2018	09/07/2018	⬇️ 🔒
Primary PMN-20180918-16:42:41 EDT	Primary PMN	TMEA		In Progress	09/18/2018		✖️
Primary PMN-20170712-16:25:43 EDT	Primary PMN	PMN		In 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		✖️

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Navigation: After clicking the ‘Lock’ icon (🔒), a prompt will display to confirm the amendment process. If you do not want to continue with the amendment, click the ‘Cancel’ button to cancel the amendment process and return to the ‘Section 5 Notices and Supports Forms’ screen. Click the ‘OK’ button to close the prompt and continue with the amendment.

Exhibit 17-2 shows a screen capture of the ‘Unlock Prompt’ message:

Exhibit 17-2 Unlock Prompt Message



After you click the ‘OK’ button, you will be taken to the ‘Enter Passphrase’ screen. You must enter the passphrase originally associated with the submission to start the amendment process. After you enter the passphrase and click the ‘Next’ button, you will be taken to the first screen in the specific Section 5 Notices and Supports form. Refer to **Section 3.7** for further instructions on the ‘Enter Passphrase’ screen.

After a submission has been unlocked, the ‘Section 5 Notices and Supports Forms’ screen will display a status of ‘In Progress’ under the ‘Status’ column, and the ‘Unlocked’ icon (🔓) will display under the ‘Action’ column; however, you will not see these changes until you navigate back to the ‘Section 5 Notices and Supports Forms’ screen.

- Refer to **Section 4.1.1** through **Section 4.1.36** for instructions on editing a revised PMN form.
- Refer to **Section 5.1.1** through **Section 5.1.12** for instructions on editing a revised Biotechnology form.
- Refer to **Section 6.1.1** through **Section 6.1.9** for instructions on editing a revised NOC form.
- Refer to **Section 7.1.1** through **Section 7.1.3** for instructions on editing a revised Support form.
- Refer to **Section 8.1.1** through **Section 8.1.17** for instructions on editing a revised Bona Fide form.
- Refer to **Section 9.1.1** through **Section 9.1.3** for instructions on editing a revised ACM form.

18 Resources

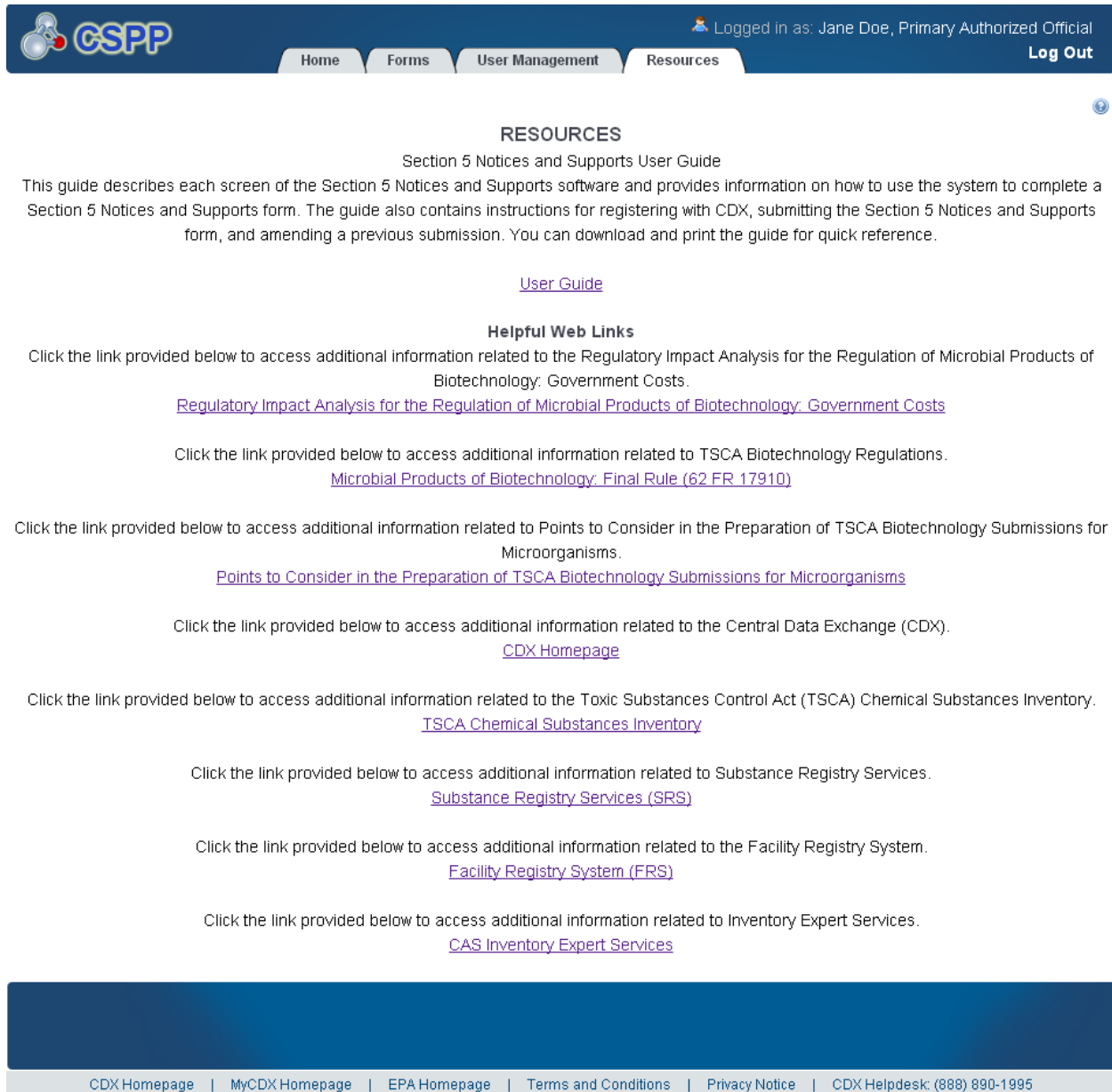
You can access the ‘Resources’ screen by clicking the ‘Resources’ tab located at the top of the screen at any time during the submission process. You can also access the ‘Resources’ screen by clicking the ‘Resources’ link from the Section 5 Notices and Supports ‘Home’ screen. The ‘Resources’ screen provides you with links to the appropriate Section 5 Notices and Supports user guides as well as additional helpful links. Click the ‘User Guide’ link to access the Section 5 Notices and Supports user guide document.

