



Section 5 Notices and Supports
User Guide - Secondary Authorized
Official

Environmental Protection Agency

Office of Pollution Prevention and Toxics

Manage Toxic Substances

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Revision Log

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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 forms application submission process. This document is the user guide for the Secondary 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 the Environmental Protection Agency (EPA) for the submission of Section 5 Notices and Supports data. As a Secondary AO, you can create or modify a Joint Submission/Letter of Support for a Section 5 Notices and Supports form as well as submit it to the Central Data Exchange (CDX). You can also delete Section 5 Notices and Supports forms, submit amendments to Joint forms, and download the Copy of Record (CoR).

For questions concerning the Toxic Substances Control Act (TSCA) Section 5 Notices and Supports software requirements, please contact the 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 – 5:00 pm EST.

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

- Internet Explorer (IE) 7 or above (Internet Explorer 8 or higher is recommended; issues found using IE 7 will be resolved on a case-by-case basis during post-production and known issues within IE 7 are identified within the appropriate sections of this guide)
 - Go to the following link to download:
<http://windows.microsoft.com/en-US/internet-explorer/downloads/ie>
- Mozilla Firefox 3.0 or above
 - Go to the following link to download:
<http://www.mozilla.com/en-US/firefox/all-older.html>
- Safari 4 or above
 - Go to the following link to download:
<http://support.apple.com/kb/dl877>
- Google Chrome
 - Go to the following link to download:
<http://www.google.com/chrome>
- Opera
 - Go to the following link to download:
<http://www.opera.com/download>

2.2 Screen Resolution

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

3 Secondary Authorized Official Functions

This section describes how to:

- Access the application
- Navigate the Section 5 Notices and Supports ‘Home’ screen
- Assign Supports to complete a Letter of Support or Joint Submission
- Start, complete, and submit the Section 5 Notices and Supports Letters of Supports and Joint Submissions for a Premanufacture Notice (PMN), Biotechnology, or Letter of Support for a Bona Fide
- Upload an Extensible Markup Language (XML) file
- Download a Copy of Record
- Create an amendment for Joint Submissions and/or Letter of Supports

The Secondary AO has the ability to submit Joint Submissions and/or Letters of Support, and is legally responsible for the information submitted to EPA. The Secondary AO is typically a senior official with management responsibility for the person(s) completing the form. The Secondary AO can create, delete, and unlock submitted Joint Submissions and or/Letters of Support for creating amendments. The Secondary AO is responsible for restricting the Secondary Support’s (and other authorized individuals) access to select forms by using the user management functionality within the system. The system uses Cross-Media Electronic Reporting Regulation (CROMERR) encryption security during the submission signing process.

The Secondary AO creates a new Joint Submission or Letter of Support and delegates to the Secondary Support to fill out required sections of the form.

The Secondary AO is responsible for receiving the unique identification number that will be sent after an original PMN, Biotechnology, or Bona Fide form is submitted and designated by the Primary Submitter as a Joint Form and/or Letter of Support form. The Joint Submission or Letter of Support will not be created until the Secondary AO creates a passphrase for a form. To link the Joint Form to the primary form, a user will enter the unique identification number.

You can save the form at any point during the data entry process. The save functionality will allow you to return to a 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	
	US	non-US	US	non-US	US	non-US	US	non-US	US	non-US	US	non-US
X=Can Perform Function												
Main forms (PMN, Biotechnology, Bona Fide Or NOC)												
Create all original main forms	X	X	X	X								
Submit original main forms	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										
Support and ACM forms												
Create Support and ACM forms	X	X	X	X								
Submit original ACM and Support forms	X	X	X	X								
Submit amendment for older cases and other support forms	X	X	X	X								
Unlock Support and ACM forms	X	X	X	X								
Edit unlocked Support and ACM forms	X	X	X	X	X	X						
Delete forms	X	X	X	X								
Assign Supports	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				
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				
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				

3.1 Log into Section 5 Notices and Supports Application

After you create an account in CDX, click the ‘Secondary 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:

Exhibit 3-2 Chemical Information Submission System Screen

CDX GSP

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

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 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.

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

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

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 Error! Reference source not found.**
- **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 Error! Reference source not found.**
- **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 12.**

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

Exhibit 3-3: Section 5 Notices and Supports Home Screen

HOME

Forms

The TSCA Section 5 Notices and Supports Reporting rule requires 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.

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

To determine if a substance is on the TSCA inventory, and therefore excluded from the requirement to provide premanufacturing notification, a submitter may submit a Bona Fide Intent to Manufacture notice ('Bona Fide Notice').

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 to individual forms.

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

Navigation: Click the ‘User Management’ link or tab to access the ‘User Management’ screen and assign Supports.

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 to have access to modify any of the Section 5 Notices and Support forms you have created. You can also assign different Supports to fill out the Section 5 Notices and Supports submission for each form alias.

Form Alias: A form alias will not be available in this menu until it has been created. Select a form alias from the drop-down menu to begin assigning Supports. Once a form alias has been selected, the ‘Assign Users’ group box will update to display only the Supports who have identified you as their AO during CDX registration.

Form Information: This box shows 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.
- **Form Type:** Displays the type of form, which may include ‘Primary PMN,’ ‘Biotechnology,’ or ‘Bona Fide.’
- **Form Subtype:** This value will be blank for Secondary AOs since this value is disjointed from the form information displayed.
- **Last Modified:** Displays the date the form was last modified.

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

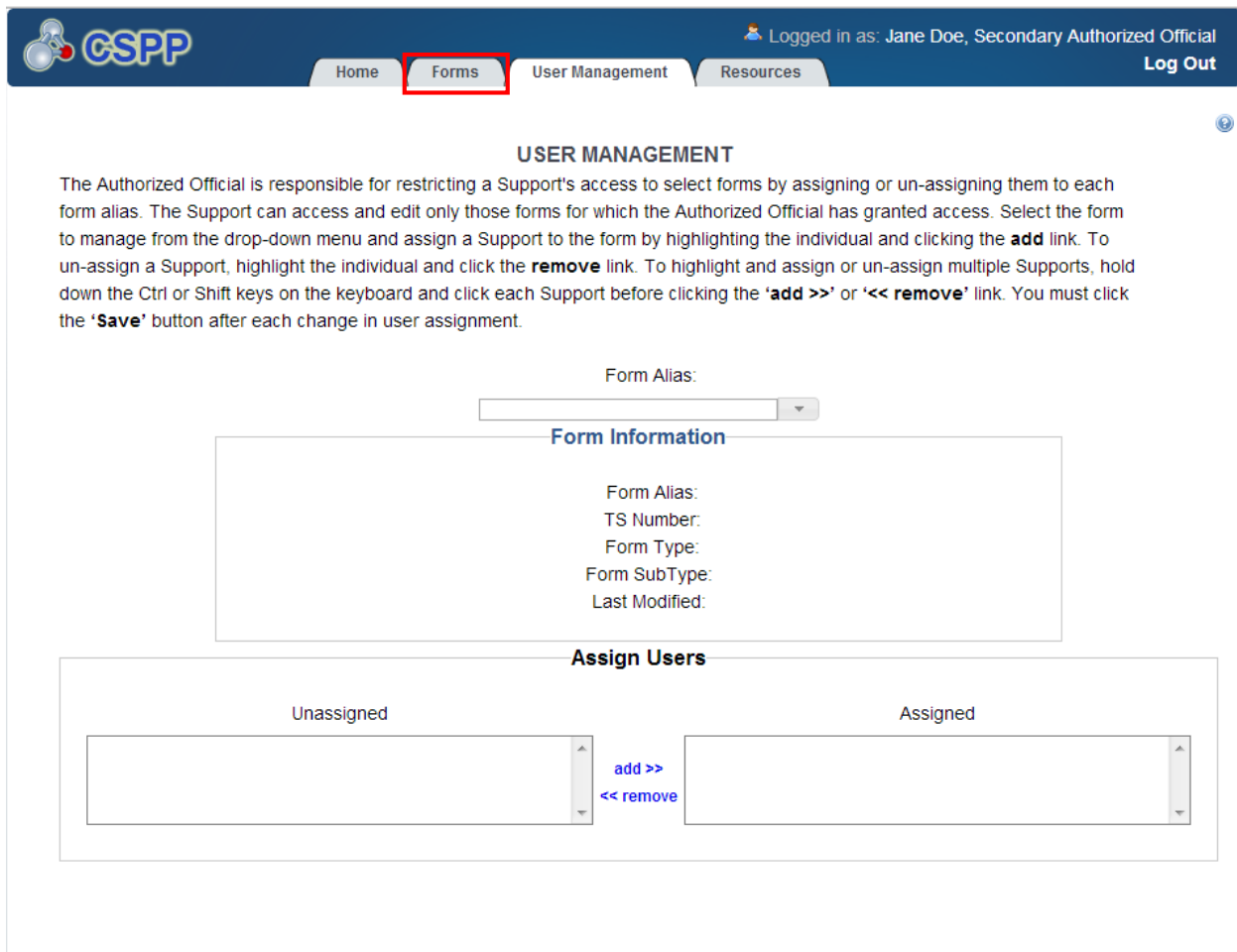
- **Unassigned:** This box/field contains the registered Supports associated with the AO who could potentially be assigned to access and edit the selected form. To move Supports from the ‘Unassigned’ group box to the ‘Assigned’ group box, highlight an individual or multiple Support(s) and click the ‘add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

- **Add >>**: Click the button to move Supports from the ‘Unassigned’ box to the ‘Assigned’ box.
- **<< Remove**: Click the button to move Supports from the ‘Assigned’ box to the ‘Unassigned’ box.

When you have finished assigning the Supports, click the ‘Save’ button that displays after selecting a form to save the selection.

Exhibit 3-4 shows a screen capture of the ‘User Management’ screen:

Exhibit 3-4: User Management Screen



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


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. 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 Joint Submission/Letter of Support, click the 'Start New Form' button. You will be required to enter the unique identification number supplied by the Primary AO or Primary Agent/Consultant and create a passphrase that will be associated with your 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 new passphrase.

Edit an 'In Progress' Form: To modify an existing Section 5 Notices and Supports form, click the 'Alias' link that has a status of 'In Progress.' You will be required to enter the passphrase associated with that particular form to access and edit the form. Refer to **Section 0** 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 form by clicking the 'Lock' icon () under the 'Action' column. You are required to enter the passphrase associated with that particular submission to gain access and amend the submission. All changes that are made will be submitted as an amendment. Refer to **Section 0** 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 provided on the 'General Form Information,' 'General Document Information,' or 'Contact Information' screen. 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: 'Joint PMN,' 'Joint Biotechnology,' or 'Joint Bona Fide.'
- **Subtype:** This column will not populate for a Secondary Authorized Official.
- **Case Number:** Displays the form case number pertaining to the reported chemical substance or mixture after EPA receives the submission. A consolidated submission will generate sequential case numbers for each chemical identified within the form. Case numbers will not be sequential for joint consolidated submissions. If the form has not been submitted and received, the field remains blank.
- **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.
- **Copy of Record:** Click the 'Copy of Record' icon (📄) to navigate to the 'Enter Passphrase' screen, then the 'Cross-Media Electronic Reporting Regulation (CROMERR) Login' screen to continue to the 'Copy of Record' screen. The 'Copy of Record' icon (📄) displays only after the form has been completed. Refer to **Section 10** for further instructions on downloading the Copy of Record. If you have just submitted via CDX, the 'Copy of Record' icon (📄) may take 15-20 minutes to display. In addition, you must refresh the 'Section 5 Notices and Supports Forms' screen for the 'Copy of Record' icon (📄) to display.
- **Action:** Displays a 'Delete' icon (✖) for all forms with a status of 'In Progress.' Click the 'Delete' icon to delete a form. This column displays a 'Lock' icon (🔒) for all forms that have been submitted. Only an AO 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 a Secondary AO.
- **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 an Excel spreadsheet, Comma-Separated Values (CSV), XML, or Portable Document Format (PDF). The export options section will not display until a form is created.
- **Start New Form:** Click this button to start a new form and navigate to the 'Create Passphrase' screen. This button is only available to Authorized Officials and Agents/Consultants.

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

Exhibit 3-5: Section 5 Notices and Supports Forms Screen

SECTION 5 NOTICES AND SUPPORTS FORMS

- If creating a form in the Section 5 Notices and Supports application, click the **Start New Form** button.
- 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.

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Items Per Page: 25

Alias	Type	Subtype	Case Number	Status	Modify Date	Submission Date	Copy of Record	Action
Joint Biotechnology- 20141208- 11:15:40 EST	Joint Biotechnology			In Progress	12/08/2014			✖
Joint Biotechnology- 20141208- 11:44:03 EST	Joint Biotechnology			Submitted	12/08/2014	12/08/2014	↓	🔒
Joint Bona Fide- 20141205- 14:52:48 EST	Joint Bona Fide			In Progress	12/08/2014			✖
Joint PMN- 20141208- 09:34:26 EST	Joint PMN			In Progress	12/08/2014			✖
Joint PMN- 20141208- 11:49:06 EST	Joint PMN			In Progress	12/08/2014			✖

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

Start New Form

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

Navigation: 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 Joint/Letter of Support PMN, Biotechnology, or Bona Fide form, click the ‘Start New Form’ button. The ‘Create Passphrase’ screen provides a text field for you to enter in the unique identifier supplied by the Primary AO and create a passphrase to associate that passphrase with the 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.

Unique Identifier: Enter the unique identifier that was provided by the Primary AO or Primary Agent/Consultant.

New Passphrase: To associate a passphrase with a form, enter a passphrase that is at least 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 3-6 shows a screen capture of the ‘Create Passphrase’ screen for a Secondary Authorized Official:

Exhibit 3-6: Create Passphrase Screen

CREATE PASSPHRASE

Please enter the unique identifier provided by the primary submitter.

Unique Identifier:

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

New Passphrase:

Confirm New Passphrase:

A passphrase can only be created by an authorized official for a reporting site. Your passphrase will be used as an encryption key to protect the contents of your data. As an authorized official, you are responsible for remembering your passphrase and distributing it to only authorized individuals.

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

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Navigation: Enter a ‘Unique Identifier,’ create a passphrase, and click the ‘Next’ button to navigate to the ‘General Form Information’ screen in a PMN or Biotechnology form. Click the ‘Next’ button to navigate to the ‘General Document Information’ screen in a Bona Fide form.

3.6 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 3-7 shows a screen capture of the ‘Enter Passphrase’ screen:

Exhibit 3-7: 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 or Biotechnology form.

3.7 Navigation Tree

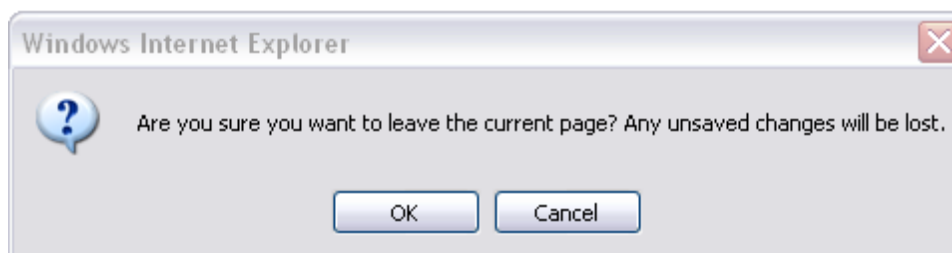
The navigation tree is located on each screen on the left hand side. It allows you to navigate between the various screens within the application and the different sections of the form. You can perform the following functions using the navigation tree:

- **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 3-8 shows a screen capture of the navigation prompt pop-up window:

Exhibit 3-8: Navigation Prompt Pop-Up Window



- **Delete chemical folders:** To delete specific chemical folders, a 'Delete' icon (✖) displays at the bottom of each chemical folder within the navigation tree of a PMN form. When a chemical folder is deleted, all information entered within the deleted chemical folder is lost and cannot be retrieved. You can add a new chemical folder by clicking the 'Add Consolidated Chemical' link, and filling in all corresponding data. This delete functionality is not applicable to the Biotechnology or Bona Fide form.
- **Copy chemical folders:** To copy a specific chemical folder, click the 'Copy' icon (📄) that displays at the bottom of each chemical folder within the navigation tree of a PMN form. 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 or Bona Fide module.
- **Delete 'Submitted Controlled Operations' or 'Operations Controlled By Others':** 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 or Bona Fide module within the Section 5 Notices and Supports application.
- **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 overwrites the contents within the PMN form. For more information about the upload XML functionality, refer to **Section 4.1.27**.

Please note that in IE 7, the scroll bar within the navigation tree may freeze or portions of the scroll bar may be missing which can prevent you from using the navigation tree. If the scroll bar freezes, click the 'Previous' and 'Next' buttons on a page to navigate, or click other links within the navigation tree to continue within the form.

Exhibit 3-9 shows a screen capture of the Premanufacture Notice navigation tree (Scroll 1):

Exhibit 3-9: Premanufacture Notice Navigation Tree (Scroll 1)

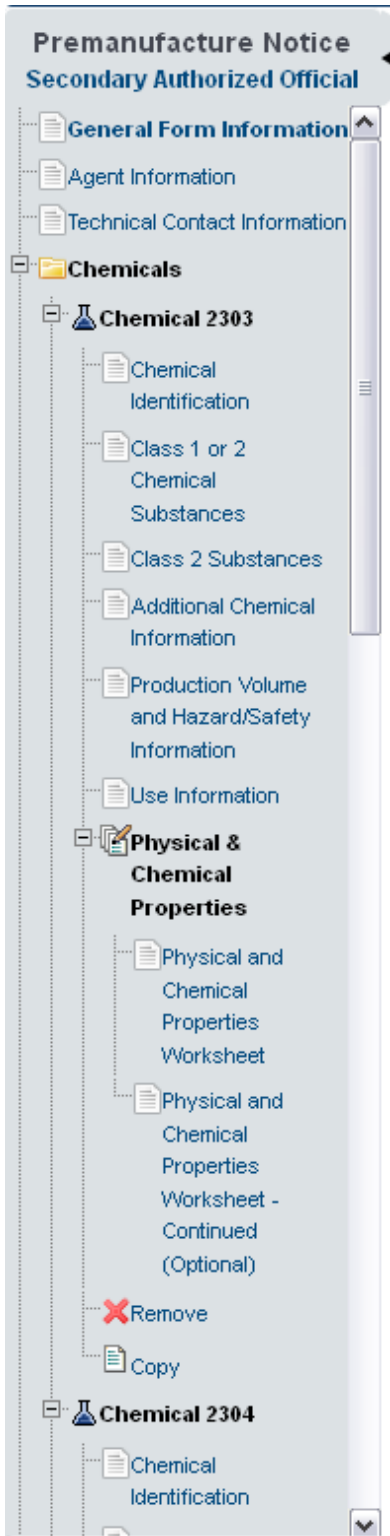


Exhibit 3-10 shows a screen capture of the Premanufacture Notice navigation tree (Scroll 2):

Exhibit 3-10: Premanufacture Notice Navigation Tree (Scroll 2)

