

# Section 8(e) Notice User Guide – Primary Authorized Official

Environmental Protection Agency
Office of Pollution Prevention and Toxics
Manage Toxic Substances

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#### **Paperwork Reduction Act Notice**

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seg. (OMB Control No. 2070-0046; EPA ICR No. 0794). Submissions of substantial risk notifications are mandatory (15 U.S.C. 2607(e)), submissions of FYI notifications are voluntary, and respondents may submit their notifications to EPA by mail, express courier, or electronically through EPA's Central Data Exchange. The annual public burden for this collection of information is estimated to be 50.06 hours per initial section 8(e) submission and 4.06 hours per follow-up/supplemental section 8(e) submission. The same estimates apply to FYI initial and follow-up submissions. For CDX registrations, burden per registration is estimated at 0.53 hours. Burden is defined in 5 CFR 1320.3(b). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. You may send comments regarding the EPA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Regulatory Support Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Please include the OMB Control No. in any correspondence. Send only comments to this address.



#### 1 Introduction

#### 1.1 Overview

This document presents the user guide for the Office of Pollution Prevention and Toxics (OPPT) 'Section 8(e) Notice' application submission process. This document is the user guide for the Primary Authorized Official (AO) user of the Section 8(e) Notice tool. The Primary AO is the person legally responsible for the submission of Section 8(e) Notice data for the reporting company. The AO is typically a senior official for the reporting company and may be the supervisor of the person (or persons) completing the submission.

As a Primary AO, you can create a new submission and assign Supports to edit and complete a submission on your behalf. You are responsible for submitting all the required information and are legally responsible for the information submitted to EPA within each Section 8(e) Notice submission.

General information on Section 8(e) Notices is available on the TSCA Section 8(e) website available at http://www.epa.gov/oppt/tsca8e/. Information on CDX registration, including user roles that apply to completing a Section 8(e) Notice, is available at <a href="http://cdx.epa.gov/About/UserGuide">http://cdx.epa.gov/About/UserGuide</a>

Toxic Substances Control Act (TSCA) regulations require industry to provide the Environmental Protection Agency (EPA) with documentation regarding chemical production, manufacture, distribution, use, disposal, import, and export. As a result, the implementation of TSCA has generated a large volume of documents submitted to the Agency by the regulated community.

TSCA Section 8(e) requires all United States chemical manufacturers, importers, processors, and distributors to notify EPA after obtaining information on any of their chemical substances or mixtures that reasonably supports the conclusion that these substances or mixtures present a substantial risk of injury to health or to the environment.

Anyone subject to the TSCA Section 8(e) reporting requirement should submit a report to EPA within thirty calendar days of obtaining said information. This information may be toxicity or exposure data, full reports, summarized results, limited studies (e.g., range-finding studies), preliminary results, and draft reports that constitute sufficient evidence for Section 8(e) reporting.

General information on TSCA Section 8(e) "notice of substantial risk" is available at <a href="http://www.epa.gov/oppt/tsca8e/">http://www.epa.gov/oppt/tsca8e/</a>

For questions concerning the TSCA Section 8(e) Notice software requirements, please contact the Central Data Exchange (CDX) Help Desk at <a href="https://helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.org/helpesk.

### 1.2 Labeling Confidential Information

This user guide presents instructions and screenshots for the 'Section 8(e) Notice' electronic application as if you were logged in as the Primary AO. As the Primary AO you are able to create, modify, delete, and submit an 8(e) notice. The user may claim certain information as Confidential Business Information (CBI). If the data is claimed as CBI, it will be treated in accordance with Agency confidentiality regulations at 40 CFR part 2, subpart B.



This TSCA Section 8(e) Notice electronic application is optional for the production and submission of these filings. The paper option for filing will continue to be allowed.

Potential users may find that the use of this application saves time, burden and, because it is in an electronic format, provides easy access to reporting forms. Potential users are reminded to carefully read and follow application instructions. Persons who wish to use this application must address all provisions in the application, including those relating to indexing information (i.e., company name, address, chemical name etc.) and those related to CBI submissions, including the requirement for the submission of sanitized or redacted filings.

Please note that certain CBI claims will not be accepted if you choose to use this electronic application for TSCA Section 8(e). For example, chemical name and/or chemical identity, if the chemical is listed on the public portion of the TSCA Inventory, may not be claimed as CBI in a submission using this application. Similarly, the user must enter a non-confidential study title, because it may not be claimed as CBI. EPA does not expect that such information, if evaluated under procedures at 40 CFR part 2, subpart B, would generally be found entitled to confidential treatment.

If the user believes that these or other data elements should be treated as CBI, then the user may use the paper option to file the Section 8(e) Notice and assert CBI claims.

If the user claims the 'Mixture Percent' or an uploaded document as CBI, they are required to complete the appropriate substantiation questions prior to submitting their Notice to EPA. If the user claims an uploaded document as CBI, a sanitized document must be provided.