- **Regulatory Impact Analysis for the Regulation of Microbial Products of Biotechnology: Government Costs:** Click this link to generate the ‘Regulatory Impact Analysis for the Regulation of Microbial Products of Biotechnology: Government Costs’ screen in a new browser window.
- **Microbial Products of Biotechnology: Final Rule (62 FR 17910):** Click this link to generate the ‘Microbial Products of Biotechnology: Final Rule (62 FR 17910)’ screen in a new browser window.
- **Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms:** Click this link to generate the ‘Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms’ PDF in a new browser window.
- **CDX Homepage:** Click this link to generate the CDX Homepage in a new browser window.
- **TSCA Chemical Substances Inventory:** Click this link to generate the ‘TSCA Chemical Substances Inventory’ screen in a new browser window.
- **Substance Registry Services (SRS):** Click this link to generate the ‘Substance Registry Services (SRS)’ screen in a new browser window.
- **Facility Registry System (FRS):** Click this link to generate the ‘Facility Registry System (FRS)’ screen in a new browser window.
- **CAS Inventory Expert Services:** Click this link to generate the ‘CAS Inventory Expert Services (IES)’ screen in a new browser window.
- **National Pollutant Discharge Elimination System (NPDES):** Click this link to generate the ‘National Pollutant Discharge Elimination System (NPDES)’ screen in a new browser window.
- **New Chemicals Program Homepage:** Click this link to generate the ‘New Chemicals Program’ screen in a new browser window.
- **Status of Section 5 Notices:** Click this link to generate the ‘Status of Section 5 Notices’ screen in a new browser window.
- **Instruction Manual for Reporting Under the TSCA §5 New Chemicals Program:** Click this link to generate the ‘Instruction Manual for Reporting Under the Toxic Substances Control Act §5 New Chemicals Program’ screen in a new browser window.
- **Questions & Answers for the New Chemicals Program:** Click this link to generate the ‘Questions & Answers for the New Chemicals Program under the Toxic Substances Control Act (TSCA)’ screen in a new browser window.

- **Points to Consider When Preparing TSCA New Chemical Notification:** Click this link to generate the ‘Points to Consider When Preparing TSCA New Chemical Notification’ screen in a new browser window.

Exhibit 18-1 shows a screen capture of the ‘Resources’ screen (Scroll 1):

Exhibit 18-1 Resources Screen (Scroll 1)



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 \(FRS\)](#)