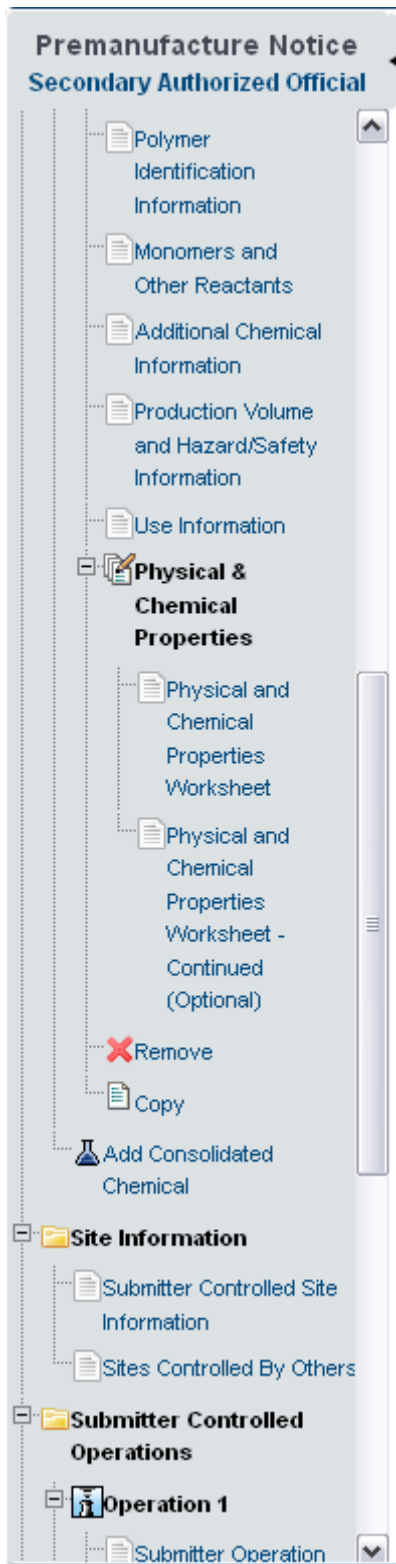


Exhibit 3-11: Premanufacture Notice Navigation Tree (Scroll 3)

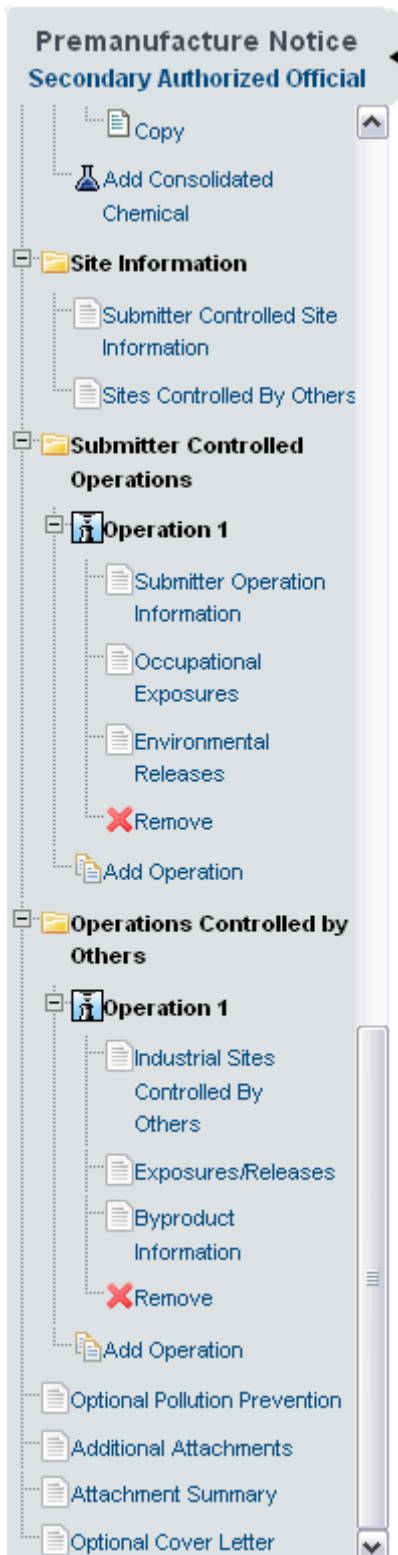


Exhibit 3-12 shows a screen capture of the Biotechnology navigation tree:

Exhibit 3-12: Biotechnology Navigation Tree



Exhibit 3-13 shows a screen capture of the Bona Fide navigation tree (Class 1 or 2 chemical substances):

Exhibit 3-13: Bona Fide Navigation Tree (Class 1 or 2 Chemical Substances)

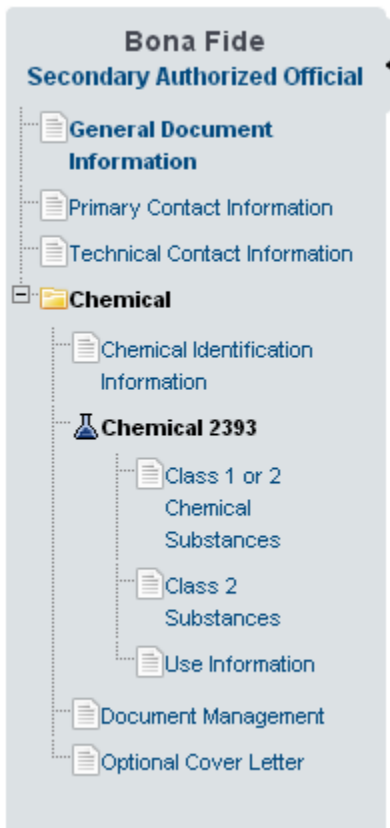
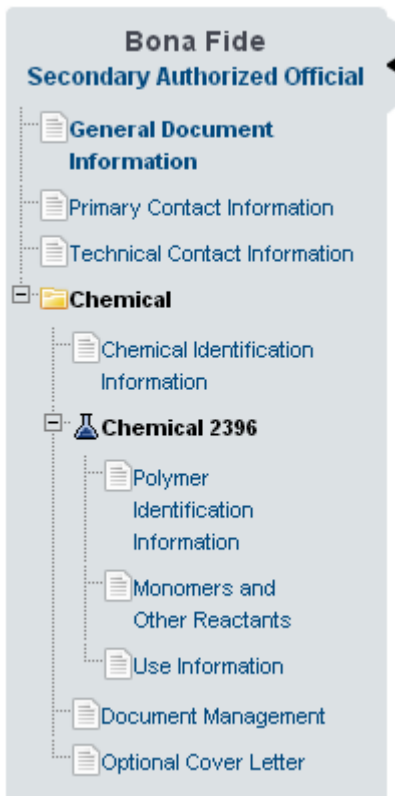


Exhibit 3-14 shows a screen capture of the Bona Fide navigation tree (polymer):

Exhibit 3-14: Bona Fide Navigation Tree (Polymer)



3.8 Action Bar

The action bar is located at the bottom of the form section on each screen. You can perform the following functions using 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 8** for more information on validating a form.

The following exhibits, Exhibit 3-15, Exhibit 3-16: Action Bar – Save

, Exhibit 3-17, and Exhibit 3-18 show a screen captures for the action bar:

Exhibit 3-15: Action Bar – Validate



- Save:** Click the ‘Save’ icon (📄) 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 (📄) within the action bar. After you click the ‘Save’ icon (📄), 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 (📄) 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 3-16: Action Bar – Save



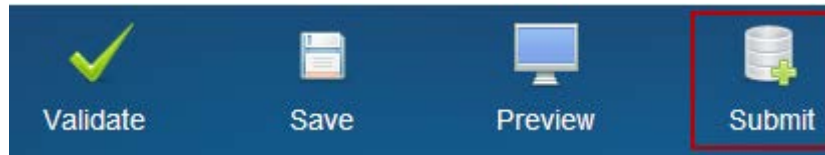
- Preview:** Click the ‘Preview’ icon (🖥️) at any stage of completing a Section 5 Notices and Supports form to preview the form. After you click the ‘Preview’ icon (🖥️), you will be given the option to view a regular version of the PDF (the confidential business information (CBI) version of the form 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.

Exhibit 3-17: Action Bar – Preview



- Submit:** As a Secondary AO you have the ability to click the ‘Submit’ icon (🗄️) to submit Letters of Support, Joint Forms, and/or amendments to Joint Forms or after you or the Support have completed all sections of the Section 5 Notices and Supports submission process. 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 Error! Reference source not found.** for further instructions on validation errors. You can continue the submission process only after clearing all validation errors. Validation warnings will not prevent you from submitting a form. Upon successful submission of a form, the application generates and sends an email indicating the successful submission of the form to the submitter’s email address. Refer to **Section Error! Reference source not found.** for more information on submitting a Section 5 Notices and Supports form.

Exhibit 3-18: Action Bar – Submit

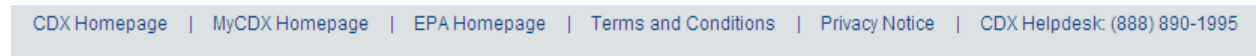


Please note that in IE 7, the action bar may align to the left or the right of the screen when viewing certain sections of the form.

- **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 3-19 shows a screen capture of the action bar ‘Help’ links:

Exhibit 3-19: Action Bar – Help Links



3.9 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. There is no limit on the size of the file that can be attached; 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.

Please note that in IE 7, the 'Cancel' button within the 'Attach Documents' pop-up window disappears and reappears when checking the 'CBI' checkbox.

- **Type:** Select the document type of the document that you upload. This drop-down menu contains the following values: 'Aquatic Ecotoxicity,' 'Chemical Structure Diagram,' 'Fate,' 'gel-permeation chromatography (GPC),' 'Genetic Toxicity,' 'Health Toxicity,' 'IES Report,' 'Safety Datasheet,' and 'Terrestrial Ecotoxicity' for PMN and Biotechnology forms. This drop-down menu contains 'Spectrum of Substance,' 'Statement of Commercialization,' 'Statement of Research and Development,' and 'Other' for Bona Fide forms. This is a required field.
- **Subtype:** Select the document type of the document that you upload. This drop-down menu contains the following values, which are grouped under specific document types: 'Partitioning (e.g., Koc, Kd, Kow, Koa, Henry's law constant),' 'Hydrolysis,' 'Fugacity,' 'Photolysis,' 'Monitoring data (e.g. air, water, soil, biota, human),' 'Biodegradation,' 'Bioconcentration Factors/Bioaccumulation Factors (BCF/BAF),' 'Material Safety Data Sheet/Safety Data Sheet (MSDS/SDS),' 'Technical Datasheet,' 'Eye Irritation,' 'Combined Repeated-Dose/Developmental/Reproductive Toxicity,' 'Sensitization,' 'Carcinogenicity,' 'Repeated-Dose Toxicity,' 'Neurotoxicity,' 'Acute Toxicity,' 'Developmental Toxicity,' 'Pharmacokinetics/Metabolism,' 'Dermal Irritation,' 'Reproductive Toxicity,' 'Fish Chronic Toxicity,' 'Invertebrate Acute Toxicity,' 'Invertebrate Chronic Toxicity,' 'Algae Toxicity,' 'Fish Acute Toxicity,' 'Chromosomal Aberrations Assay,' 'Unscheduled DNA Synthesis,' 'Genetic Mutation Assay,' 'Plant Toxicity,' 'Invertebrate Toxicity,' 'Avian Toxicity,' and 'Other.' Document subtypes are not applicable to a Bona Fide form. 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, .mol, .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 in a PMN or Biotechnology form. This field is not applicable to a Bona Fide form.
- **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. This checkbox is not applicable to a Bona Fide form.
- **Sanitized Attachment:** Click the 'Browse' button to generate the 'File Upload' window to search for a particular file 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. This field is not applicable to a Bona Fide form.

- **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 3-20 shows a screen capture of the ‘Attach Documents’ pop-up window that displays within the majority of forms:

Exhibit 3-20: 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.

3.10 Search Substance Registry Services

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' 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 CASRNs, 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.

Please note in IE 7, the CSPP logo might be misaligned in the 'Search Substance Registry Services' window.

- **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 SRS' 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 3-21 shows a screen capture of the ‘Search Substance Registry Services’ pop-up window:

Exhibit 3-21: Search Substance Registry Services Pop-Up Window

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.
- **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’ 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 3-22 shows a screen capture of the ‘Chemical Not Found In Substance Registry Services’ pop-up window:

Exhibit 3-22: Chemical Not Found In Substance Registry Services Pop-Up Window

CSPP

CHEMICAL NOT FOUND IN SUBSTANCE REGISTRY SERVICES

Complete all known chemical substance information in the below fields. Click the 'OK' button when all known chemical substance information has been fulfilled.

If you need to go back to the Search SRS screen, please click 'Cancel'.

Chemical ID

CBI:

Chemical Name:

CASRN:

Maximum Percent:

Cancel **OK**

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 SRS’ pop-up window. Click the ‘X’ located in the upper right 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 Joint PMN form. This button also displays on the ‘Submitter Site Identification’ screen within a Bona Fide form. 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 further 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 site that you will be reporting on from the drop-down menu.
- **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 3-23 shows a screen capture of the 'Add Facility' pop-up window:

Exhibit 3-23: Add Facility Pop-Up Window

CSPP

ADD FACILITY

Select a site from the drop-down menu below:

CBI:

Alias:

EPA Registry ID:

Facility Name:

Facility Address:

City:

State:

Postal Code:

Add Facility Cancel

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

4 PMN Secondary User

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 submission. A PMN must be submitted at least ninety (90) days prior to the manufacture or import of the chemical.

The PMN joint process is a multi-step process with coordination needed on the parts of Primary and Secondary users (including AOs and Agents/Consultants). The Primary user will first identify that a Joint Submission and/or Letter of Support(s) will supplement a form. Based on the selection, the 'Joint Submission' folder and/or 'Letter of Support' folder will generate in the navigation tree. Each folder will contain a section for the Primary user to enter contact information and instruction information with the Joint and/or Letter of Support unique identification number (ID).

When the Primary user enters the relevant 'Joint' or 'Letter of Support' folder, the user will enter the Secondary AO or Secondary Agent/Consultant's contact information on the first screen. The Primary user will use the email address entered on this screen to send the Secondary user the unique identification number. The next screen in the 'Joint' or 'Letter of Support' folder will display the unique identification number that will be sent to the Secondary AO or Secondary Agent/Consultant, and a text box for the Primary user to provide instructions or information to the Secondary user about what is to be filed.

The Secondary user will register in CDX as a Secondary AO and access the Section 5 Notices and Supports application. Once you arrive at the 'Section 5 Notices and Supports Forms' screen, click the 'Start New Form' button and navigate to the 'Create Passphrase' screen. For 'Joint PMN' and 'Letter of Support' forms, the process will work the same; other than being able to enter a foreign address for 'Letter of Support.' Once the Secondary AO has created a new form and assigned a passphrase, the Secondary AO may enter the required information on the form. On the 'Create Passphrase' screen, the Secondary AO will enter the unique identification number sent via email from the Primary AO's form. Once the Secondary AO has entered the unique identification number, the form will display.

4.1 Create Joint Submission

As a Secondary AO, you can start a new Letter of Support or Joint Submission and assign your Supports to complete the form.

4.1.1 General Form Information (Joint PMN)

You can navigate to the 'General Form Information' screen by entering the unique identification number provided by the AO and creating a passphrase on the 'Create Passphrase' screen. The 'General Form Information' screen allows you to identify information that is specific to the form type selected from the 'Section 5 Notices and Supports Forms' screen.

The 'General Form Information' screen provides fields to input identifying information for a specific 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 'PMN Identification' section provides fields for you to enter information regarding other communications with EPA by entering a 'TS Number' and 'Payment ID.' The TS number is determined by a company and is used to identify the form for both payment and to connect 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 numeric series are not recommended. 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 allows you to identify data that is included in the notice the Primary AO or Primary Agent/Consultant 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.' If you check 'Other Data,' the system will not allow you to enter in the specific other information. More often than not, the remaining options under 'Test Data' provide sufficient information for information included in the PMN form.

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 to you, if these data are 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).

- **Form Alias:** Enter the form alias. Upon navigating to the screen, the screen will auto-generate an editable form alias in the following format: <Form Type-YYYYMMDD-HH:MM:SS Time Zone>. This is a required field.
- **TS Number:** Enter the TS number related to the PMN form; this field accepts any six (6) character alphanumeric combination. It is used by the financial institution that receives payment for EPA when it notifies the Agency that the fee has been received. The TS number should include two (2), three (3), or four (4) letters. Company names, recognizable words, and numeric series are not recommended. TS numbers should be unique to the submission and should not be reused in subsequent submissions.
- **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.

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

Exhibit 4-1: General Form Information Screen (Joint Submission)

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.

4.1.2 Agent Information

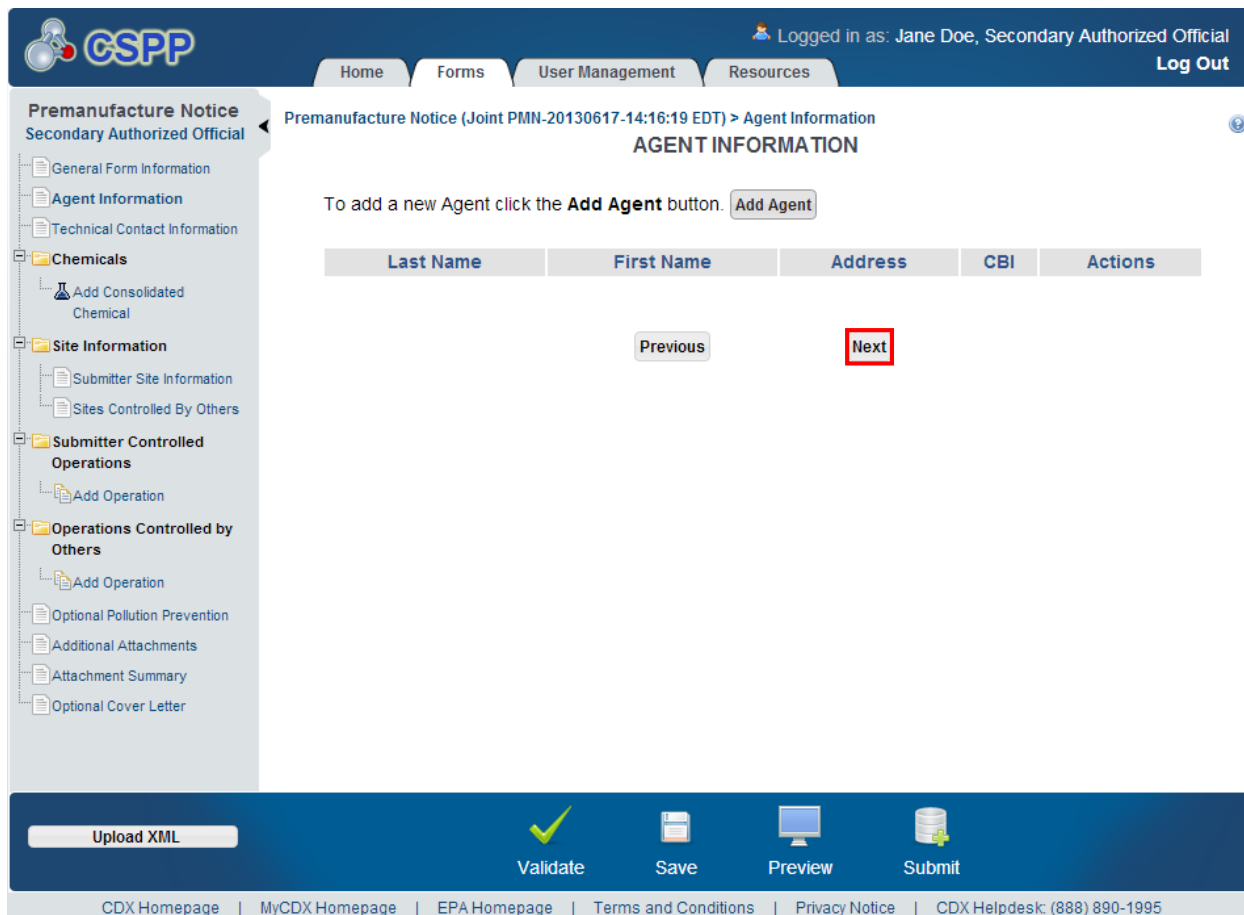
You can access the ‘Agent Information’ screen by clicking the ‘Next’ button from the ‘General Form Information’ screen. You can also navigate to this screen by clicking the ‘Agent Information’ link within the navigation tree.

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 4-2 shows a screen capture of the ‘Agent Information’ screen (Joint Submission):

Exhibit 4-2: Agent Information Screen (Joint Submission)



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.