The following fields can be claimed as CBI within the 'Section 8(e) Notice' application:

- Technical Contact Information
- Submitting on Behalf of Company information
- Submitting on Behalf of Consortium information
- A single chemical substance that is not on the public TSCA Inventory
- The chemical substances comprising a mixture
- The percent concentrations of individual chemical substances in a mixture
- Any document uploaded within the 'Document Management' pop-up window
- All responses to substantiation questions
- Submitting Official Information



## 2 System Requirements:

To use the Section 8(e) Notice application the following are required:

- An e-mail account
- A supported web browser (see Section Error! Reference source not found. below) with Java Script enabled.
- Internet access
- Adobe Acrobat Reader 5.0 or higher
- CDX username and password

#### 2.1 Supported Browsers

One of the following supported browsers is required to access the Section 8(e) Notice application:

- Internet Explorer 7 or above
- Go to the following link to download:
   http://windows.microsoft.com/en-US/internet-explorer/downloads/ie
- Mozilla Firefox 3.5 or above
- Go to the following link to download:
   <a href="http://www.mozilla.com/en-US/firefox/all-older.html">http://www.mozilla.com/en-US/firefox/all-older.html</a>
- 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

#### 2.2 Screen Resolution

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



## 3 Primary Authorized Official Functions

This section describes how to:

- Access the application
- Navigate the Section 8(e) Notice 'Home' screen
- Assign Supports to complete a Section 8(e) Notice submission
- Start and complete a Section 8(e) Notice submission
- Submit to EPA via CDX
- Download the Copy of Record
- Create an amendment

The Primary AO is the person legally responsible for the submission of Section 8(e) Notice data for the reporting company. The AO is typically a senior official for the reporting company and may be the supervisor of the person (or persons) completing the submission.

As a Primary AO, you can create a new submission and assign Supports to edit and complete a submission on your behalf. You are responsible for submitting all the required information and are legally responsible for the information submitted to EPA within each Section 8(e) Notice submission.

You can save the submission at any point during the data entry process. The save functionality will allow you to return to that same submission at any point in the future. You can print the document at any point; however, the 'Not For Submission' watermark will be placed on the portable document format (PDF) document each time the submission is printed.

#### 3.1 Log into Section 8(e) Notice Application

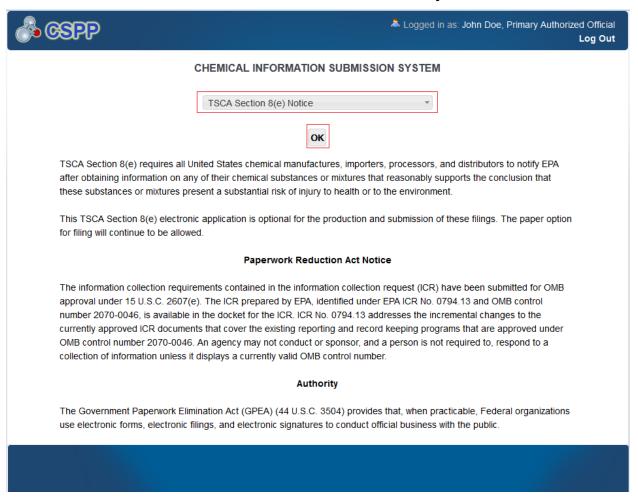
After you create an account in CDX and click the 'Primary Authorized Official' link under the Chemical Safety and Pesticide Programs (CSPP) program service, you will be taken to the 'Chemical Information Submission System' screen.

Note: Information on CDX registration, including user roles that apply to completing a Section 8(e) Notice, is available at <a href="http://cdx.epa.gov/About/UserGuide">http://cdx.epa.gov/About/UserGuide</a>



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

**Exhibit 3-1: Chemical Information Submission System Screen** 



**Navigation:** Select 'TSCA Section 8(e) Notice' from the drop-down menu and click the 'OK' button to navigate to the Section 8(e) Notice 'Home' screen.

#### 3.2 Home Screen Navigation

You can access the Section 8(e) Notice 'Home' screen by selecting 'Section 8(e) Notice' from the 'Chemical Information Submission System' screen drop-down menu and by clicking the 'OK' button.

The Section 8(e) Notice 'Home' screen is the first screen within the Section 8(e) Notice application. It provides you with links and tabs to access the 'Section 8(e) Notice' submissions, 'User Management,' and 'Resources' screens. To navigate to any of these screens, click the screen link (highlighted in blue text), or click the screen tab (located within the application header). The links and tabs provide the same functionality.