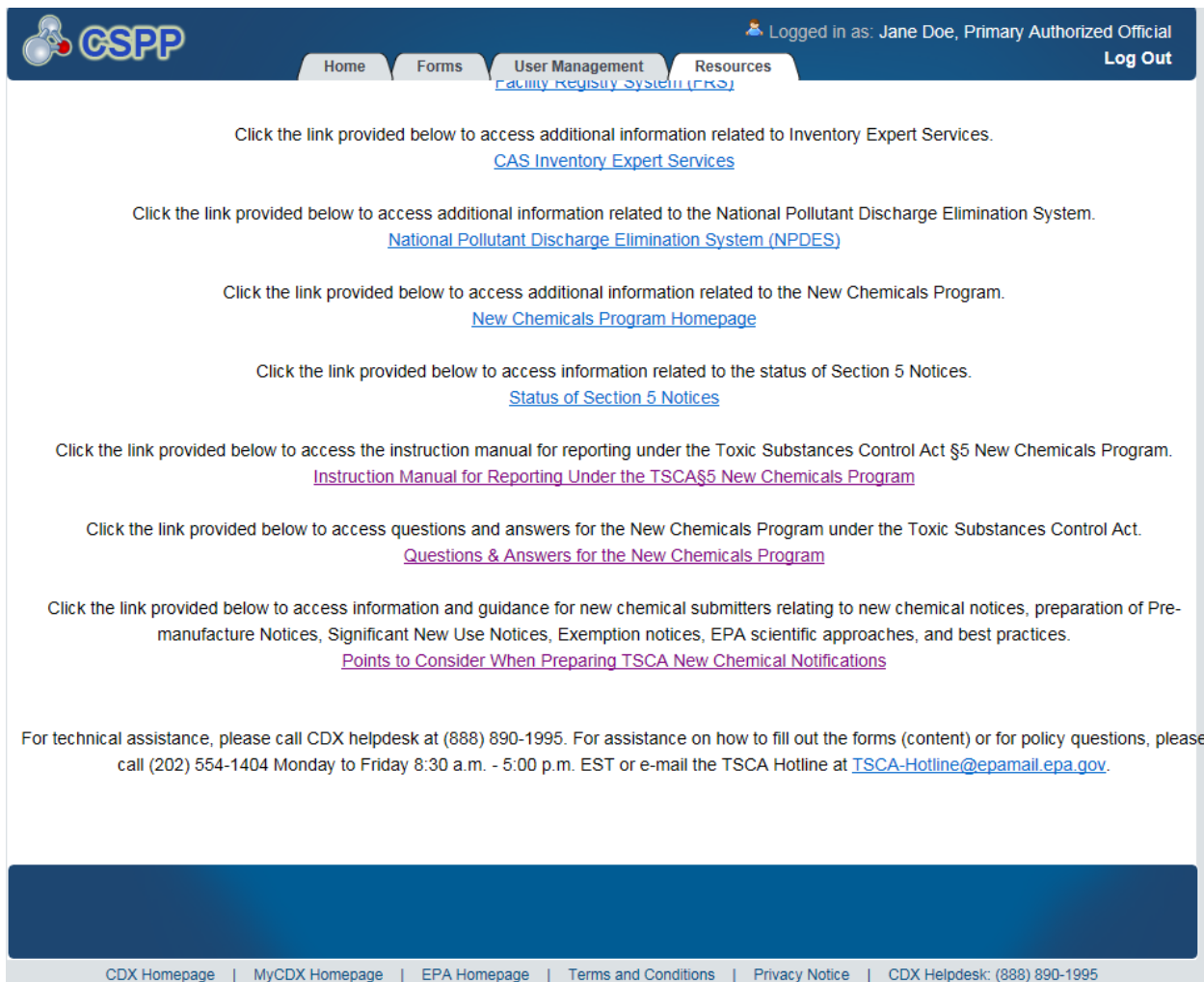
Click the link provided below to access additional information related to Inventory Expert Services.


[CAS Inventory Expert Services](#)

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Exhibit 18-2 shows a screen capture of the ‘Resources’ screen (Scroll 2):

Exhibit 18-2 Resources Screen (Scroll 2)




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

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

[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.

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Appendix A

The following table displays all the definitions, acronyms, and abbreviations used in this document and their full name.

Definitions, Acronyms, and Abbreviations

Acronym	Full Name
ACH	Automated Clearing House
ACM	Alternative Control Measures
AO	Authorized Official
BCF/BAF	Bioconcentration Factors/Bioaccumulation Factors
CBI	Confidential Business Information
CA	Chemical Abstracts
CAS	Chemical Abstracts Service
CASRN	Chemical Abstracts Service Registry Number
CDX	Central Data Exchange
CFR	Code of Federal Regulations
CoR	Copy of Record
CROMERR	Cross-Media Electronic Reporting Regulation
CSPP	Chemical Safety and Pesticide Programs
CSV	Comma-Separated Values
DNA	Deoxyribonucleic Acid
EPA	Environmental Protection Agency
EST	Eastern Standard Time
ETI	Environmental Technology Initiative
FR	Federal Regulation
FRS	Facility Registry System
GPC	Gel-permeation Chromatography
ID	Identification
IE	Internet Explorer
IES	Inventory Expert Service
IH	Industrial Hygienist
IR	Infrared
KG	Kilogram
LOREX	Low Release/Low Exposure Exemption
LOS	Letter of Support
LVE	Low Volume Exemption
MCAN	Microbial Commercial Activity Notice
MS	Mass Spectrometry
MSDS	Material Safety Data Sheet
NIOSH	National Institute for Occupational Safety and Health
NMR	Nuclear Magnetic Resonance
NOC	Notice of Commencement

Acronym	Full Name
NPDES	National Pollutant Discharge Elimination System
OPPT	Office of Pollution Prevention and Toxics
PDF	Portable Document Format
PMN	Premanufacture Notice
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
PPM	Parts Per Million
RCRA	Resource Conservation and Recovery Act
SAR	Structure-Activity Relationship
SDS	Safety Data Sheet
SME	Subject Matter Expert
SNUN	Significant New Use Notice
SNUR	Significant New Use Rule
SRS	Substance Registry Services
STN	Scientific and Technical Information Network
TERA	TSCA Experimental Release Application
	Tier I Exemption
TME	Test Market Exemption
TMEA	Test Marketing Exemption Application
TS	Toxic Substances
TSCA	Toxic Substances Control Act
UV	Ultraviolet
XML	Extensible Markup Language