4.1.2.1 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 stop populating agent information. 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 4-3 shows a screen capture of the ‘Add Agent’ pop-up window:

Exhibit 4-3: Add Agent Pop-Up Window



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:

Navigation: Click the ‘Cancel’ button or the ‘X’ icon in the upper right-hand corner to stop populating agent information 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.

4.1.3 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.

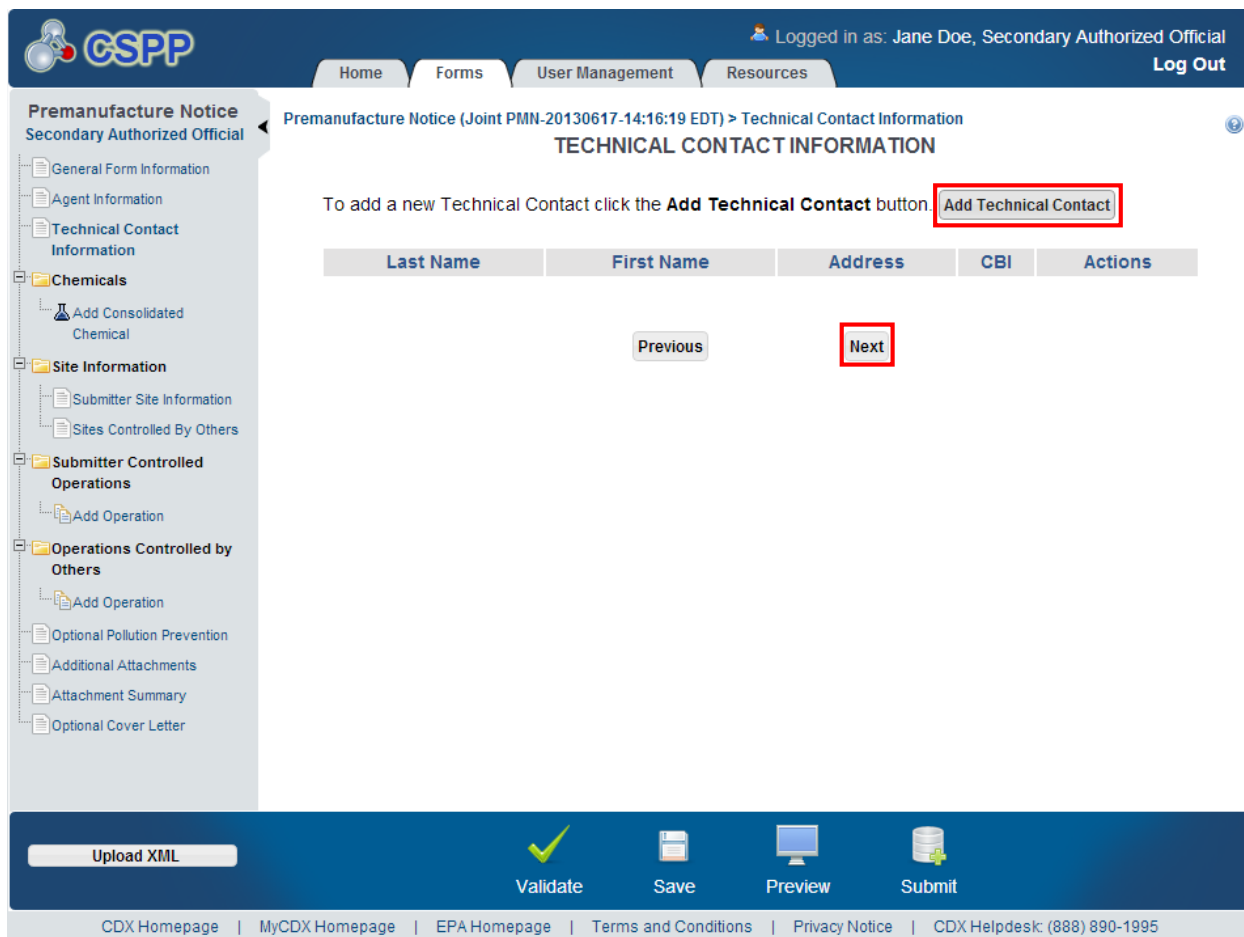
The technical contact should be able to answer, or obtain answers to, questions related to the chemical submitted to EPA within the joint PMN form or Letter of Support. The technical contact does not have to physically work at the site reported on the form, but must be readily available by phone or email. 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 4-4 shows a screen capture of the ‘Technical Contact Information’ screen (Joint Submission):

Exhibit 4-4: Technical Contact Information Screen (Joint Submission)



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

4.1.3.1 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 ‘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. To claim a technical contact as confidential, check the 'CBI' checkbox after importing CDX registration information.

- **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 4-5 shows a screen capture of the ‘Add Technical Contact’ pop- up window:

Exhibit 4-5: Add Technical Contact Pop-Up Window

CSPP

ADD TECHNICAL CONTACT

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

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

Check here to claim this information as CBI:

First Name:

Last Name:

Position:

Company Name:

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

Phone Extension:

Email Address:

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

Mailing Address 2:
Apartment, suite, etc.

City:

State:



Postal Code:

Country:

Navigation: Click the ‘Cancel’ button or ‘X’ icon at the top right 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.

4.1.4 Chemical Identification

You can access the ‘Chemical Identification’ screen by clicking the ‘Next’ button from the ‘Technical Contact Information’ screen. You may also click the ‘Add Consolidated Chemical’ or ‘Chemical Identification’ links within the navigation tree 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 Joint 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.

Exhibit 4-6 shows a screen capture of the ‘Chemical Identification’ screen (Joint Submission):

Exhibit 4-6: Chemical Identification Screen (Joint Submission)

CDX GSPP

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

Home Forms User Management Resources

Premanufacture Notice (Joint PMN-20130617-14:16:19 EDT) > Chemical Identification

CHEMICAL IDENTIFICATION

Chemical Type
Complete either item 1 (Class 1 or 2 chemical substances, PMN page 4/4a) or item 2 (Polymers, PMN Page 5/5a) as appropriate. Indicate which selection you intend to complete below.

Class 1 or 2 Chemical Substance
Polymer

Chemical Alias:

Chemical report folder alias is an optional field that changes the folder name in the navigation tree on the left. The chemical report folder alias is required if a joint submission and/or letter of support is being filed. Its purpose is to make it easier to distinguish between chemical folders when there is more than one and for joint and/or letter of support submitters to refer to when they supply information for that chemical.

*To add a consolidated chemical, please click the 'Add Consolidated Chemical' link within the navigation tree after you have selected 'Class 1 or 2 Chemical Substance' or 'Polymer' above and then selected 'Next' below.

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

Upload XML

Validate Save Preview Submit

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

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.

4.1.5 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.

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 should clearly and completely indicate 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 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 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 Error! Reference source not found.** 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.
- **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.
- **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** Error! Reference source not found. 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 3.8** for more information regarding the save functionality in an expandable/collapsible field set.

Exhibit 4-7 shows a screen capture of the ‘Class 1 or 2 Chemical Substances’ screen (Joint Submission):

Exhibit 4-7: Class 1 or 2 Chemical Substances Screen (Joint Submission)

Premanufacture Notice (Joint PMN-20141208-09:34:26 EST) > Class 1 or 2 Chemical Substances

CLASS 1 OR 2 CHEMICAL SUBSTANCES

Expand All | Collapse All

Cancel

B.1.a. Class of Substance: Class 1 Class 2 CBI:

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

Search SRS

CASRN:
Chemical Name:
CBI:

B.1.c. ID Method
 Method 1 (CAS Inventory Expert Service) Method 2 (Other Method)
Include an attachment for the ID Method below.

B.1.d. Molecular Formula: CBI:

B.1.e. Chemical Structure Diagram:
Include an attachment for the chemical structure diagram below.

Choose a section to attach a document:

Attach Document

Section	File Name	Description	Pages	CBI	Actions
---------	-----------	-------------	-------	-----	---------

Save

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

Add New Chemical

*Consolidated chemicals are entered by clicking the 'Add Consolidated Chemical' link within the navigation tree on the left.

Previous **Next**

Upload XML

Validate Save Preview Submit

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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.

4.1.6 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.

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 Error! Reference source not found.** 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 Error! Reference source not found.** 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 4-8 shows a screen capture of the ‘Class 2 Substances’ screen (Joint Submission) (Scroll 1):

Exhibit 4-8: Class 2 Substances Screen (Joint Submission) (Scroll 1)

The screenshot displays the CDX web application interface for a Premanufacture Notice (PMN-20130502-14:09:03 EDT) under the 'Class 2 Substances' section. The user is logged in as Jane Doe, a Secondary Authorized Official.

Navigation: Home, Forms, User Management, Resources, Log Out.

Sidebar Menu:

- General Form Information
- Agent Information
- Technical Contact Information
- Chemicals**
 - Chemical 2303**
 - Chemical Identification
 - Class 1 or 2 Chemical Substances
 - Class 2 Substances**
 - Additional Chemical Information
 - Production Volume and Hazard/Safety Information
 - Use Information
 - Physical & Chemical Properties**
 - Physical and Chemical Properties Worksheet
 - Physical and Chemical Properties Worksheet - Continued (Optional)
 - Copy
- Chemical 2304**
 - Chemical Identification
 - Polymer

Main Content:

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	Actions

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

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

Attachments

Footer: Upload XML, Validate, Save, Preview, Submit.

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

Exhibit 4-9 shows a screen capture of the ‘Class 2 Substances’ screen (Joint Submission) (Scroll 2):

Exhibit 4-9: Class 2 Substances Screen (Joint Submission) (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.

4.1.7 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. There is no limit to the number of trade names that may be added. 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 Error! Reference source not found.** 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 Error! Reference source not found.** 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. There is no limit to the number of trade names that can be added. 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** Error! Reference source not found. 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 4-10 shows a screen capture of the ‘Additional Chemical Information’ screen (Scroll 1) (Joint Submission):

Exhibit 4-10: Additional Chemical Information Screen (Joint Submission) (Scroll 1)

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

Home | Forms | User Management | Resources

Premanufacture Notice (Joint PMN-20141208-09:34:26 EST) > Additional Chemical Information

ADDITIONAL CHEMICAL INFORMATION

Premanufacture Notice
Secondary Authorized Official
Joint PMN-20141208-09:34:26 EST

General Form Information
Agent Information
Technical Contact Information
Chemicals
Chemical 8394
Chemical Identification
Class 1 or 2 Chemical Substances
Class 2 Substances
Additional Chemical Information
Production Volume and Hazard/Safety Information
Use Information
Physical & Chemical Properties
Physical and Chemical Properties Worksheet
Physical and Chemical Properties Worksheet - Continued (Optional)
Remove
Copy
Add Consolidated Chemical
Site 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.

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.

Byproduct Name	CASRN	CBI	Action

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

Synonym	Actions
<input type="text"/>	<input type="button" value="Remove"/> <input type="button" value="Add"/>

B.5. Trade Identification CBI
List trade names for the new chemical substance.

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Exhibit 4-11 shows a screen capture of the ‘Additional Chemical Information’ screen (Joint Submission) (Scroll 2):

Exhibit 4-11: Additional Chemical Information Screen (Joint Submission) (Scroll 2)

The screenshot displays the 'Additional Chemical Information' screen for a Premanufacture Notice (PMN-20141208-09:34:26 EST). The user is logged in as Jane Doe, a Secondary Authorized Official. The navigation tree on the left shows the 'Chemicals' section expanded to 'Chemical 8394'. The main content area includes sections for 'Byproducts', 'Synonyms', and 'Trade Identification', each with a table for data entry and a 'Search SRS' button. The 'Next' button is highlighted in a red box, indicating the next step in the process. The footer contains 'Upload XML', 'Validate', 'Save', 'Preview', and 'Submit' buttons, along with a navigation bar for CDX, MyCDX, EPA, and other resources.

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.

4.1.8 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.

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 link located at the upper-right of the expandable/collapsible field sets to expand a series of field sets.
- **Collapse All:** Click the link located at the upper-right 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 Error! Reference source not found.** 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.
- **B.6 Generic chemical name:** Enter the generic name to associate with a chemical. This field displays when ‘Chemical Name’ and ‘CASRN’ are CBI. This is a required field.
- **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 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 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 Error! Reference source not found.** 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’ 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 3.8** for more information regarding the save functionality in an expandable/collapsible field set.

Exhibit 4-12 shows a screen capture of the ‘Polymer Identification Information’ screen (Joint Submission) (Scroll 1):

Exhibit 4-12: Polymer Identification Information Screen (Joint Submission) (Scroll 1)

Premanufacture Notice
Secondary Authorized Official
Joint PMN-20141208-09:34:26
EST

Premanufacture Notice (Joint PMN-20141208-09:34:26 EST) > Polymer Identification Information
POLYMER IDENTIFICATION INFORMATION

Expand All | Collapse All

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

CASRN:
Chemical Name:
CBI:

ID Method
 Method 1 (CAS Inventory Expert Service) Method 2 (Other Method)
 Include an attachment for the ID Method below.

Chemical Structure Diagram:
Include an attachment for the chemical structure diagram below.

Choose a section to attach a document:

Attach Document

Section	File Name	Description	Pages	CBI	Action
Save					

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

*Consolidated chemicals are entered by clicking the 'Add Consolidated Chemical' link within the navigation tree on the left.

Next

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

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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.

4.1.9 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.

Please note that in IE 7, the % symbols that display to the right of the ‘max. weight % below 500 molecular weight’ and ‘max weight % below 1000 molecular weight’ fields might be slightly misaligned.

- **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 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 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 Error! Reference source not found.** 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 3.8** 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 Error! Reference source not found.** 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 4-12 shows a screen capture of the ‘Monomers and Other Reactants’ screen (Joint Submission) (Scroll 1):

Exhibit 4-12: Monomers and Other Reactants Screen (Joint Submission) (Scroll 1)

Premanufacture Notice (Joint PMN-20130502-14:09:03 EDT) > 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 measure

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.

[Expand All](#) | [Collapse All](#)

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

Upload XML

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Exhibit 4-13 shows a screen capture of the ‘Monomers and Other Reactants’ screen (Joint Submission) (Scroll 2):

Exhibit 4-13: Monomers and Other Reactants Screen (Joint Submission) (Scroll 2)

The screenshot displays the GSPP (Global Submission and Processing Platform) interface. At the top, it shows the user is logged in as Jane Doe, a Secondary Authorized Official. The navigation menu on the left includes sections for Premanufacture Notice, Chemicals (with sub-items like Chemical 8394, Chemical Identification, Polymer Identification, Monomers and Other Reactants, etc.), Physical & Chemical Properties, and Site Information. The main content area is titled 'B.2.b. Monomers and Other Reactants' and contains instructions for entering monomer data. A modal window is open, allowing the user to search EPA's Substance Registry Services (SRS) for a chemical. The modal includes fields for Monomer or other reactant, CAS Registry Number, Chemical Name, Typical Composition, and Maximum Residual, each with a CBI (Confidential Business Information) checkbox. A 'Save' button is present in the modal. Below the modal, there is an 'Add Monomer' button and a 'Composition Total: 0%' indicator. An 'Attachments' section with an 'Attach Document' button is also visible. At the bottom, a toolbar contains buttons for 'Upload XML', 'Validate', 'Save', 'Preview', and 'Submit'. The 'Next' button in the navigation area is highlighted with a red box.

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 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. 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** Error! Reference source not found. 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 4-14 shows a screen capture of the ‘Production Volume and Hazard/Safety Information’ screen (Joint Submission):

Exhibit 4-14: Production Volume and Hazard/Safety Information Screen (Joint Submission)

The screenshot displays the CDX Premanufacture Notice (PMN) system interface. At the top, the user is logged in as Jane Doe, a Secondary Authorized Official. The navigation menu includes Home, Forms, User Management, Resources, and Log Out. The main content area is titled 'PRODUCTION VOLUME AND HAZARD/SAFETY INFORMATION' and contains the following sections:

- Instructions:** On a 100% new chemical substance basis, please provide the following production volume information. Check the binding option if you are willing to submit to being regulated based on the information provided. LVE submissions that are not bound will be assessed at 10,000 kg production volume.
- C.1. Production Volume:** Includes a CBI (Chemical Binding Information) checkbox and two input fields for 'Maximum first 12-month production' and 'Maximum 12-month production' in kg/yr.
- 3. Hazard Information:** Includes a Binding checkbox and a text area for providing hazard warning statements, labels, and material safety data sheets.
- Attachment Section:** A dropdown menu to select the section the attachment applies to, followed by an 'Attach Document' button.
- Table:** A table with columns for Section, File Name, Description, Pages, CBI, and Actions.
- Navigation:** 'Previous' and 'Next' buttons are located below the table, with the 'Next' button highlighted in red.
- Bottom Toolbar:** Contains an 'Upload XML' button and icons for 'Validate', 'Save', 'Preview', and 'Submit'.

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.

4.1.11 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 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 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** Error! Reference source not found. 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 3.8** 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 4-15 shows a screen capture of the ‘Use Information’ screen (Joint Submission) (Scroll 1):

Exhibit 4-15: Use Information Screen (Joint Submission) (Scroll 1)

The screenshot displays the 'USE INFORMATION' screen for a Premanufacture Notice (Joint Submission). 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, Secondary Authorized Official'. The main content area contains the following elements:

- Instructions:** A text block explaining that if a use is claimed as confidential, the Generic Use Description (public version of the CBI use) field must be completed. It instructs the user to click the 'CBI' checkbox for 'Category of Use' to hide details.
- Category of Use:** A form field with 'CBI' checked and 'Binding' unchecked. Below it, the text '(by function and application i.e. a dispersive dye for finishing polyester fibers)' is displayed.
- Generic Use Description:** A large text area labeled 'C.2.b. Generic Use Description:' for providing details.
- Production and Formulation Data:**
 - Total Production for this Use: [] CBI: []
 - In Formulation: []% CBI: []
 - % of substance expected per use: [] CBI: [] Binding: []
 - Site Limited: []%
 - Consumer*: []%
 - Industrial: []%

The bottom toolbar features an 'Upload XML' button and four action buttons: 'Validate' (with a green checkmark icon), 'Save' (with a floppy disk icon), 'Preview' (with a monitor icon), and 'Submit' (with a database icon).

Exhibit 4-16 shows a screen capture of the ‘Use Information’ screen (Joint Submission) (Scroll 2):

Exhibit 4-16: Use Information Screen (Joint Submission) (Scroll 2)

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

Home Forms User Management Resources

Premanufacture Notice
Secondary Authorized Official

- General Form Information
- Agent Information
- Technical Contact Information
- Chemicals
 - Chemical 2303
 - Chemical Identification
 - Class 1 or 2 Chemical Substances
 - Class 2 Substances
 - Additional Chemical Information
 - Production Volume and Hazard/Safety Information
 - Use Information
 - Physical & Chemical Properties
 - Physical and Chemical Properties Worksheet
 - Physical and Chemical Properties Worksheet - Continued (Optional)
 - Chemical 2304
 - Chemical Identification
 - Polymer Identification

Total Production CBI:

for this Use:

In Formulation: % CBI:

% of substance expected per use: CBI: Binding:

Site Limited: %

Consumer*: %

Industrial: %

Commercial: %

Total: 0 %

* If you have provided a "consumer" use, provide details: CBI:

Attach Document

File Name	Description	Pages	CBI	Actions
Save				

Click the **Add Use** button to populate a Use. **Production Total:0.0%**

Upload XML

Validate Save Preview Submit

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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 Worksheet’ link within the navigation tree.

4.1.12 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.

Please note that in IE 7, all physical/chemical properties you wish to add must be identified before navigating away from this page; otherwise, the properties are removed from the 'Add Property' drop-down menu. In addition, you will be able to add the 'Henry's Law constant' property more than once, and the chemical property fields located within the expandable/collapsible fields sets on this page will be disorganized. After clicking the 'Next' button, you will navigate to the 'Physical and Chemical Properties Worksheet – Continued (Optional)' screen. After clicking the 'Previous' button, the physical/chemical properties have been removed from the 'Add Property' drop-down menu.