• **Submissions:** Click the 'Submissions' link or tab to navigate to the 'Section 8(e) Notice' submissions screen. You can create or modify a Section 8(e) Notice submission using the 'Section 8(e) Notice' submissions screen. For additional details about the 'Section 8(e) Notice' submissions screen, please refer to **Section 3.4.1.** 



- 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 submission using the 'User Management' screen. For additional details about the 'User Management' screen, please refer to Section 3.3.
- **Resources:** Click the 'Resources' link or tab to navigate to the 'Resources' screen. You can view the Section 8(e) Notice user guide, as well as useful links for further usability instructions on the 'Resources' screen. For additional details about the 'Resources' screen, please refer to **Section 8**.

Exhibit 3-2 shows a screen capture for the Section 8(e) Notice 'Home' screen:

👗 Logged in as: John Doe, Primary Authorized Official HOME Submissions TSCA Section 8(e) requires that any person who manufactures (including imports), processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform EPA of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information. **User Management** Manage the access rights of Supports for each Section 8(e) Notice submission. For every Support the Authorized Official may grant him/her the ability to edit (but not unlock, create, delete, or submit) the data. Resources A helpful guide that describes the Section 8(e) Notice system and provides useful links for further usability instruction **Authorized Official** An Authorized Official has the ability to create, amend, and unlock Section 8(e) Notice submissions. The Authorized Official must also submit completed data electronically. Finally, the Authorized Official has the ability to assign Supports to individual submissions. CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

Exhibit 3-2: Section 8(e) Notice Home Screen

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

#### 3.3 User Management Screen

You can access the 'User Management' screen by clicking the 'User Management' link from the Section 8(e) Notice 'Home' screen, or by clicking the tab located within the application header.

On the 'User Management' screen, you can assign your Supports to fill out Section 8(e) Notice submissions. You have the ability to assign access to one or more Supports to modify any of the Section 8(e) Notice submissions you have created. In order to grant a Support access to a Section 8(e) Notice submission, you must create a new submission and assign a passphrase to that



submission. You can also assign different Supports to fill out each Section 8(e) Notice submission.

**Section 8(e) Notice Submission:** Submissions will not be available in this menu until one has been created. Select a submission from the drop-down menu to begin assigning Supports. Once a submission 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.

**Assign Users:** This box shows all the Supports you can assign to complete a Section 8(e) Notice submission for the submission selected. To move Supports from the 'Unassigned' group box to the 'Assigned' group box, highlight the individual or multiple Supports and click the 'add >>' button.

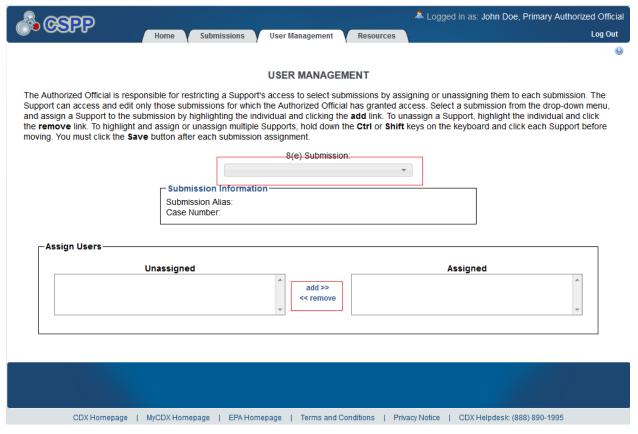
- Unassigned: This box contains the registered Supports who have identified you as their AO that can be assigned to access and edit the selected submission. To highlight multiple Supports hold down the <Ctrl> key on your keyboard while clicking each Support. To highlight multiple consecutive Supports, hold down the <Shift> key on your keyboard while clicking the first and last Support.
- Assigned: This box contains the registered Supports who have been given permission, by you, to access and edit the selected submission. 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 Support.

When you have finished assigning Supports, click the 'Save' button to save the assignments.

Exhibit 3-3 shows a screen capture of the 'User Management' screen:



**Exhibit 3-3: User Management Screen** 



**Navigation:** Click the 'Submissions' tab located within the application header to navigate to the 'Section 8(e) Notice' submissions screen.

#### 3.4 Create New Submission

As a Primary AO, you can start a new submission and assign your Supports to complete identified submissions.

#### 3.4.1 Section 8(e) Notice Submissions Screen

You can access the 'Section 8(e) Notice' submissions screen by clicking the 'Submissions' link from the Section 8(e) Notice 'Home' screen, or by clicking the tab located within the application header.

Only one Section 8(e) Notice submission is created per case number. Case numbers only generate upon submission. Each column within the table of the 'Section 8(e) Notice' submissions screen can be sorted by clicking the column headers.

**Start a New Submission:** To create a new Section 8(e) Notice submission, click the 'Start New Submission' button. You will be required to create a passphrase that will be associated with that particular submission. Make sure to create a passphrase that you will remember, as it cannot be retrieved or reset.

**Edit a Submission:** To modify an existing Section 8(e) Notice submission, click the 'Submission Alias' link for a submission that has a status of 'In Progress.' You will be required



to enter the passphrase associated with that particular submission to access and continue editing the submission.

**Submitted Submission:** To edit an already submitted Section 8(e) Notice submission (i.e., to create an amendment), you must first unlock the particular submission by clicking the lock icon ( ) under the 'Action' column. You will be required to enter the passphrase associated with that particular submission to gain access and amend the submission. All submitted changes will be considered an amendment. Refer to **Section 7** for further instructions on creating an amendment.

The 'Section 8(e) Notice' submissions screen displays the following columns:

- **Submission Alias:** Displays the submission alias you provided within the 'Technical Contact Information' screen. The 'Submission Alias' column will display a time stamp unless you define a unique submission alias on the 'Technical Contact Information' screen. The submission alias is to help identify each Section 8(e) Notice submission.
- Case Number: Displays the case number for the submission. The case number generates upon submission. The 'Case Number' column will display as blank until the Section 8(e) Notice has been submitted successfully.
- **Status:** Displays the status of the Section 8(e) Notice submission. The column will display values as either 'In Progress' or 'Submitted.'
- Modify Date: Displays the date the submission was last modified.
- **Submission Date:** Displays the date you sent the submission to EPA. This date populates only after you submit.
- Copy of Record: Click the 'Copy of Record' icon to continue the download copy of record process. The 'Copy of Record' icon is displayed only after you submit to EPA via CDX. The 'Copy of Record' icon is confirmation that your submission has been successfully received by EPA. Note that the 'Copy of Record' icon may take 15-20 minutes to display on the 'Section 8(e) Notice' submissions screen. Refer to Section 6 for further instructions on downloading the copy of record.
- Action: Displays a 'Delete' icon (ເ) for all submissions with a status of 'In Progress.'

  Displays a 'Lock' icon (□) for all submissions that have been submitted. Only an AO can unlock a submission by clicking the 'Unlocked' icon (□).
- Export Options: Displays 'CSV,' 'Excel,' 'XML,' and 'PDF' links for you to export the 'Section 8(e) Notice' submissions screen in one of the specified formats as an Excel spreadsheet, Comma-Separated Values (CSV), Extensible Markup Language (XML), or Portable Document Format (PDF).

Exhibit 3-4 shows a screen capture of the 'Section 8(e) Notice' submissions screen:



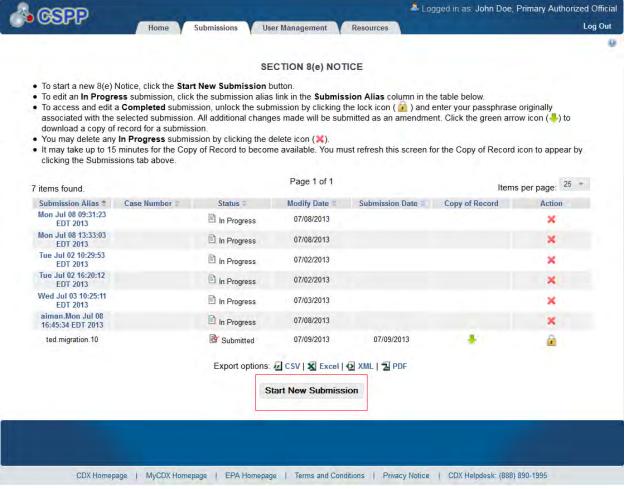


Exhibit 3-4: Section 8(e) Notice Submissions Screen

**Navigation:** Click the 'Start New Submission' button to navigate to the 'Create Passphrase' screen.

#### 3.4.2 Create Passphrase Screen

To start a new Section 8(e) Notice submission, click the 'Start New Submission' button on the 'Section 8(e) Notice' submissions screen. The 'Create Passphrase' screen allows you to create a passphrase and associate that passphrase with your submission.

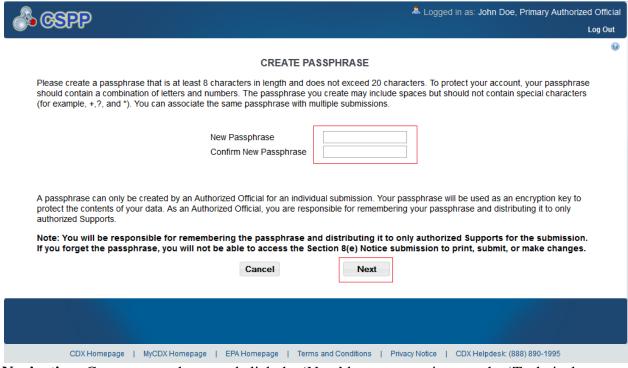
**New Passphrase:** To associate a passphrase with a submission, enter a passphrase that is at least 8 characters in length. To protect your account, your passphrase should contain a combination of letters and numbers. The passphrase you create may include spaces, but should **not** contain special characters (for example, +, and \*). You can associate the same passphrase with multiple submissions.