- **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 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 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.

- **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.
- **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 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 4-17 shows a screen capture of the ‘Physical and Chemical Properties Worksheet’ screen (Joint Submission) (Scroll 1):

Exhibit 4-17: Physical and Chemical Properties Worksheet Screen (Joint Submission) (Scroll 1)

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

Home Forms User Management Resources

Premanufacture Notice Secondary Authorized Official

Premanufacture Notice (Joint PMN-20130502-14:09:03 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.

[Expand All](#) | [Collapse All](#)

▶ Adsorption/ Coefficient	Edit	✗
▶ Boiling/sublimation temperature @ 15 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 15	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	✗

[Upload XML](#)
 Validate
 Save
 Preview
 Submit

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

Exhibit 4-18 shows a screen capture of the ‘Physical and Chemical Properties Worksheet’ screen (Joint Submission) (Scroll 2):

Exhibit 4-18: Physical and Chemical Properties Worksheet Screen (Joint Submission) (Scroll 2)

The screenshot displays the 'Physical and Chemical Properties Worksheet' for Chemical 2303. 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, Secondary Authorized Official'. The left sidebar shows a navigation tree with 'Physical & Chemical Properties' selected. The main content area lists various properties such as 'Adsorption/ Coefficient', 'Boiling/sublimation temperature @ 15 torr pressure', 'Density/ relative density', etc., each with an 'Edit' button and a red 'X' delete icon. At the bottom, a 'Next' button is highlighted with a red box, indicating the next step in the process.

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.

4.1.13 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 display.

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’ window for you to select with which properties an attachment is associated. 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.

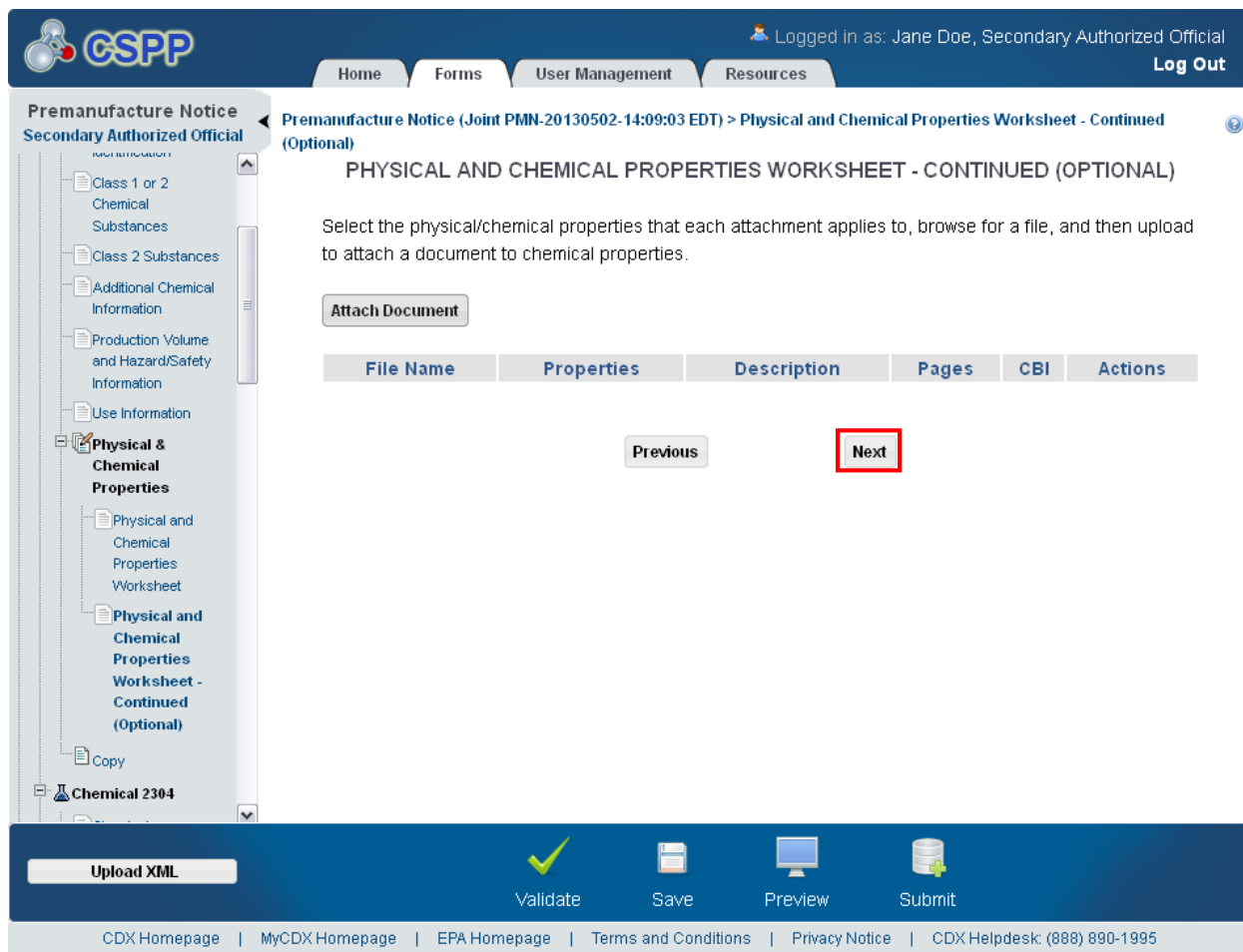
The system provides functionality to claim an uploaded document as CBI. If a document is claimed as CBI, the system requires you to upload the sanitized version of the attached document. To view, open, or edit previously attached documents, click the appropriate file name of the document within the ‘File 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 Error! Reference source not found.** 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 4-19 shows a screen capture of the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ screen (Joint Submission):

Exhibit 4-19: Physical and Chemical Properties Worksheet – Continued (Optional) Screen (Joint Submission)



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.

4.1.14 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 4-20 shows a screen capture of the ‘Physical and Chemical Properties Worksheet – Continued (Optional) Attach Documents’ pop-up window (Scroll 1):

Exhibit 4-20: Physical and Chemical Properties Worksheet – Continued (Optional) Attach Documents Pop-Up Window (Joint Submission) (Scroll 1)

ATTACH DOCUMENTS

Type and Subtype
Select the type and subtype of the attachment

Type: Health Toxicity

Subtype:

Chemical Properties

- Adsorption/ Coefficient
- Boiling/ sublimation temperature @
- Density/ relative density
- Dissociation constant
- Explosibility
- 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

Attachment
Select the file to attach

File: Browse

Description
Provide a description of the attachment

Exhibit 4-21 shows a screen capture of the ‘Physical and Chemical Properties Worksheet – Continued (Optional) Attach Documents’ pop-up window (Joint Submission) (Scroll 2):

Exhibit 4-21: Physical and Chemical Properties Worksheet – Continued (Optional) Attach Documents Pop-Up Window (Joint Submission) (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

Attachment File:

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:

Select the sanitized file to attach

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

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.

4.1.15 Site Information

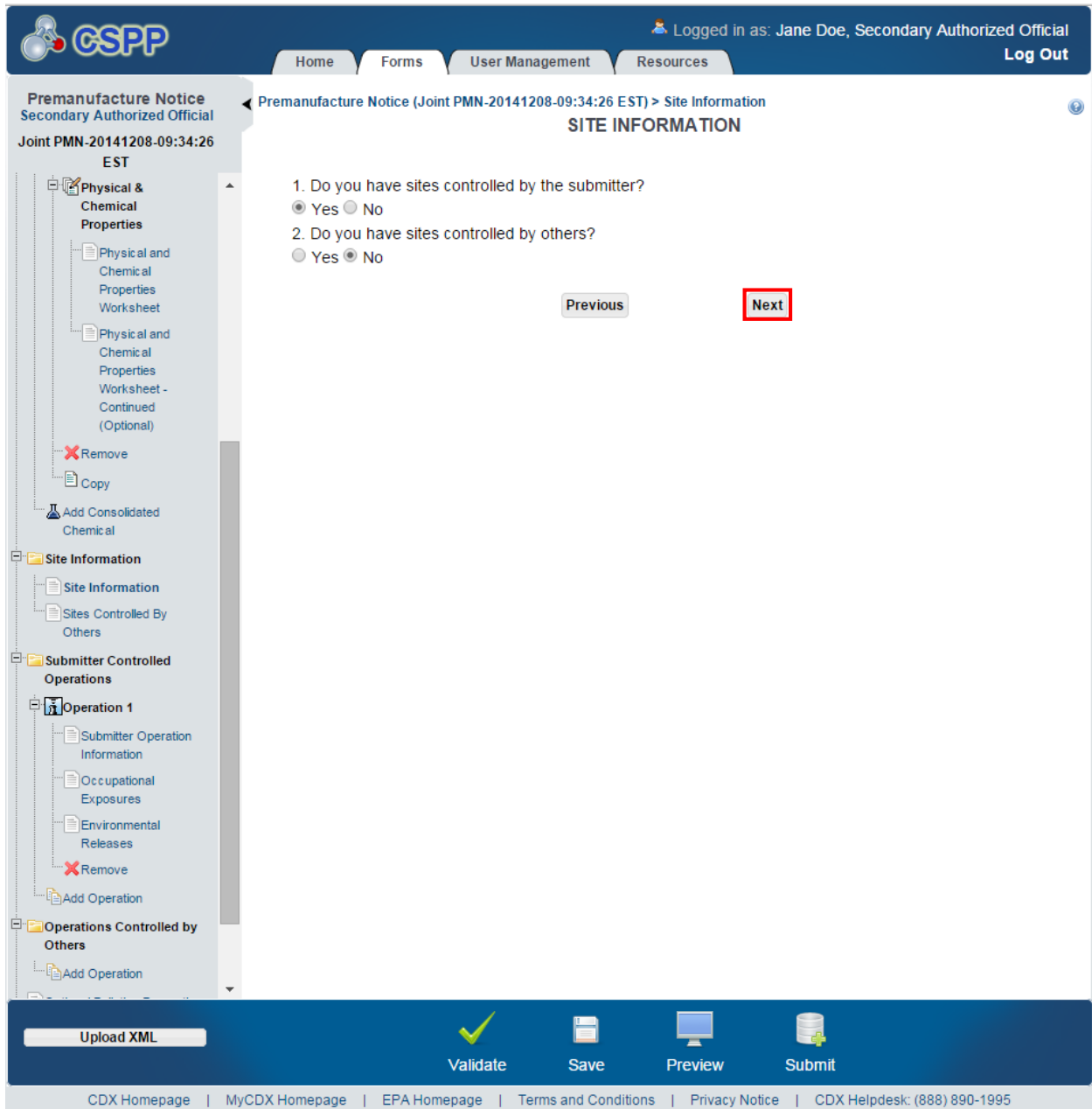
You can navigate to the ‘Site Information’ screen by clicking the ‘Next’ button from the ‘Physical and Chemical Properties Worksheet – Continued (Optional)’ screen. You can also access this screen by clicking the ‘Site Information’ link within the navigation tree.

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 within 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 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 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 4-22 shows a screen capture of the ‘Site Information’ screen (Joint Submission):

Exhibit 4-22: Site Information Screen (Joint Submission)



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.

4.1.16 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.

Please note that in IE 7, after adding a site, the '# of unknown sites' text box label disappears but the text field and 'CBI' checkbox are still displayed.

- **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,' an error 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 4-23 shows a screen capture of the ‘Sites Controlled By Others’ screen (Joint Submission):

Exhibit 4-23: Sites Controlled By Others Screen (Joint Submission)

CDX logo

Logged in as: Jane Doe, Secondary Authorized Official

Home Forms User Management Resources Log Out

Premanufacture Notice
Secondary Authorized Official
Joint PMN-20141208-09:34:26 EST

Premanufacture Notice (Joint PMN-20141208-09:34:26 EST) > Sites Controlled By Others

SITES CONTROLLED BY OTHERS

Do you have any sites controlled by others for which you have information to report?
 Yes No

B.1.a. Operation description
 Do you have site-specific information?
 Yes No

The '# of Unknown Sites' field is required. Enter '0' if none.

of unknown sites: CBI:

Previous **Next**

Upload XML

Validate Save Preview Submit

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

4.1.17 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.
- **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.
- **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 Error! Reference source not found.** 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 4-24 shows a screen capture of the ‘Submitter Operation Information’ screen (Joint Submission) (Scroll 1):

Exhibit 4-24: Submitter Operation Information Screen (Joint Submission) (Scroll 1)

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Premanufacture Notice
Secondary Authorized Official
Joint PMN-20141208-09:34:26 EST

Premanufacture Notice (Joint PMN-20141208-09:34:26 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:						
<input checked="" type="checkbox"/> Chemical 8394						

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?

1. Batch 2. Continuous

max kg/batch:
(100% new chemical substance)

hours/batch:
 batches/year:

A.1.d Process Description

Upload XML | Validate | Save | Preview | Submit

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Exhibit 4-25 shows a screen capture of the ‘Submitter Operation Information’ screen (Joint Submission) (Scroll 2):

Exhibit 4-25: Submitter Operation Information Screen (Joint Submission) (Scroll 2)

CDX logo | Logged in as: Jane Doe, Secondary Authorized Official | Log Out

Home | Forms | User Management | Resources

Premanufacture Notice
Secondary Authorized Official
Joint PMN-20141208-09:34:26

EST
 - Chemical Properties Worksheet
 - Physical and Chemical Properties Worksheet - Continued (Optional)
 - Remove
 - Copy
 - Add Consolidated Chemical

Site Information
 - Site Information
 - Sites Controlled By Others

Submitter Controlled Operations
 - Operation 1
 - Submitter Operation Information
 - Occupational Exposures
 - Environmental Releases
 - Add Operation

Operations Controlled by Others
 - Add Operation
 - Optional Pollution Prevention
 - Additional Attachments
 - Attachment Summary
 - Optional Cover Letter

Chemical 8394

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?

1. Batch 2. Continuous
 max kg/batch:
 (100% new chemical substance)
 hours/batch:
 batches/year:

A.1.d Process Description
 CBI:
 Please describe the attached process/operation. (optional)

Attach Document

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

Upload XML | Validate | | |

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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.

4.1.18 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 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 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 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 3.8** for more information regarding the save functionality in an expandable/collapsible field set.

Exhibit 4-26 shows a screen capture of the ‘Occupational Exposures’ screen (Joint Submission):

Exhibit 4-26: Occupational Exposures Screen (Joint Submission)

The screenshot displays the 'Occupational Exposures' screen for a Premanufacture Notice (PMN-20141208-09:34:26 EST). The user is logged in as Jane Doe, a Secondary Authorized Official. The main content area is titled 'A.2 Occupational Exposure - Submitter Controlled Sites' and contains a form with the following fields:

- Worker Category (1): A dropdown menu.
- Protective Equipment/ Engineering Controls (3): A text area.
- Physical Form(s) (5): A text input field.
- % New Substance (5): A percentage input field.
- # Workers Exposed (8): A text input field.
- Maximum Duration: A text input field.
- Hours/Day (10): A text input field.
- Days/Year (11): A text input field.

Each field has a corresponding checkbox for 'CBI' and 'Binding'. A 'Save' button is located at the bottom of the form. Below the form, there is an 'Add' button and a text prompt: 'Click the **Add** button to add an occupational exposure.' The bottom action bar contains buttons for 'Upload XML', 'Validate', 'Save', 'Preview', and 'Submit'. The 'Next' button is highlighted with a red box.

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.

4.1.19 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 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 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 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 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 Error! Reference source not found.** 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 4-27 shows a screen capture of the ‘Environmental Releases’ screen (Joint Submission):

Exhibit 4-27: Environmental Releases Screen (Joint Submission)

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.

4.1.20 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 Error! Reference source not found.** 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 Error! Reference source not found.** 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 4-28 shows a screen capture of the ‘Industrial Sites Controlled By Others’ screen (Joint Submission):

Exhibit 4-28: Industrial Sites Controlled By Others Screen (Joint Submission)

The screenshot displays the CDX web application interface. At the top, the user is logged in as 'Jane Doe, Secondary Authorized Official'. The navigation menu includes 'Home', 'Forms', 'User Management', and 'Resources'. The main content area is titled 'INDUSTRIAL SITES CONTROLLED BY OTHERS' and contains the following sections:

- Operation Alias:** A text input field.
- Text:** '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:** A section with an 'Add Facility' button and a table with columns: Site Name, Address, City, State, Postal Code, CBI, and Actions.
- Select the chemical(s) that this submission pertains to:** A section with a checked checkbox for 'Chemical 8394'.
- Operation Description:** A text area with the instruction 'B.1.b. Please describe the attached process/operation (optional)'. Below it is a 'CBI' checkbox.
- Attach Document:** A section with an 'Attach Document' button and a table with columns: File Name, Description, Pages, CBI, and Actions. Below the table are 'Previous' and 'Next' buttons, with 'Next' highlighted in a red box.

At the bottom of the screen, there is a blue bar with buttons for 'Upload XML', '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 ‘Exposures/Releases’ screen. You can also access this screen by clicking the ‘Exposures/Releases’ link within the navigation tree.

4.1.21 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 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 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 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 Error!** Reference source not found. for more information regarding the save functionality in an expandable/collapsible field set.

Exhibit 4-29 shows a screen capture of the ‘Exposures/Releases’ screen (Joint Submission) (Scroll 1):

Exhibit 4-29: Exposures/Releases Screen (Joint Submission) (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 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) 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.
- **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 Error! Reference source not found.** for more information regarding the save functionality in an expandable/collapsible field set.

Exhibit 4-30 shows a screen capture of the ‘Exposures/Releases’ screen (Joint Submission) (Scroll 2):

Exhibit 4-30: Exposures/Releases Screen (Joint Submission) (Scroll 2)

The screenshot displays the 'Exposures/Releases' screen for a Joint Submission. The top navigation bar shows the user is logged in as 'Jane Doe, Secondary Authorized Official'. The main content area contains the following elements:

- Navigation Tree (Left):** Includes 'Premanufacture Notice Secondary Authorized Official', 'Site Information', 'Submitter Controlled Operations', 'Operations Controlled by Others', and 'Optional Pollution Prevention'.
- Form Fields:**
 - % New Substance (6): %
 - % in Formulation (7): %
 - Release Number (9):
 - Amt New Substance Released Directly into Environment (10a): Kg/Day Kg/Batch
 - Amt New Substance Released Directly into Control Technology (10b): Kg/Day Kg/Batch
 - Media of Release (12):
 - Control Technology (12):
- Buttons:** 'Save', 'Add' (for worker exposure), 'Add' (for environmental disposal), 'Previous', and 'Next' (highlighted with a red box).
- Footer:** 'Upload XML', 'Validate', 'Save', 'Preview', and 'Submit' buttons.

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.

4.1.22 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.

Note that in IE 7, the right side of the 'Byproduct' text box may be cut off.





- **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 4-31 shows a screen capture of the ‘Byproduct Information’ screen (Joint Submission):

Exhibit 4-31: Byproduct Information Screen (Joint Submission)

The screenshot displays the 'Byproduct Information' screen within the CDX system. At the top, the user is logged in as 'Jane Doe, Secondary Authorized Official'. The navigation menu includes 'Home', 'Forms', 'User Management', and 'Resources'. The main content area is titled 'BYPRODUCT INFORMATION' and contains the following text: 'Identify byproducts that may result from the operation. Check the CBI checkbox if the information is confidential.' Below this, there is a section for 'B.2.14. Byproducts CBI:' with an unchecked checkbox. A table with two columns, 'Byproduct' and 'Actions', is present, with a 'Next' button highlighted in a red box. The bottom of the screen features an 'Upload XML' button and four action buttons: '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.