You will be responsible for remembering the passphrase and distributing it to only authorized Supports for the submission. If you forget the passphrase, you will not be able to access the Section 8(e) Notice submission to print, submit, or make changes. If you lose or forget the passphrase, you must create a new submission 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.



Exhibit 3-5 shows a screen capture of the 'Create Passphrase' screen:

**Exhibit 3-5: Create Passphrase Screen** 



**Navigation:** Create a passphrase and click the 'Next' button to navigate to the 'Technical Contact Information' screen.

#### 3.4.3 Enter Passphrase Screen

To edit a submission click the 'Submission Alias' link for a submission with a status of 'In Progress' on the 'Section 8(e) Notice' submissions screen. The 'Enter Passphrase' screen allows you to enter the passphrase associated with the submission.

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

Exhibit 3-6 shows a screen capture of the 'Enter Passphrase' screen:



**Exhibit 3-6: Enter Passphrase Screen** 



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

**Navigation:** Enter the passphrase that you originally created and associated with the submission and click the 'Next' button to navigate to the 'Technical Contact Information' screen.

#### 3.4.4 Navigation Tree

The navigation tree is located on the left hand side of each screen. You can perform the following functions using the navigation tree:

- Collapse and Expand folders: Each section of the submission 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.
- Open and Close the Navigation Tree: To provide more visual form space, a navigation arrow ( ◀) that opens and closes the navigation tree is located to the right of the navigation tree. Click the arrow ( ◀) 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.
- Navigate between screens: You can use the navigation tree to navigate between the various screens within the application. Each screen of the submission is denoted with a form icon ( ). You can click the form icon ( ) or the screen title link to navigate to the selected screen. 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.' If you click the 'OK' button, you will be taken to the requested screen without saving any of the data in the previous screen. If you click the 'Cancel' button, the prompt will close and you will not be taken to the requested screen.

• Add Chemical: You can click the 'Add Chemical' button located at the bottom of the navigation tree to add another chemical report within a single submission. Clicking the 'Add Chemical' button will generate another chemical report folder containing a 'Chemical Identification' screen and a 'Document Management' screen. The system provides a 'Remove' icon (\*) that allows you to remove any unwanted chemical report folders.

Exhibit 3-7 shows a screen capture of the navigation prompt window:

**Exhibit 3-7: Navigation Prompt** 



Exhibit 3-8 shows a screen capture of the navigation tree:





**Exhibit 3-8: Navigation Tree** 

#### 3.4.5 Action Bar

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

• Validate: You can click the 'Validate' icon (✓) at any stage of completing a Section 8(e) Notice submission to check for certain types of errors in a submission. A 'Section 8(e) Notice Validation' pop-up window generates when you click the 'Validate' icon (✓). The 'Section 8(e) Notice Validation' pop-up window displays a report of all validation errors relating to a failed validation. Refer to Section 4 for more information on validating a submission.

The following exhibits, Exhibit 3-9, Exhibit 3-10, Exhibit 3-11, and Exhibit 3-12 show the screen captures for the action bar:



Exhibit 3-9: Action Bar - Validate



• Save: You can click the 'Save' icon ( □) at any stage of completing a Section 8(e) Notice submission. After you click the 'Save' icon ( □), the data entered on the screen will save. The 'Save' function does not validate any entered data.

Exhibit 3-10: Action Bar - Save



• **Preview:** You can click the 'Preview' icon ( ) at any stage of completing a Section 8(e) Notice submission to preview the submission. After you click the 'Preview' icon ( ), a watermarked PDF version of the submission will generate.

Exhibit 3-11: Action Bar - Preview



• Submit: You can click the 'Submit' icon ( ) to submit the Section 8(e) Notice submission after you or the Support have completed all required sections of the Section 8(e) Notice submission process. After you click the 'Submit' icon ( ), the validation process is initiated. Refer to Section 4 for further instructions on validation errors. You can continue the submission process only after clearing all validation errors. Refer to Section 5 for more information on submitting a Section 8(e) Notice.

Exhibit 3-12: Action Bar - Submit



- **Help Links:** You can click any of the 'Help' links, located at the bottom of each screen, at any stage of completing a Section 8(e) Notice submission.
- If you click the 'CDX Homepage' link, you will be taken to the CDX Homepage.
- If you click the 'MyCDX Homepage' link, you will be taken to the CDX Login screen.
- If you click the 'EPA Homepage' link, you will be taken to the EPA Homepage.



- If you click the 'Terms and Conditions' link, you will be taken to the CDX Terms and Conditions screen.
- If you click the 'Privacy Notice' link, you will be taken to the CDX Privacy and Security Notice screen.

Exhibit 3-13 shows the screen capture of the action bar 'Help' links:

#### Exhibit 3-13: Action Bar - Help Links

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

#### 3.4.6 Technical Contact Information Screen

You can access the 'Technical Contact Information' screen by clicking the 'Start New Submission' button on the 'Section 8(e) Notice' submissions screen and creating a new passphrase, or by accessing a Section 8(e) Notice submission that is in progress and entering the passphrase associated with the selected submission.

The 'Technical Contact Information' screen allows you to submit on behalf of another company or submit on behalf of a consortium. To identify if you are submitting on behalf of another entity, the system provides the radio button for 'This is a submission on behalf of a consortium.' To identify if you are submitting on behalf of another company, the system provides the radio button 'This is a submission on behalf of another company.' The system will not allow you to select more than one radio button per submission.

If you are submitting on behalf of another company, select the 'This is a submission on behalf of another company' radio button. This functionality has been implemented to accommodate a company that may use an agent or another individual. If this radio button is selected, you can enter the contact information for the manufacturing or processing establishment on whose behalf the submission is being made into the 'Submitting on Behalf Of Company' screen upon clicking the 'Next' button. If you select the radio button for 'This is a submission on behalf of a consortium,' you are taken to the 'Submitting on Behalf of Consortium' screen upon clicking the 'Next' button.

If you are not submitting on behalf of another company or on behalf of a consortium, you must select the 'N/A' radio button.

The following fields are displayed on the 'Technical Contact Information' screen:

- CBI: Checking this checkbox will claim the technical contact information as CBI.
- **Submission Alias:** This field is auto-populated with a time stamp and displays on the 'Section 8(e) Notice' submissions screen within the 'Submission Alias' column. This field is editable should you choose to provide your own submission alias.
- N/A: Selecting the 'N/A' radio button allows you to signify that you are neither making a submission on behalf of a consortium nor making a submission on behalf of another company.
- This is a submission on behalf of a consortium: Selecting the 'This is a submission on behalf of a consortium' radio button allows you to identify yourself as an individual submitting on behalf of a consortium.

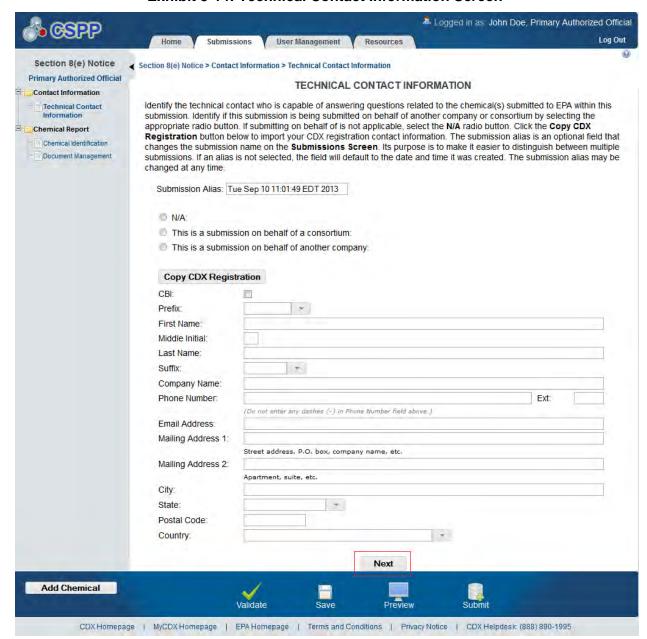


- This is a submission on behalf of another company: Selecting the 'This is a submission on behalf of another company' radio button allows you to identify yourself as an individual submitting on behalf of another company.
- Copy CDX Registration: Clicking the 'Copy CDX Registration' button will automatically populate the fields with your contact information provided during CDX registration.
- **Prefix:** Displays all optional prefixes. If applicable, select the appropriate prefix. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration.
- **First Name:** Enter the technical contact's first name. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Middle Initial:** Enter the technical contact's middle initial. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration.
- Last Name: Enter the technical contact's last name. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Suffix:** Displays all optional suffixes. If applicable, select the appropriate suffix. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration.
- Company Name: Enter the technical contact's company name. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Phone Number:** Enter the technical contact's daytime phone number; US or international. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- Email Address: Enter the technical contact's email address. The email address must follow the standard email address format: <a href="john.doe@abc.com">john.doe@abc.com</a>. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- Mailing Address 1: Enter the first line of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate 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. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration.
- **City:** Enter the city of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.



- **State:** Enter the state of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field if the 'Country' field is 'United States.'
- **Postal Code:** Enter the postal code of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Country:** Displays all available countries. Select the country of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.