4.1.23 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 Error! Reference source not found.** 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 4-32 shows a screen capture of the ‘Optional Pollution Prevention’ screen (Joint Submission):

Exhibit 4-32: Optional Pollution Prevention Screen (Joint Submission)

The screenshot shows the GSPPP web application interface. At the top, there is a navigation bar with 'Home', 'Forms', 'User Management', and 'Resources' tabs, and a 'Log Out' button. The user is logged in as 'Jane Doe, Secondary Authorized Official'. The main content area is titled 'Optional Pollution Prevention' and contains instructions for providing information not reported elsewhere. Below the instructions is a large text input box. At the bottom of the page, there is a navigation bar with buttons for 'Upload XML', 'Validate', 'Save', 'Preview', and 'Submit'. The 'Next' button is highlighted with a red box.

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.

4.1.24 Additional Attachments

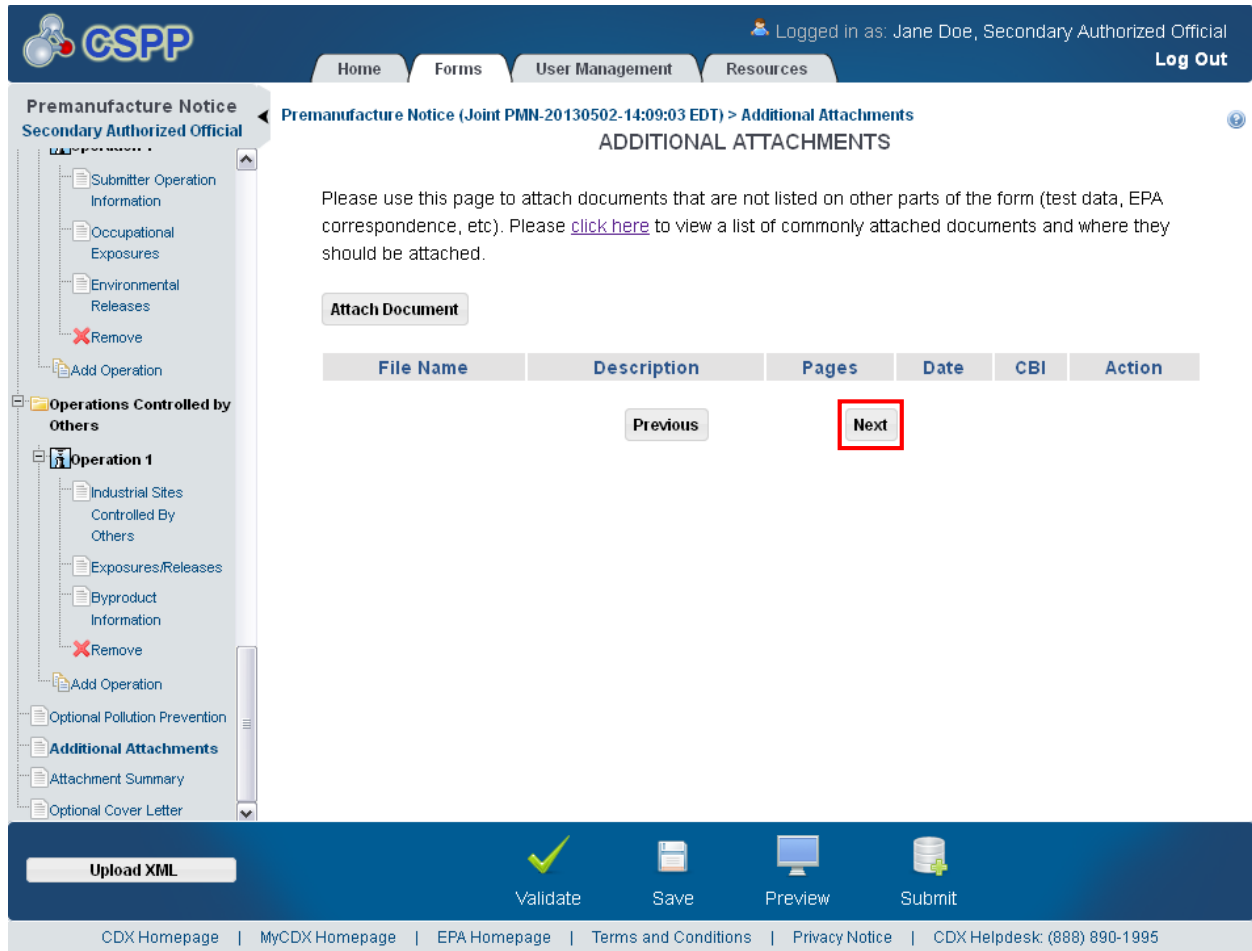
You can navigate to the ‘Additional Attachments’ screen by clicking the ‘Next’ button from the ‘Optional Pollution Prevention’ screen. You can also access this screen by clicking the ‘Additional Attachments’ link within the navigation tree.

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](#):** Clicking the link displays 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 3.9** for further information 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.
- **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 4-33 shows a screen capture of the ‘Additional Attachments’ screen (Joint Submission):

Exhibit 4-33: Additional Attachments Screen (Joint Submission)



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.

4.1.25 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 4-34 shows a screen capture of the ‘Attachment Summary’ screen (Joint Submission):

Exhibit 4-34: Attachment Summary Screen (Joint Submission)

Premanufacture Notice (Joint PMN-20141208-09:34:26 EST) > Attachment Summary

ATTACHMENT SUMMARY

The documents included in the form are listed below. The attachments displayed are for viewing purposes only; edits can be made by navigating back to the original page where they were uploaded.

Section	File Name	Description	Pages	Date	CBI
Previous Next					

Navigation tree (left):

- EST
 - Copy
 - Add Consolidated Chemical
 - Site Information
 - Site Information
 - Sites Controlled By Others
 - Submitter Controlled Operations
 - Operation 1
 - Submitter Operation Information
 - Occupational Exposures
 - Environmental Releases
 - Remove
 - Add Operation
 - Operations Controlled by Others
 - Operation 1
 - Industrial Sites Controlled By Others
 - Exposures/Releases
 - Byproduct Information
 - Remove
 - Add Operation
 - Optional Pollution Prevention
 - Additional Attachments
 - Attachment Summary
 - Optional Cover Letter

Bottom navigation bar:

- Upload XML
- Validate
- Save
- Preview
- Submit

Footer: 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.

4.1.26 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.

- **Click here to claim this information as CBI:** Check the ‘Click 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 4-35 shows a screen capture of the ‘Optional Cover Letter’ screen (Joint Submission):

Exhibit 4-35: Optional Cover Letter Screen (Joint Submission)

The screenshot displays the GSPPP web application interface. At the top, the user is logged in as 'Jane Doe, Secondary Authorized Official'. The navigation menu on the left includes sections for 'Site Information', 'Submitter Controlled Operations', and 'Operations Controlled by Others'. The main content area is titled 'OPTIONAL COVER LETTER' and contains the following text: 'If you would like to include text for a cover letter, please use the space below.' Below this text is a large empty text input field. A checkbox labeled 'Check here to claim this information as CBI:' is present. A 'Previous' button is located below the text input field. The bottom action bar features an 'Upload XML' button, a 'Validate' button with a green checkmark icon, a 'Save' button with a document icon, a 'Preview' button with a monitor icon, and a 'Submit' button 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'.


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

4.1.27 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 joint PMN form for joint PMN forms with numerous chemicals. You also have the option to export a current joint 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.

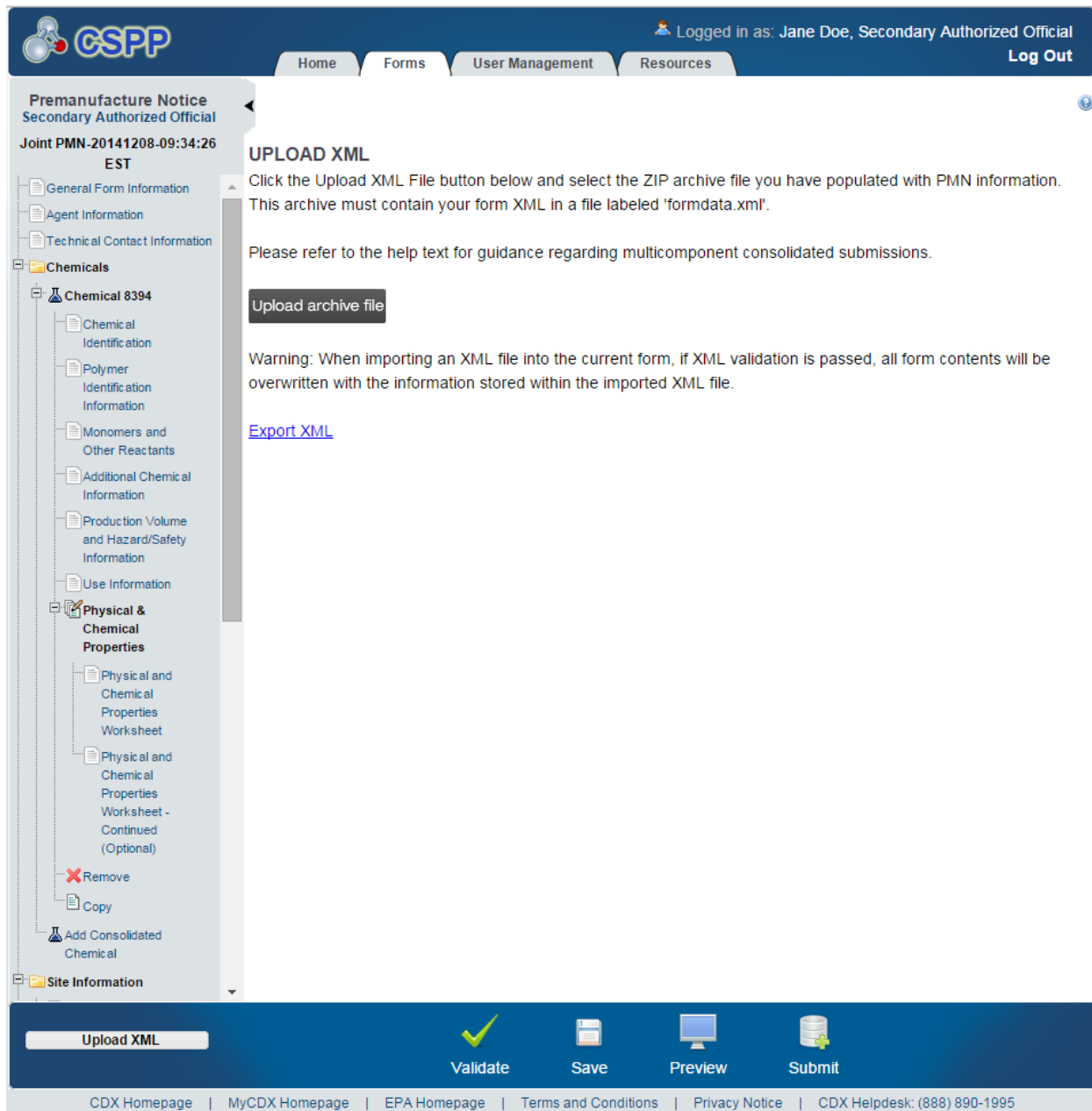
After uploading a file, click the 'Preview' icon () located in the bottom action bar to view a PDF preview of the form ensuring that all the data has populated correctly and any other information is displayed accurately. In particular, ensure that the 'Letter of Activity (1),' 'Protective Equipment/Engineering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

Please note that in IE 7, if an upload fails, the action bar at the bottom of the screen might be misaligned when the 'Upload XML' screen reloads.

- **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 4-36 shows a screen capture of the ‘Upload XML’ screen:

Exhibit 4-36: Upload XML Screen



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 Biotechnology Secondary User

5.1 Joint and Letter of Support Process

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.

The Biotechnology Joint and/or Letter of Support process will be a multi-step process with coordination required between the Primary, Joint, and/or Letter of Support submitters. The Primary user would first state that a Joint Submission and/or Letter of Support would supplement the application on the ‘General Form Information’ screen. Based on the selection, the ‘Joint Submission’ and/or ‘Letter of Support’ folder will populate. Each folder will contain a section for you to enter contact information, field information, and instruction information with the secondary user’s unique identification number. The Primary submitter may identify up to two Joint Submissions and an unlimited number of Letters of Support.

When the Primary user enters the relevant Joint Submission and/or Letter of Support folder, the Primary user will be asked to enter contact information for the Joint and/or Letter of Support submitter on the first screen. The Primary user will use the email address entered on this screen will be used to send the Joint and/or Letter of Support Submitter the unique identifier. The second screen in the Joint and/or Letter of Support folder will display the unique ID that will be sent to the Secondary use at and a text box for the Primary user to provide the Secondary user instructions or information about what is to be filed. The Secondary user will not be sent the information that the Primary user captured or be able to access the Joint and/or Letter of Support form until the Primary AO has submitted the original Biotechnology form.

The secondary submitter will register in CDX as a Secondary AO and access the Section 5 Notices and Supports application. Once you arrive at the ‘Section 5 Notices and Supports Forms’ screen, click the ‘Start New Form’ button and enter in the unique identifier on the ‘Enter Passphrase’ screen sent via email by the Primary user which will generate the appropriate form that the secondary submitter will be populating. The unique ID will link the primary and joint forms on the backend. The joint form will contain the same screens listed for the primary Biotechnology form, except the Joint submitter will not be supplied the ‘Joint Folder.’ All screens will be identical with regards to requirements and view with the exception of the ‘Section 5 Notices and Supports Forms’ screen and the ‘General Form Information’ screen, which are listed below. The secondary submission process will also be identical to the primary submission.

5.1.1 General Form Information

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

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 Error! Reference source not found.**

- **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.
- **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).'
- **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 numeric series are not recommended. This field is required if 'MCAN' is selected from the 'Type of Submission' drop-down menu, but is also required regardless of the submission type if a Letter of Support is pending, and/or if a joint Biotechnology form is being filed.
- **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 even if a Letter of Support or Joint Submission is claimed. Please refer to **Section Error! Reference source not found.** 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.

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

Exhibit 5-1 General Form Information Screen (Joint Biotechnology)

Biotechnology
Secondary Authorized Official
Joint Biotechnology-20141208-11:15:40 EST

Home Forms User Management Resources **Log Out**

Biotechnology (Joint Biotechnology-20141208-11:15:40 EST) > 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
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 ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Technical Contact Information’ link within the navigation tree.

5.1.2 Technical Contact Information

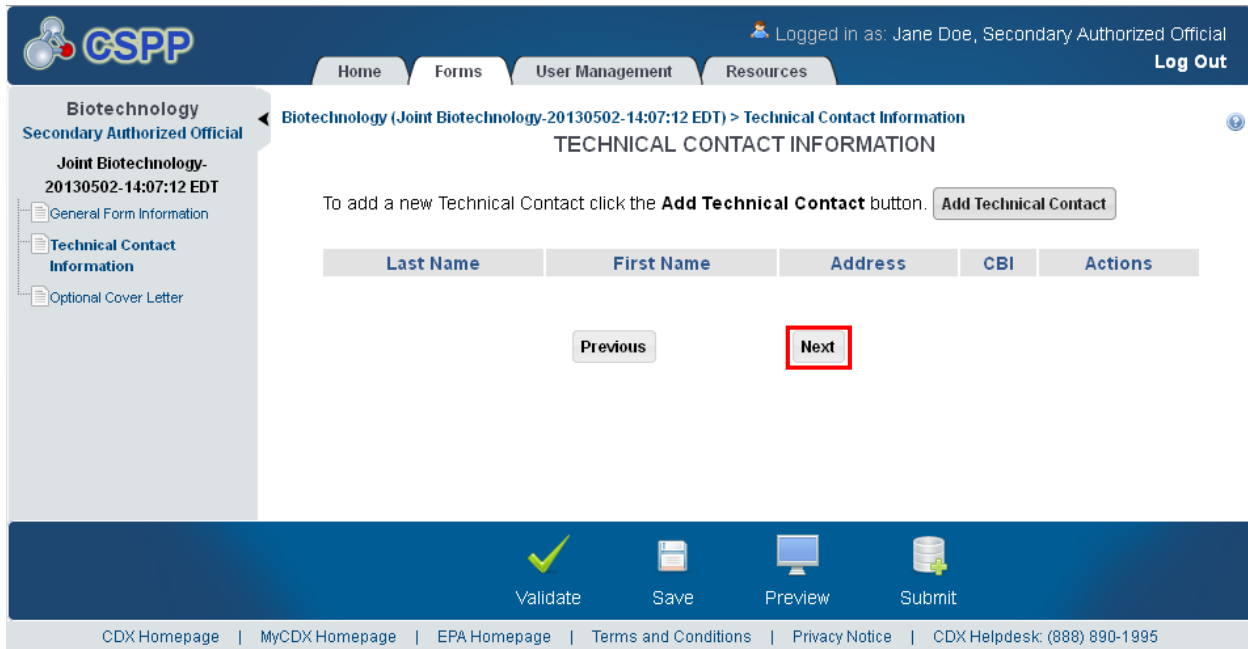
You can access the ‘Technical Contact Information’ screen by clicking the ‘Next’ button from the ‘General Form Information’ screen. You can also navigate to the ‘Technical Contact Information’ screen by clicking the ‘Technical Contact Information’ link within the navigation tree.

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 technical contact’s last name.
- **First Name:** Displays the technical contact’s first name.
- **Address:** Displays the technical contact’s address.
- **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 5-2 shows a screen capture of the ‘Technical Contact Information’ screen (Joint Biotechnology):

Exhibit 5-2: Technical Contact Information Screen (Joint Biotechnology)



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.

5.1.2.1 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 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@domain. 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 5-3 shows a screen capture of the ‘Add Technical Contact’ pop-up window:

Exhibit 5-3: Add Technical Contact Pop-Up Window

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.

5.1.3 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.

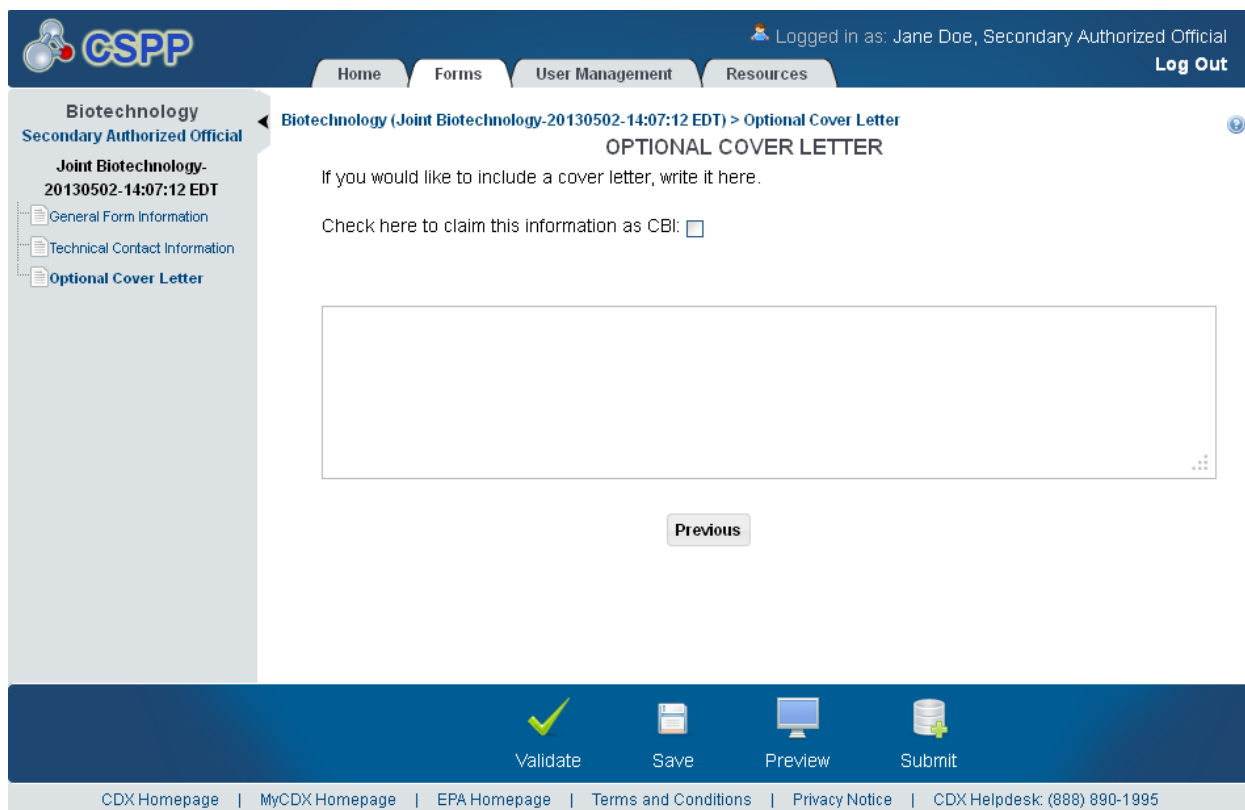
The ‘Optional Cover Letter’ screen is used to communicate information to EPA not collected elsewhere in the form. The cover letter is used to give OPPT resources and special instructions

regarding the application. 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 5-4 shows a screen capture of the ‘Optional Cover Letter’ screen:

Exhibit 5-4: Optional Cover Letter Screen



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 of 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.