Exhibit 3-14 shows the screen capture of the 'Technical Contact Information' screen:



**Exhibit 3-14: Technical Contact Information Screen** 



**Navigation:** If you selected the 'This is a submission on behalf of another company' radio button, click the 'Next' button to navigate to the 'Submitting on Behalf of Company' screen. You can also access this screen by clicking the 'Submitting on Behalf of Company' link within the navigation tree. If you selected the 'This is a submission on behalf of a consortium' radio button, click the 'Next' button to navigate to the 'Submitting on Behalf of Consortium' screen. You can also access this screen by clicking the 'Submitting on Behalf of Consortium' screen. If you selected the 'N/A' radio button, click the 'Next' button to navigate to the 'Chemical Identification' screen. You can also access this screen by clicking the 'Chemical Identification' link within the navigation tree.

#### 3.4.7 Submitting on Behalf Of Company Screen

You can access the 'Submitting on Behalf Of Company' screen by selecting the 'This is a submission on behalf of another company' radio button and clicking the 'Next' button from the 'Technical Contact Information' screen. You can also access this screen by clicking the 'Submitting on Behalf of Company' link within the navigation tree.

The 'Submitting on Behalf Of Company' screen presents you with a list of fields that allows you to input the contact information for the manufacturing or processing establishment on whose behalf the submission is being made.

The following fields are displayed on the 'Submitting on Behalf of Company' screen:

- CBI: Checking this checkbox will claim the 'Submitting on Behalf of Company' information as CBI.
- **Prefix:** The 'Prefix' drop-down menu displays all optional prefixes. If applicable, select the appropriate prefix.
- **First Name:** Enter the first name of the manufacturing or processing establishment contact for which the submission is being made. This is a required field.
- **Middle Initial:** Enter the middle initial of the manufacturing or processing establishment contact for which the submission is being made.
- Last Name: Enter the last name of the manufacturing or processing establishment contact for which the submission is being made. This is a required field.
- **Suffix:** The 'Suffix' drop-down menu displays all optional suffixes and captures the suffix of the manufacturing or processing establishment contact for which the submission is being made. If applicable, select the appropriate suffix.
- **Company Name:** Enter the company name of the manufacturing or processing establishment. This is a required field.
- **Phone Number:** Enter the daytime telephone number of the manufacturing or processing establishment contact for whom the submission is being made; US or international. This field does not accept dashes. This is a required field.
- Email Address: Enter the email address of the manufacturing or processing establishment contact for which the submission is being made. The email address must follow the standard email address format: john.doe@abc.com. This is a required field.
- **Mailing Address 1:** Enter the first line of the mailing address of the manufacturing or processing establishment contact. This is a required field.



- Mailing Address 2: Enter the second line of the mailing address of the manufacturing or processing establishment contact.
- **City:** Enter the city of the mailing address of the manufacturing or processing establishment contact. This is a required field.
- **State:** Enter the state of the mailing address of the manufacturing or processing establishment contact. This is a required field if the 'Country' field is defined as 'United States.'
- **Postal Code:** Enter the postal code of the mailing address of the manufacturing or processing establishment contact. This is a required field.
- **Country:** Enter the country of the mailing address of the manufacturing or processing establishment contact. This is a required field.

Exhibit 3-15 shows the screen capture of the 'Submitting on Behalf of Company' screen:

Logged in as: John Doe, Primary Authorized Official Submissions User Management Section 8(e) Notice Section 8(e) Notice > Contact Information > Submitting on Behalf of Company **Primary Authorized Official** SUBMITTING ON BEHALF OF COMPANY Contact Information Technical Contact Fill out the fields below for the manufacturing or processing establishment on whose behalf this submission is being Information Submitting on Behalf of Company CBI: Chemical Report \* Prefix: Chemical Identification First Name: Document Management Middle Initial X Remove Last Name: Chemical Report 100 Suffix: Document Management Company Name: **X**Remove Phone Number: (Do not enter any dashes (-) in Phone Number field above. Email Address: Mailing Address 1: Street address, P.O. box, company name, etc Mailing Address 2: Apartment, suite, etc. City: State Postal Code Country: -Previous Next Add Chemical CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

Exhibit 3-15: Submitting on Behalf of Company Screen



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

#### 3.4.8 Submitting on Behalf of Consortium Screen

You can access the 'Submitting on Behalf of Consortium' screen by selecting the 'This is a submission on behalf of a consortium' radio button and by clicking the 'Next' button from the 'Technical Contact Information' screen. You can also access this screen by clicking the 'Submitting on Behalf of Consortium' link within the navigation tree.

The 'Submitting on Behalf of Consortium' screen allows you to enter contact information for each consortium member. The system provides you with the ability to identify the consortium name. The contact information of the logged in user will pre-populate the first consortium field set; this information is editable. To add a consortium member, click the 'Add' button to display fields that can be populated and saved. You can click the 'Save' button for each consortium member added to capture all information entered on the screen. A minimum of two consortium members must be added to pass validation.