6 Bona Fide Form Secondary User

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.

6.1 Edit Bona Fide Form

To edit a Joint 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.

6.1.1 General Document Information

You can access the ‘General Document Information’ screen by entering the unique identification number provided by the AO and creating a passphrase on the ‘Create Passphrase’ screen.

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 within the form. The application will generate a ‘Technical Contact Information’ screen when you check the ‘Technical Contact’ checkbox.

- **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 the submission as CBI:** Check the ‘I claim the entirety of the submission as CBI’ checkbox to flag all data contained within the form as confidential business information.
- **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.

Exhibit 6-1 shows a screen capture of the ‘General Document Information’ screen (Letter of Support):

Exhibit 6-1: General Document Information Screen (Letter of Support)

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.

6.1.2 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. This is a required field.
- **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. This is a required field.
- **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 6-2 shows a screen capture of the ‘Primary Contact Information’ screen:

Exhibit 6-2: Primary Contact Information Screen

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

Home Forms User Management Resources

Bona Fide Secondary Authorized Official
Joint Bona Fide-20141205-14:52:48 EST

General Document Information
Primary Contact Information
Chemical
Chemical Identification Information
Test Chemical 1
Class 1 or 2/Biotechnology Chemical Substances
Use Information
Document Management
Optional Cover Letter

Bona Fide (Joint Bona Fide-20141205-14:52:48 EST) > Primary Contact Information

PRIMARY CONTACT INFORMATION

The primary contact fields have been pre-populated based on the information you provided during CDX registration but may be edited if necessary. The 'Job Title' field is required.

Prefix: Mrs

First Name: Jane

Middle Initial:

Last Name: Doe

Suffix:

Title:

Company Name: TESTORCGGI1

Phone Number: 7032277445
(Do not enter any dashes (-) in Phone Number field above.)

Phone Extension:

Email Address: jeffrey.bronick@cgifederal.com

Mailing Address 1: 12601 FAIR LAKES CIRCLE
Street address, P.O. box, company name, etc.

Mailing Address 2:
Apartment, suite, etc.

City: FAIRFAX

State: Alabama

Postal Code: 20120

Country: United States

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 ‘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.

6.1.3 Technical Contact Information

If you indicated on the 'General Document Information' screen that technical contact information will be provided, then you can navigate to the 'Technical Contact Information' screen by clicking the 'Next' button from the 'Primary 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.

Please note that if you are using IE 7, there will be a spacing issue between the 'Suffix' drop-down menu and the 'Title' text field.

- **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 6-3 shows a screen capture of the ‘Technical Contact Information’ screen:

Exhibit 6-3: Technical Contact Information Screen

CDX | Logged in as: Jane Doe, Secondary Authorized Official | Log Out

Home | Forms | User Management | Resources

Bona Fide (Joint Bona Fide-20141205-14:52:48 EST) > 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.

City:

State:

Postal Code:

Country: United States

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 ‘Chemical Identification Information’ screen. You can also access this screen if you click the ‘Chemical Identification Information’ link within the navigation tree.

6.1.4 Chemical Identification Information

You can navigate to the ‘Chemical Identification Information’ screen by clicking the ‘Next’ button from the ‘Chemical Identification 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 enter 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 an error 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 an error 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 6-4 shows a screen capture of the ‘Chemical Identification Information’ screen:

Exhibit 6-4: Chemical Identification Information Screen

The screenshot displays the 'Chemical Identification Information' screen. The top navigation bar includes 'Home', 'Forms', 'User Management', 'Resources', and 'Log Out'. The user is logged in as 'Jane Doe, Secondary Authorized Official'. The left sidebar shows a tree view with 'Chemical Identification Information' selected. The main content area is titled 'CHEMICAL IDENTIFICATION INFORMATION' and contains the following sections:

- Chemical Type:** Complete either item 1 (Class 1 or 2 Chemical Substance) or 2 (Polymer) as appropriate. Indicate which selection you intend to complete below.
 - Class 1 or 2 Chemical Substance
 - Polymer
- Chemical Alias:** The chemical alias is an optional field that changes the folder name in the navigation tree on the left-hand side of the screen. Below this is a text input field.

At the bottom of the main content area, there are two buttons: 'Previous' and 'Next'. The 'Next' button is highlighted with a red box. Below the main content area is a dark blue bar with an 'Upload XML' button and four icons: a checkmark (Validate), a floppy disk (Save), a monitor (Preview), and a database cylinder (Submit). The footer contains links for 'CDX Homepage', 'MyCDX Homepage', 'EPA Homepage', 'Terms and Conditions', 'Privacy Notice', and 'CDX Helpdesk: (888) 890-1995'.

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. If you selected the ‘Polymer’ radio button, click the ‘Next’ button to navigate to the ‘Polymer Identification Information’ screen.

6.1.5 Class 1 or 2/Biotechnology Chemical Substance

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.

Please note that if you are using IE 7, part of the content on this screen displays behind the Bona Fide navigation tree and certain fields on this screen may display twice.

- **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 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 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. Refer to **Section Error! Reference source not found.** for additional details regarding the search SRS functionality.
- **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. 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 Error! Reference source not found.** for more information regarding the save functionality in an expandable/collapsible field set.


Exhibit 6-5 shows a screen capture of the ‘Class 1 or 2/Biotechnology Chemical Substances’ screen (Joint Bona Fide):

Exhibit 6-5: Class 1 or 2/Biotechnology Chemical Substances Screen (Joint Bona Fide)

The screenshot shows the CDX system interface. At the top, the user is logged in as Jane Doe, a Secondary Authorized Official. The navigation menu includes Home, Forms, User Management, and Resources. The left sidebar shows a navigation tree with 'Chemical' expanded to 'Test Chemical 1' and 'Class 1 or 2/Biotechnology Chemical Substances' selected. The main content area is titled 'CLASS 1 OR 2/BIO TECHNOLOGY CHEMICAL SUBSTANCES' and contains a form for 'Chemical Identification Information'. The form includes radio buttons for 'Class 1' and 'Class 2/Biotechnology', a search button 'Add Chemical ID', fields for 'CASRN' and 'Chemical Name', radio buttons for 'Method 1 (CAS Inventory Expert Service)' and 'Method 2 (Other Method)', an 'Attach IES Report' button, and two tables for attachments. The first table has columns 'File Name', 'Description', and 'Actions'. Below the tables are fields for 'Molecular Formula: (optional)' and 'Chemical Structure Diagram: (optional)', followed by an 'Attach Chemical Structure' button and another table with the same columns. At the bottom of the form is a 'Save' button. Below the form, there is a 'Click the Add New Chemical button to add chemical name and structural information for a new chemical.' section with an 'Add New Chemical' button. At the bottom of the page, there are 'Previous' and 'Next' buttons, with 'Next' highlighted in a red box. A footer bar contains 'Validate', 'Save', 'Preview', and 'Submit' buttons, and a footer with links to CDX Homepage, MyCDX Homepage, EPA Homepage, Terms and Conditions, Privacy Notice, and CDX Helpdesk: (888) 890-1995.

Navigation: If you selected the ‘Class 1’ radio button and clicked the ‘Save’ button within the expandable/collapsible field set, 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. If you selected the ‘Class 2/Biotechnology’ radio button and clicked the ‘Save’ button within the expandable/collapsible field set, then 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.

6.1.6 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 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 Error! Reference source not found.** 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 Error! Reference source not found.** 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 6- shows a screen capture of the ‘Class 2 Substances’ screen (Scroll 1):

Exhibit 6-6: Class 2 Substances Screen

Bona Fide
Secondary Authorized Official

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

Home Forms User Management Resources

Bona Fide (Joint Bona Fide-20130502-14:16:22 EDT) > Class 2 Substances

CLASS 2 SUBSTANCES

Class 2 Substance Details

Fill in below for a class 2 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 and the typical 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	Actions

Nature of Reaction

Range of Composition (Optional)

Optional Attachments

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 6-7 shows a screen capture of the ‘Class 2 Substances’ screen (Scroll 2):

Exhibit 6-7: Class 2 Substances Screen (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.

6.1.7 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 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 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) 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' (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. Refer to **Section 3.10** for further details regarding the search SRS functionality.
- **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 Error! Reference source not found.** 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 will be displayed 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. The system provides functionality for you to delete unwanted documents by clicking the 'Delete' icon (✖) located under the 'Actions' column. 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 6-5 shows a screen capture of the ‘Polymer Identification Information’ screen:

Exhibit 6-5: Polymer Identification Information Screen

The screenshot displays the 'POLYMER IDENTIFICATION INFORMATION' screen. The top navigation bar includes 'Home', 'Forms', 'User Management', and 'Resources'. The user is logged in as 'Jane Doe, Secondary Authorized Official'. The left sidebar shows a navigation tree with 'Chemical' expanded, and 'Polymer Identification Information' selected. The main content area contains a form with the following elements:

- Add Chemical ID** button
- CASRN: _____
- Chemical Name: _____
- ID Method** section with radio buttons for 'Method 1 (CAS Inventory Expert Service)' and 'Method 2 (Other Method)'
- Chemical Structure Diagram (optional): Include an attachment for the chemical structure diagram below.
- Attach Chemical Structure** button
- Table with columns: **File Name**, **Description**, **Actions**
- Save** button
- Add New Chemical** button
- Previous** and **Next** navigation buttons (the 'Next' button is highlighted with a red box)

At the bottom of the screen, there is a blue bar with icons and labels for 'Validate', 'Save', 'Preview', and 'Submit'. The footer contains links for '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 ‘Monomers and Other Reactants’ screen. You can also access this screen by clicking the ‘Monomers and Other Reactants’ link within the navigation tree.

6.1.8 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 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 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 Error! Reference source not found.** 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 Error! Reference source not found.** 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 Error! Reference source not found.** 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 6-6 shows a screen capture of the ‘Monomers and Other Reactants’ screen:

Exhibit 6-6: Monomers and Other Reactants Screen

The screenshot displays the 'Monomers and Other Reactants' screen within the GSPPP application. The user is logged in as Jane Doe, a Secondary Authorized Official. The page title is 'MONOMERS AND OTHER REACTANTS'. A dialog box is open, prompting the user to search EPA's Substance Registry Services (SRS) for a chemical. The dialog includes a 'Search SRS' button, a 'CAS Registry Number' field, a checkbox for 'Monomer or other reactant: Include in Identity', and a 'Typical Composition' field. Below the dialog, there is an 'Add Monomer' button and a 'Composition Total:0.0%' indicator. The 'Optional Attachments' section shows an 'Attach Document' button. At the bottom, a table with columns 'File Name', 'Description', and 'Actions' is visible, with 'Previous' and 'Next' buttons below it. The 'Next' button is highlighted with a red box. The footer contains navigation links for CDX, MyCDX, EPA, and CDX Helpdesk.

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.

6.1.9 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 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 6-7 shows a screen capture of the ‘Use Information’ screen:

Exhibit 6-7: Use Information Screen

The screenshot displays the 'USE INFORMATION' screen within the GSPP application. The user is logged in as Jane Doe, a Secondary Authorized Official. The page features a navigation tree on the left with 'Use Information' selected. The main content area prompts the user to enter 'How will the substance be used?' with a large text input field. Below the input field are 'Previous' and 'Next' navigation buttons, with the 'Next' button highlighted in red. The bottom of the screen includes an 'Upload XML' button and a row of action buttons: 'Validate', 'Save', 'Preview', and 'Submit'. The footer contains various utility links and the CDX Helpdesk contact information.

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.

6.1.10 Document Management

You can navigate to the 'Document Management' screen by clicking the 'Next' button from the 'Use Information' screen. You can also access this screen by clicking the 'Document Management' link within the navigation tree.

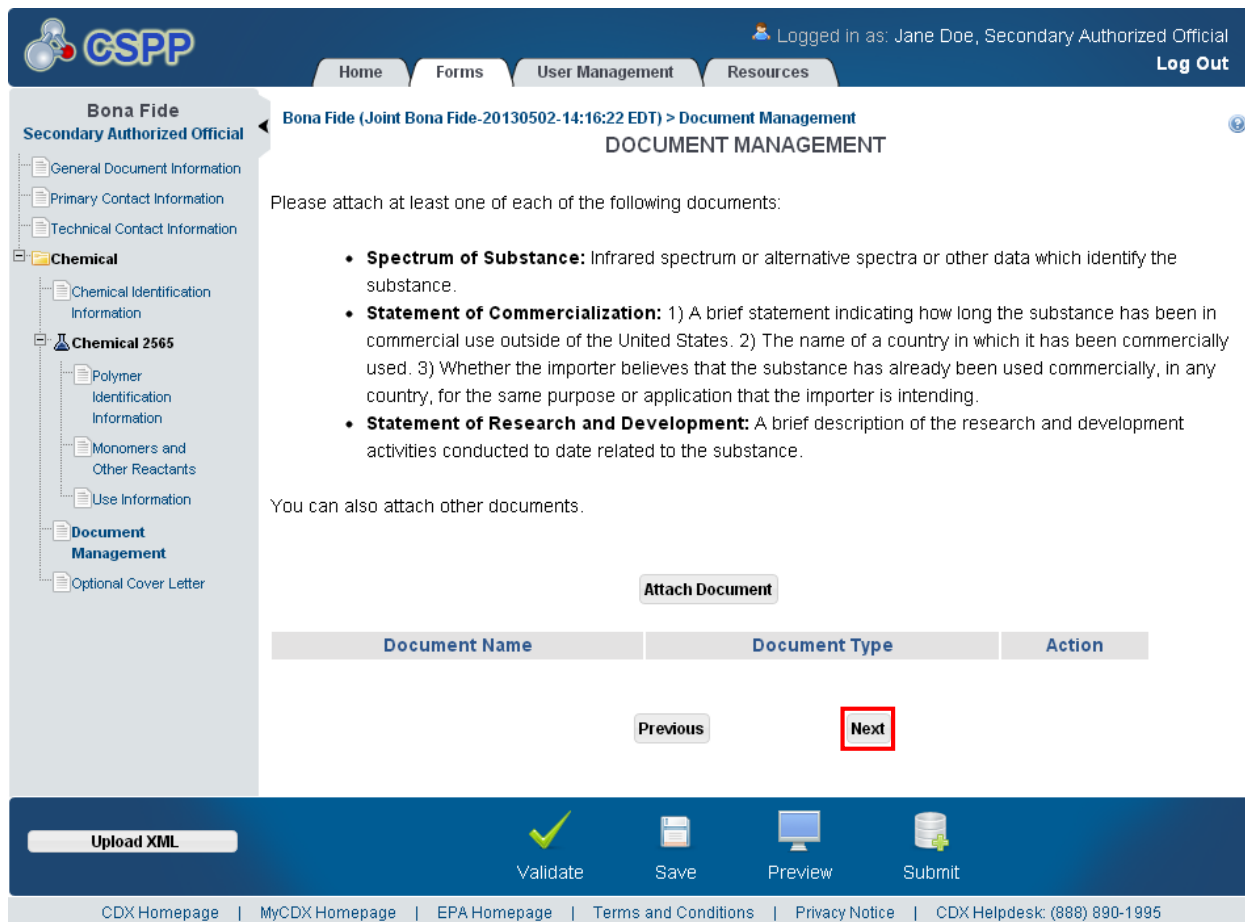
The 'Document Management' screen is used to attach required documents to the electronic form. The user must attach three required documents: 'Spectrum of Substance,' 'Statement of Commercialization,' and 'Statement of Research and Development.' The application also allows the user to attach 'Other' documents.

Please note that in IE 7, you must attach the three required documents before clicking the 'Next' button and navigating to the next screen. If you click the 'Next' button with only one or two documents attached, you will be taken to an error screen. Navigate away from this screen using the back button on your browser and check that the correct documents have been attached.

- **Attach Document:** Click the 'Attach Document' button to generate the 'Attach Documents' pop-up window to upload documents. Refer to **Section Error! Reference source not found.** 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 6-8 shows a screen capture of the ‘Document Management’ screen:

Exhibit 6-8: Document Management Screen



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.

6.1.11 Optional Cover Letter

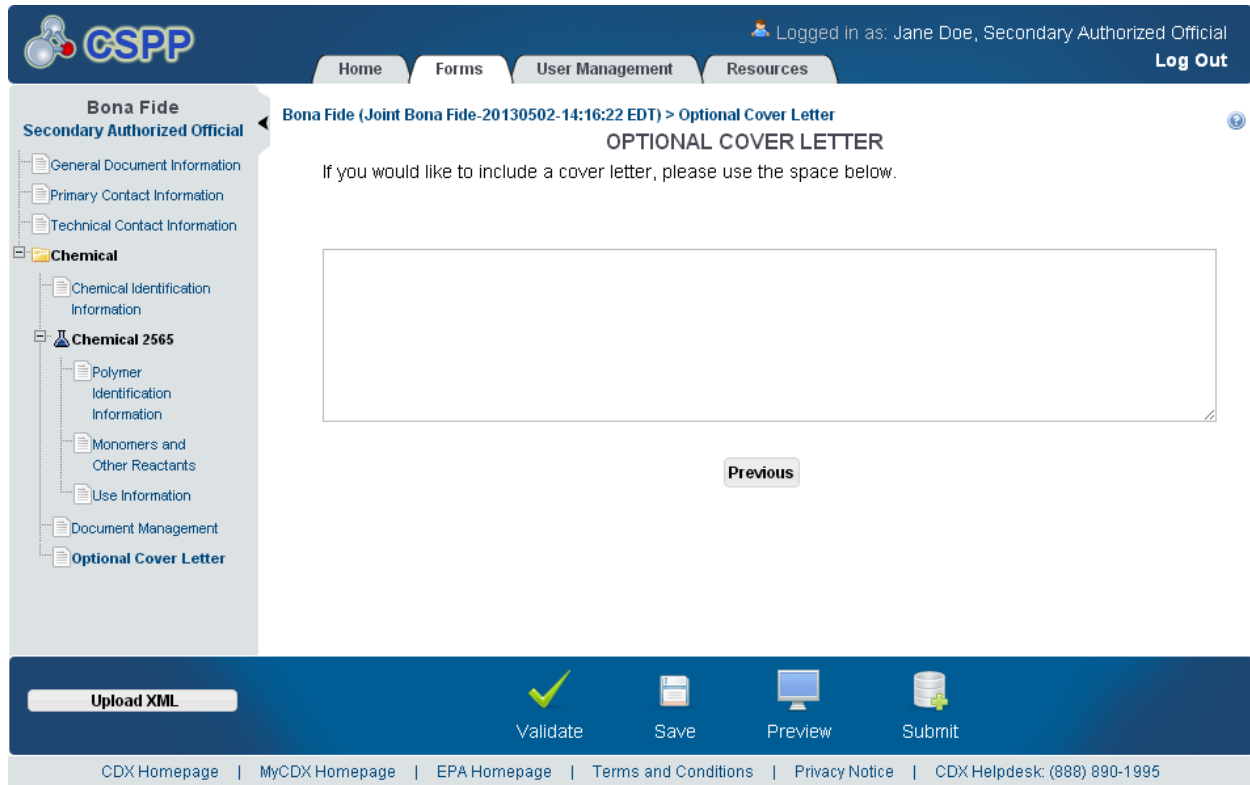
You can navigate to the ‘Optional Cover Letter’ screen by clicking the ‘Next’ button from the ‘Document Management’ screen. You can also access this screen by clicking the ‘Optional Cover Letter’ link within the navigation tree.

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 6-9 shows a screen capture of the ‘Optional Cover Letter’ screen:

Exhibit 6-9: Optional Cover Letter Screen



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 view a PDF preview of the form. Click the ‘Submit’ icon (🗄️) located in the bottom action bar to begin the submission process and navigate to the ‘Submitting Official Information’ screen.

7 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.

Please note in IE 7, the 'Preview EPMN FORM' screen text might be misaligned.

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 7-1 shows a screen capture for the 'Preview' of the Biotechnology form:

Exhibit 7-1: Preview Biotechnology Form Screen

The screenshot displays the 'Preview EPMN Form' interface. At the top, the CSPP logo is on the left, and the user is logged in as 'Jane Doe, Secondary Authorized Official' with a 'Log Out' button on the right. A navigation bar includes 'Home', 'Forms', 'User Management', and 'Resources'. The left sidebar shows the user's role and a list of form sections: 'General Form Information', 'Technical Contact Information', and 'Optional Cover Letter'. The main content area is titled 'PREVIEW EPMN FORM' and contains the instruction 'Please choose a Regular or Sanitized PDF.' Below this is an icon representing two overlapping PDF documents. Two buttons, 'Full Version' and 'Sanitized Version', are positioned below the icon. A note states: 'Note: If you make no CBI claims, the two versions will be the same.' At the bottom of the page, a dark blue bar contains four icons with labels: a checkmark for 'Validate', a floppy disk for 'Save', a monitor for 'Preview', and a database cylinder for 'Submit'. The footer of the page lists various links: 'CDX Homepage', 'MyCDX Homepage', 'EPA Homepage', 'Terms and Conditions', 'Privacy Notice', and 'CDX Helpdesk: (888) 890-1995'.

Exhibit 7-2 shows a screen capture for the 'Preview' of the Biotechnology form:

Exhibit 7-2: Preview Biotechnology Form PDF

		CBI SUBMISSION	
BIO2014P1		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"/>	
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)			CBI <input type="checkbox"/>
First Name		Last Name	
Position		Company	
Mailing Address (Number & Street)			
City		State	Postal Code
e-mail		Telephone (include area code)	
II. TECHNICAL CONTACT 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)	
III. TYPE OF SUBMISSION (Check One)			
<input type="checkbox"/> MCAN (Microbial Commercial Activity Notice) <input type="checkbox"/> TERA (TSCA Experimental Release Application) <input type="checkbox"/> Tier I Exemption <input type="checkbox"/> Tier II Exemption <input type="checkbox"/> Biotech TME (Test Market Exemption)			
IV. TEXT / COMMENTS			CBI <input type="checkbox"/>

EPA Form Number 6300-17 (6-09)

8 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.

Please note in IE 7, the ‘Help’ button aligns to the right side of the ‘Section 5 Notices and Supports Validation’ pop-up window.


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 top right corner of the window.

Exhibit 8-1 shows a screen captures for the ‘Section 5 Notices and Supports Validation’ pop-up window:

Exhibit 8-1: Section 5 Notices and Supports Validation Pop-Up Window



CSDP

SECTION 5 NOTICES AND SUPPORTS VALIDATION

Errors:

- **Technical Contact Information**
 - ❗ [Contact is required.](#)
- **Additional Submission Information**
 - ❗ [Values are required.](#)
- **Site Information**
 - ❗ ['Do you have sites controlled by the submitter?' is required.](#)
 - ❗ ['Do you have sites controlled by others?' is required.](#)
 - ❗ [Do you have sites controlled by the submitter? must be answered with Yes since a Submitter Controlled Operation has been added.](#)
 - ❗ [Do you have sites controlled by others? must be answered with Yes since an Operation Controlled by Others has been added.](#)
- **Submitter Controlled Operations**
 - **Operation 1**
 - **Submitter Operation Information**
 - ❗ [Operation Alias is required.](#)
- **Operations Controlled by Others**
 - **Operation 1**
 - **Industrial Sites Controlled By Others**
 - ❗ [Alias is required.](#)

Warnings:


- **Joint Submission 1**
 - **Joint Submission Information**
 - ⚠ [You did not notify the Secondary Submitter of the joint submission.](#)
- **LOS Submission 1**
 - **Letter of Support Submission Information**
 - ⚠ [You did not notify the Secondary Submitter of the letter of support submission.](#)


9 Submit to EPA via CDX

As the Secondary AO, you have the ability to sign and submit a Joint or Letter of Support form for a Section 5 Notices and Supports form to EPA. You may also submit amendments for Joint forms. 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 allows you to return to a form at any point in the future.

Once you complete all required information and pass validation, the system will allow a Section 5 Notices and Supports form to be successfully submitted.

9.1 Submitting Official Information

Click the 'Submit' icon () located in the bottom action bar of the Section 5 Notices and Supports application to access the 'Submitting Official Information' screen. This screen displays to a Secondary AO upon submission.

After clicking the 'Submit' icon (), the system requires you to review your contact information provided during CDX registration. The system also requires you to identify your job title. Click the 'Home' button to navigate to the Section 5 Notices and Supports 'Home' screen.

The following statement, which displays to the Primary AO and Secondary 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 the checkbox associated with this statement, the application navigates to either the appropriate certification screen or the 'Cross-Media Electronic Reporting Regulation (CROMERR)' screen. The checkbox must be checked in order to continue with the submission.

A 'Submitting On Behalf Of' checkbox will be displayed on the screen if you are submitting an amendment. After you check the checkbox, click the 'Next' button to navigate to the 'Submitting On Behalf Of' screen. The 'Submitting On Behalf Of' checkbox is only displayed for amendments/revisions/updates to the original submission.

Please note in IE 7, the 'Cancel' and 'Next' buttons will be misaligned in the center of the 'Submitting Official Information' screen.

- **Submitting On Behalf Of:** This checkbox only displays for amendments/revisions/updates to an original submission.
- **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:** Enter the job title of the submitting official. This is a required field.
- **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 9-1 shows a screen capture of the ‘Submitting Official Information’ screen:

Exhibit 9-1: Submitting Official Information Screen

Navigation: Click the ‘Next’ button to continue with submitting the form and proceed to the ‘Submission Process: Validation’ screen.

9.2 Submitting On Behalf Of

Click the ‘Submit’ icon () that is located in the bottom action bar of the Section 5 Notices and Supports application to access the ‘Submitting Official Information’ screen. This screen only displays for amendments/revisions/updates/etc. to an original submission.

After checking the ‘Submitting On Behalf Of’ checkbox on the ‘Submitting Official Information’ screen (which is only displayed for amendments/revisions/updates/etc. to an

original submission), you will be taken to the ‘Submitting On Behalf Of’ screen to enter in the information about the company on which you are submitting the form. Click the ‘Home’ button to navigate to the Section 5 Notices and Supports ‘Home’ screen.


- **CBI:** Check the ‘CBI’ checkbox to claim the ‘Submitting On Behalf Of’ information as confidential.
- **First Name:** Enter the first name of the ‘Submitting On Behalf Of’ individual on whose behalf you are submitting this form.
- **Middle Initial:** Enter the middle initial of the ‘Submitting On Behalf Of’ individual on whose behalf you are submitting this form.
- **Last Name:** Enter the last name of the ‘Submitting On Behalf Of’ individual on whose behalf you are submitting this form.
- **Job Title:** Enter the job title of the ‘Submitting On Behalf Of’ individual on whose behalf you are submitting this form.
- **Company Name:** Enter the company name of the ‘Submitting On Behalf Of’ individual on whose behalf you are submitting this form.
- **Phone Number:** Enter the phone number of the ‘Submitting On Behalf Of’ individual on whose behalf you are submitting this form.
- **Email Address:** Enter the email address of the ‘Submitting On Behalf Of’ individual on whose behalf you are submitting this form. The email address must follow the standard email address format: John.Doe@abc.com.
- **Mailing Address 1:** Enter the first line of the mailing address of the ‘Submitting On Behalf Of’ individual on whose behalf you are submitting this form.
- **Mailing Address 2:** Enter the second line of the mailing address of the ‘Submitting On Behalf Of’ individual on whose behalf you are submitting this form.
- **City:** Enter the city of the mailing address of the ‘Submitting On Behalf Of’ individual on whose behalf you are submitting you are submitting this form.
- **State:** Enter the state of the mailing address of the ‘Submitting On Behalf Of’ individual on whose behalf you are submitting this form.
- **Postal Code:** Enter the postal code of the ‘Submitting On Behalf Of’ individual on whose behalf you are submitting this form.
- **Country:** Enter the country of the ‘Submitting On Behalf Of’ individual on whose behalf you are submitting this form.

Exhibit 9-2 shows a screen capture of the ‘Submitting On Behalf Of’ screen:

Exhibit 9-2: Submitting On Behalf Of Screen

Navigation: Click the ‘Next’ button to continue with submitting the form and proceed to the ‘Submission Process: Validation’ screen. Click the ‘Home’ button to navigate back to the Section 5 Notices and Supports ‘Home’ screen.

9.3 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.

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 will generate a PDF.

Exhibit 9-3 shows a screen capture of the ‘Submission Process: Validation’ screen:

Exhibit 9-3: Submission Process: Validation Screen

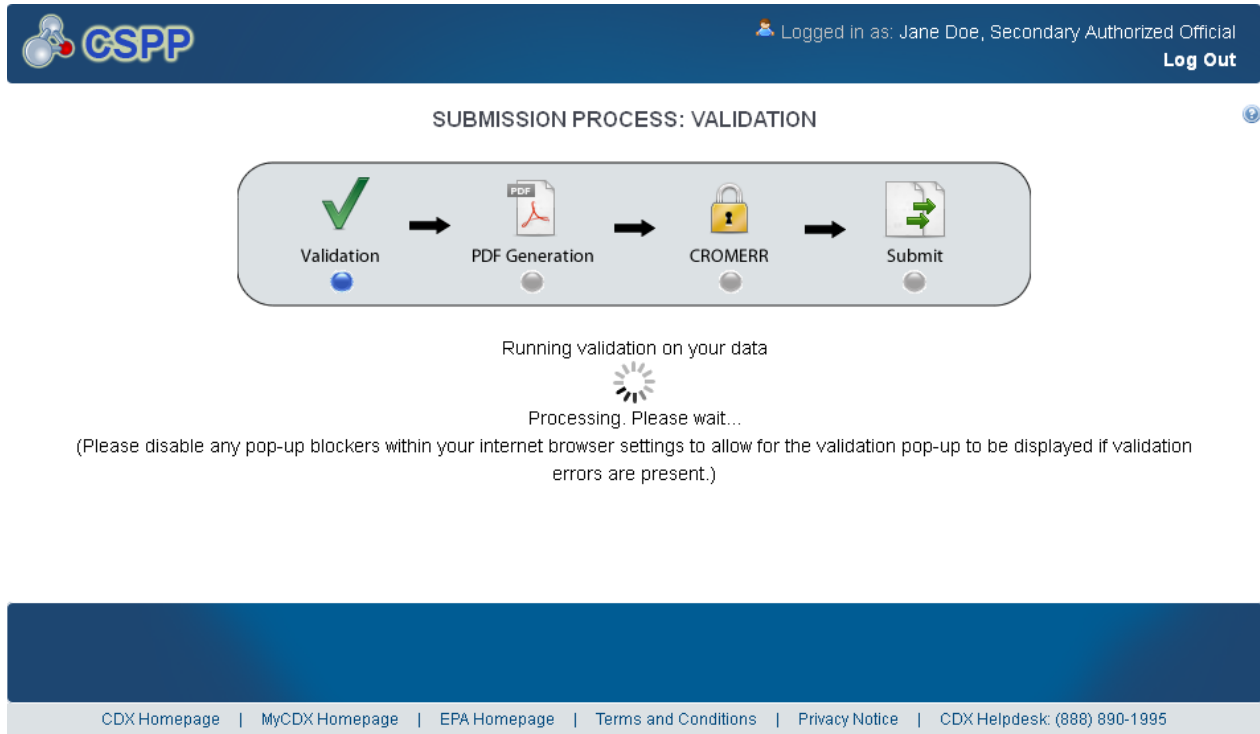
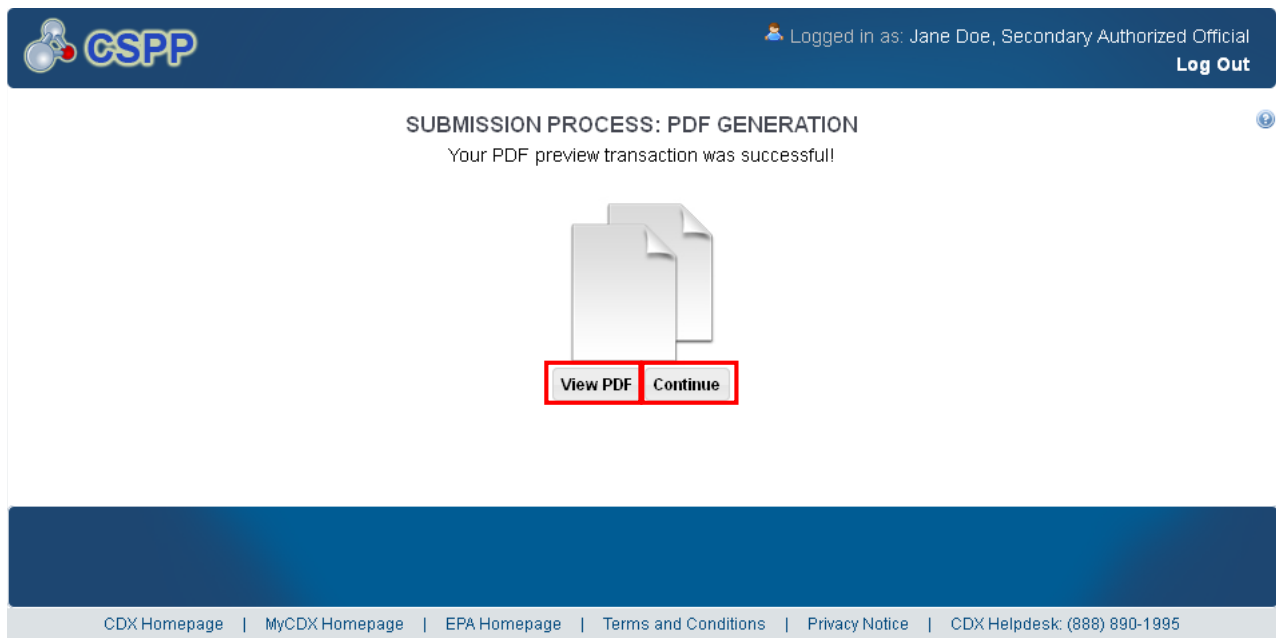


Exhibit 9-4 shows a screen capture of the ‘Submission Process: PDF Generation’ screen:

Exhibit 9-4: Submission Process: PDF Generation Screen



Navigation: Click the ‘View PDF’ button to generate and view a PDF of the form. Click the ‘Continue’ button to continue with submitting the form and proceed to the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Certification’ screen.

9.4 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 9-5 shows a screen capture for the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Certification’ screen:

Exhibit 9-5: 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.

9.5 Cross-Media Electronic Reporting Regulation (CROMERR) Login

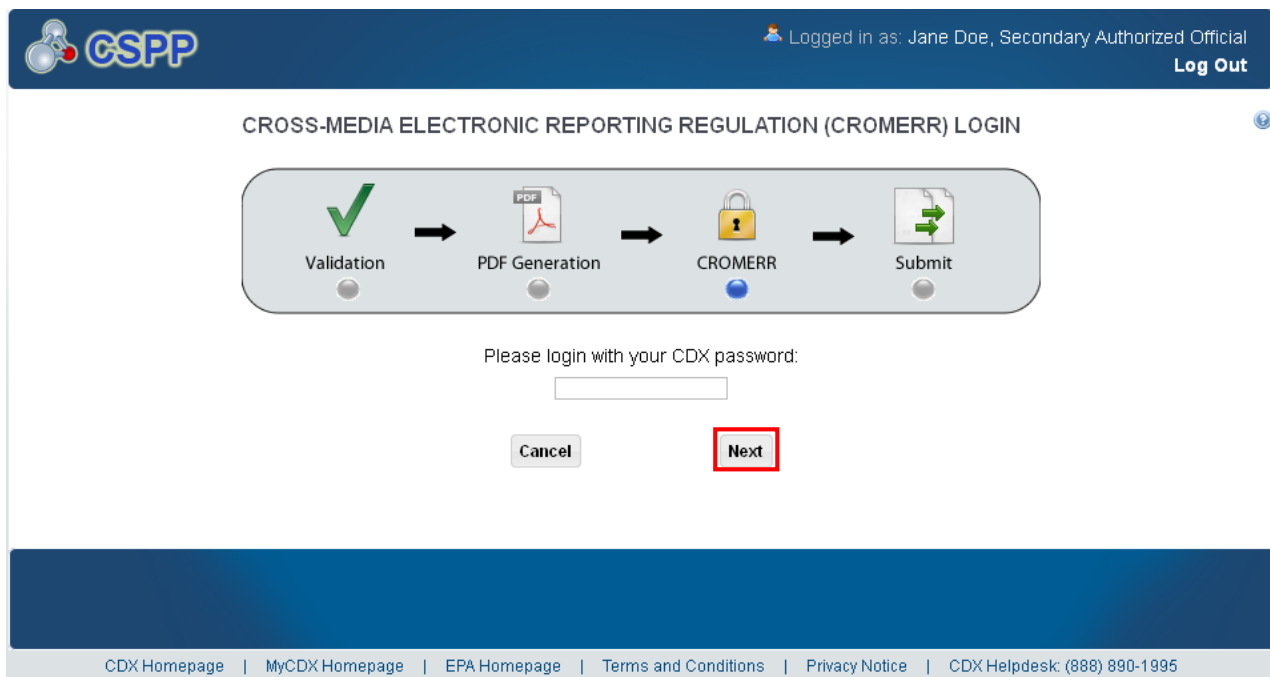
You can access the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Login’ screen by clicking the ‘I Certify’ button on the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Certification’ screen.

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 9-6 shows a screen capture of the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Login’ screen.

Exhibit 9-6: Cross-Media Electronic Reporting Regulation (CROMERR) Login Screen



Navigation: Enter your CDX registration password and click the ‘Next’ button to navigate to the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen.

9.6 Cross-Media Electronic Reporting Regulation (CROMERR) Security Question

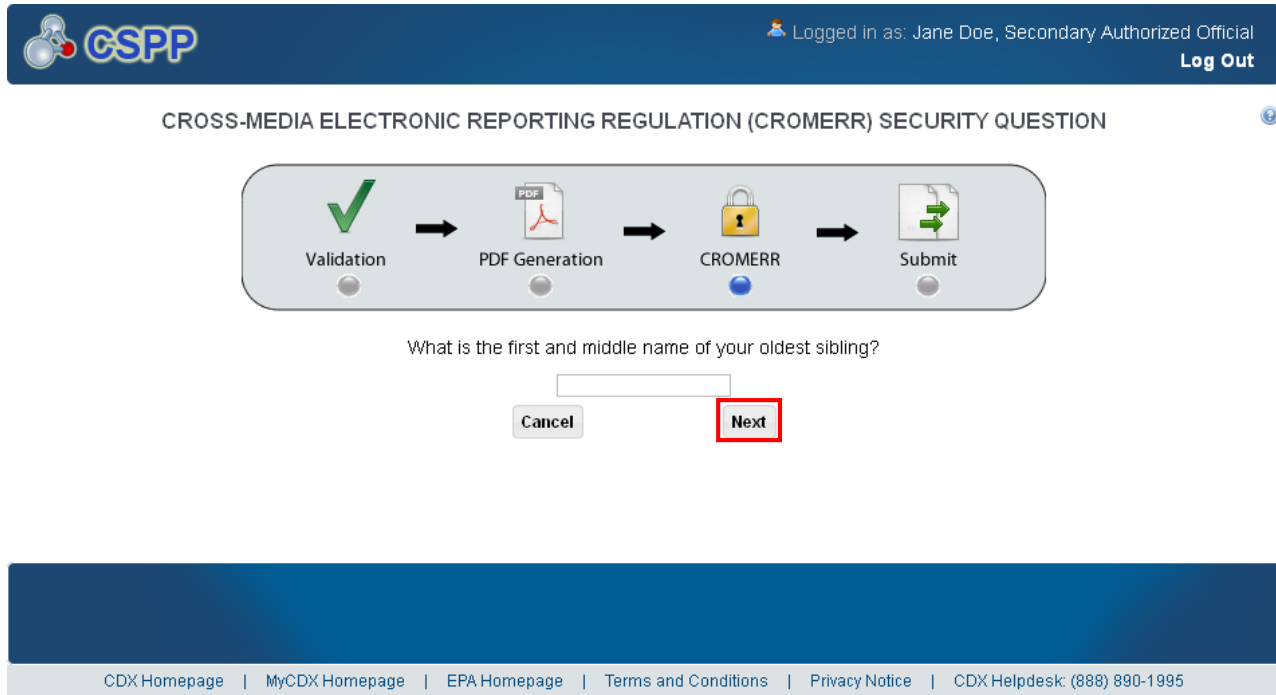
You can access the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen by entering your CDX registration password on the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Login’ screen and clicking the ‘Next’ button.

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 9-7 shows a screen capture of the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen:

Exhibit 9-7: 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.

9.7 Submit to CDX

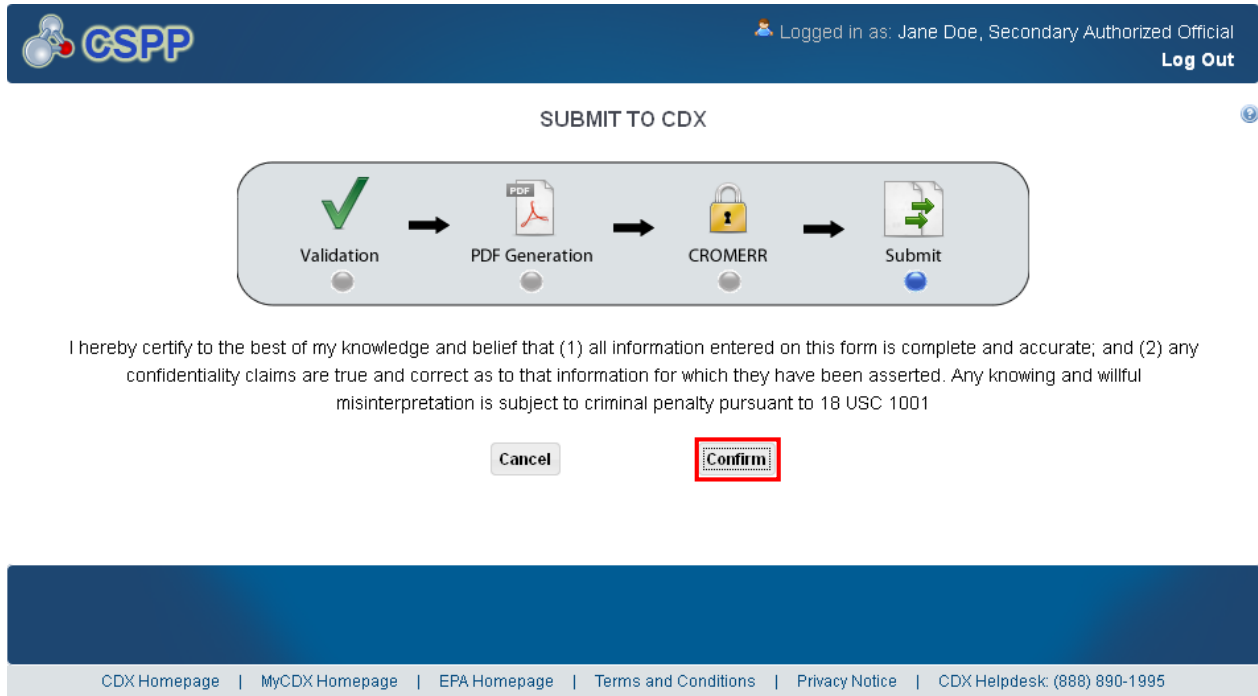
You can access the ‘Submit to CDX’ screen after answering the 20-5-1 security question on the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen and clicking the ‘Next’ button.

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, Biotechnology, and Bona Fide). This screen will display during the submission process for joint submissions and Letters of Support.

Exhibit 9-8 shows a screen capture of the ‘Submit to CDX’ screen:

Exhibit 9-8: Submit to CDX Screen



Navigation: Click the ‘Confirm’ button to navigate to the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Submission’ screen.

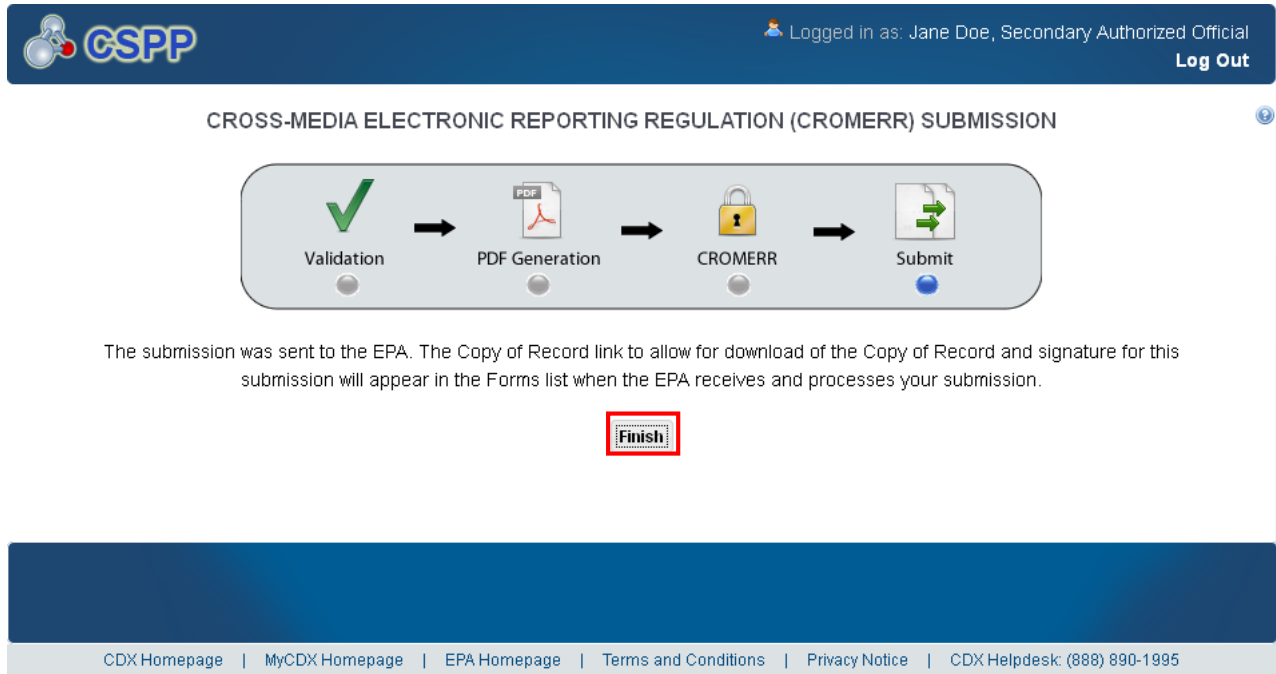
9.8 Cross-Media Electronic Reporting Regulation (CROMERR) Submission

You can access the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Submission’ screen by acknowledging the certification to submit to EPA via CDX by clicking the ‘Confirm’ button.

On the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Submission’ screen, you will see a message indicating the submission has been successfully submitted to EPA via CDX.

Exhibit 9-9 shows a screen capture of the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Submission’ screen:

Exhibit 9-9: 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 processed 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.’

10 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 your 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 10-1 shows a screen capture of the ‘Download Copy of Record’ screen:

Exhibit 10-1: Download Copy of Record Screen

CDX logo

GSPP

Logged in as: Jane Doe, Secondary 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	↓

Home

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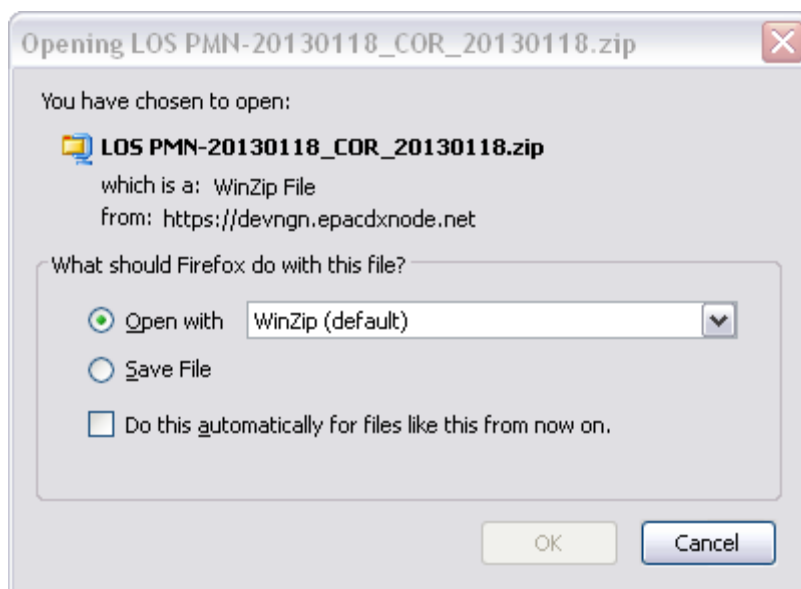
The ‘Download Copy of Record’ screen displays the ‘File Name’ and ‘Action’ columns in a table format. Click the ‘Copy of Record’ icon (↓) to download the individual files uploaded during the submission process, PDF version of the submission or the XML version of the Section 5 Notices and Supports form. 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 to 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.

Exhibit 10-2 shows a screen capture of the download prompt screen:

Exhibit 10-2: Download Prompt Screen



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

11 Create an Amendment

To amend a submitted Joint PMN, Joint Biotechnology, or Bona Fide Letter of Support submission, navigate to the ‘Section 5 Notices and Supports Forms’ screen and locate a previously submitted form 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 11-1 shows a screen capture of the ‘Section 5 Notices and Supports Forms’ screen:

Exhibit 11-1: Section 5 Notices and Supports Form

SECTION 5 NOTICES AND SUPPORTS FORMS

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

Home Forms User Management Resources

- If creating a form in the Section 5 Notices and Supports application, click the **Start New Form** button.
- 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.

5 items found. Page 1 of 1 Items Per Page: 25

Alias	Type	Subtype	Case Number	Status	Modify Date	Submission Date	Copy of Record	Action
Joint Biotechnology-20141208-11:15:40 EST	Joint Biotechnology			In Progress	12/08/2014			✖
Joint Biotechnology-20141208-11:44:03 EST	Joint Biotechnology			In Progress	12/08/2014	12/08/2014	↓	🔒
Joint Bona Fide-20141205-14:52:48 EST	Joint Bona Fide			In Progress	12/08/2014			✖
Joint PMN-20141208-09:34:26 EST	Joint PMN			In Progress	12/08/2014			✖
Joint PMN-20141208-11:49:06 EST	Joint PMN			In Progress	12/08/2014			✖

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

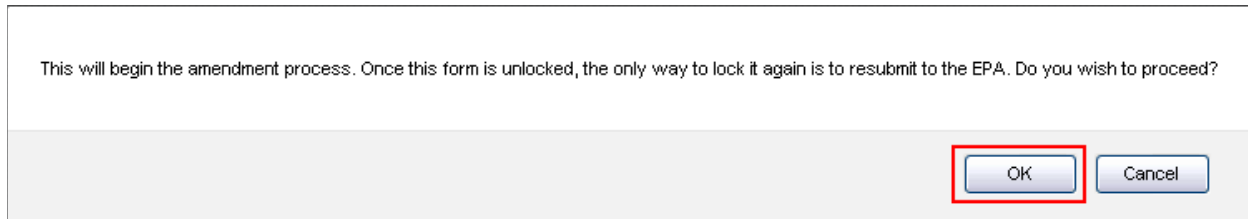
[Start New Form](#)

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Navigation: After clicking the ‘Lock’ icon (🔒), you will receive a prompt to confirm the unlock 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 11-2 shows a screen capture of the ‘Unlock Prompt’ message:

Exhibit 11-2: 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 revised notice process. After you enter the passphrase and click the ‘Next’ button you will be taken to the ‘General Form Information’ screen. Refer to **Section 3.6** 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 an ‘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 1 through Section 4.1.26** for instructions on editing a revised PMN form. Refer to **Section 5.1.1** through **Section 5.1.3** for instructions on editing a revised Biotechnology form.

12 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:** If you click this link, a new internet browser window will generate displaying the ‘Regulatory Impact Analysis for the Regulation of Microbial Products of Biotechnology: Government Costs’ screen.
- **Microbial Products of Biotechnology: Final Rule (62 FR 17910):** If you click this link, a new internet browser window will generate displaying the ‘Microbial Products of Biotechnology: Final Rule (62 FR 17910)’ screen.
- **Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms:** If you click this link, a new internet browser window will generate displaying the ‘Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms’ PDF.
- **CDX Homepage:** If you click this link, a new internet browser window will generate displaying the CDX Homepage.
- **TSCA Chemical Substances Inventory:** If you click this link, a new internet browser window will generate displaying the ‘TSCA Chemical Substances Inventory’ screen.
- **Substance Registry Services (SRS):** If you click this link, a new internet browser window will generate displaying the ‘Substance Registry Services (SRS)’ screen.
- **Facility Registry System (FRS):** If you click this link, a new internet browser window will generate displaying the ‘Facility Registry System (FRS)’ screen.

The FRS generally includes such core data elements as name, address, affiliated organizations and contacts, and industrial classifications. When using this query to search for facilities, use any combination of facility name, geographic location, facility industrial classification, affiliated organization and contact, program category, and national systems information. Enter in as many fields as possible, otherwise the system will return a results list too big to display.

To search for a specific facility, search by Facility Name, Registry ID, Zip Code, and State for an accurate list of results. Search by City Name, Zip Code, and State to return a truncated list of results within a geographic region.

- **CAS Inventory Expert Services:** If you click this link, a new internet browser window will generate displaying the ‘CAS Inventory Expert Services (IES)’ screen.
- **National Pollutant Discharge Elimination System (NPDES):** If you click this link, a new internet browser window will generate displaying the ‘National Pollutant Discharge Elimination System (NPDES)’ screen.

- **New Chemicals Program Homepage:** If you click this link, a new internet browser window will generate displaying the ‘New Chemicals Program’ screen.
- **Status of Section 5 Notices:** If you click this link, a new internet browser window will generate displaying the ‘Status of Section 5 Notices’ screen.

Exhibit 12-1 shows a screen capture of the ‘Resources’ screen (Scroll 1):

Exhibit 12-1: 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.

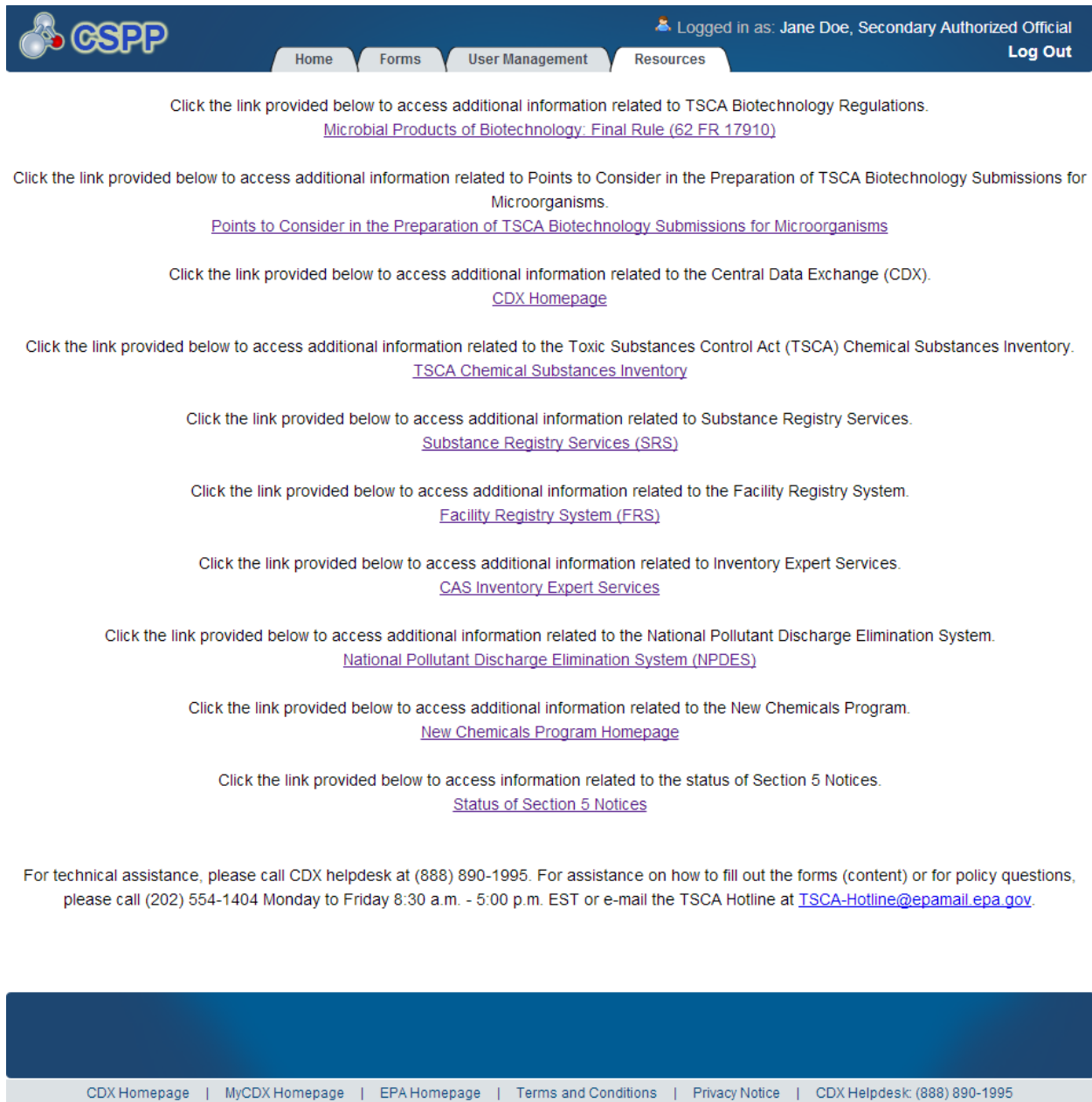
[CAS Inventory Expert Services](#)

Click the link provided below to access additional information related to the National Pollutant Discharge Elimination System.

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Exhibit 12-2 shows a screen capture of the ‘Resources’ screen (Scroll 2):

Exhibit 12-2: Resources Screen (Scroll 2)



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

Home Forms User Management Resources

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](#)

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](#)

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
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
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
TME	Test Market Exemption
TMEA	Test Marketing Exemption Application
TS	Toxic Substances
TSCA	Toxic Substances Control Act
UV	Ultraviolet
XML	Extensible Markup Language