The following fields are displayed on the 'Submitting on Behalf of Consortium' screen:

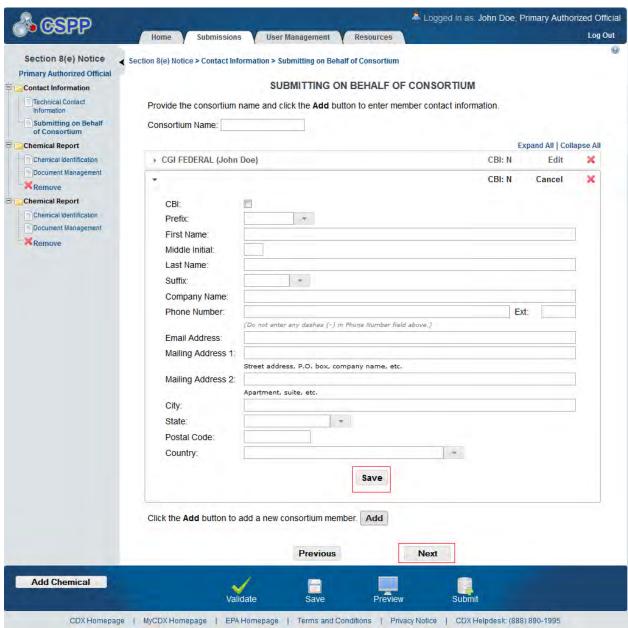
- CBI: Checking this checkbox will claim the 'Submitting on Behalf of Consortium' information as CBI.
- Consortium Name: Enter the name of the consortium.
- **Prefix:** The 'Prefix' drop-down menu displays all optional prefixes and captures the consortium member contact's prefix. If applicable, select the appropriate prefix.
- First Name: Enter the consortium member contact's first name. This field is required.
- Middle Initial: Enter the consortium member contact's middle initial.
- Last Name: Enter the consortium member contact's last name. This field is required.
- **Suffix:** The 'Suffix' drop-down menu displays all optional suffixes and captures the consortium member contact's suffix.
- **Company Name:** Enter the consortium member contact's company name. This field is required.
- **Phone Number:** Enter the consortium member contact's day time telephone number; US or international. This field does not accept dashes. This field is required.
- **Email Address:** Enter the consortium member contact's email address. The email address must follow the standard email address format: <a href="mailto:john.doe@abc.com">john.doe@abc.com</a>. This field is required.
- Mailing Address 1: Enter the first line of the consortium member contact's mailing address. This field is required.
- **Mailing Address 2:** Enter the second line of the consortium member contact's mailing address.
- City: Enter the city of the consortium member contact's mailing address. This is a required field.
- **State:** Enter the state of the consortium member contact's mailing address. This field is required only if the country field is set to 'United States.'



- **Postal Code:** Enter the postal code of the consortium member contact's mailing address. This field is required.
- **Country:** Enter the country of the mailing address of the consortium contact. This is a required field.

Exhibit 3-16 shows the screen captures for the 'Submitting on Behalf of Consortium' screen:

Exhibit 3-16: Submitting on Behalf of Consortium Screen



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

#### 3.4.9 Chemical Identification Screen

You can access the 'Chemical Identification' screen by clicking the 'Next' button from the 'Submitting on Behalf Of Company' screen (if you selected the 'This is a submission on behalf



of another company' radio button), by clicking the 'Next' button from the 'Submitting on Behalf of Consortium' screen (if you selected the 'This is a submission on behalf of a consortium' radio button), or by clicking the 'Next' button from the 'Technical Contact Information' screen (if you selected the 'N/A' radio button). You can also access this screen by clicking the 'Chemical Identification' link within the navigation tree.

The 'Chemical Identification' screen provides a 'Chemical Alias' field to help distinguish between chemical reports when there is more than one chemical report. If you provide a chemical alias, the chemical alias will display within the navigation tree. If you do not provide a chemical alias, 'Chemical Report' will remain as the title of each chemical report folder.

To access Substance Registry Services (SRS) you will identify if you are reporting for a mixture by selecting the 'Yes' or 'No' radio button for 'Is this a submission for a mixture?.' If you identify you are submitting for a mixture, the system provides a 'Please provide the mixture, compound, or product name' optional text box. The mixture name text box does not appear if you select 'No' for 'Is this a submission for a mixture?'.

The following fields are displayed on the 'Chemical Identification' screen:

- Chemical Alias: The chemical alias is used to help distinguish between chemical reports within the navigation tree when there is more than one. A chemical alias can be created for each chemical report folder. If a chemical alias is not identified, 'Chemical Report' will remain as the chemical report folder title within the navigation tree.
- This is a submission for a mixture: Selecting the 'Yes' radio button captures if you are reporting for a mixture.
- Please check this checkbox if the mixture is CBI: Clicking this checkbox will claim the entire chemical mixture as CBI. Checking the CBI checkbox will disable all individual chemical CBI checkboxes.
- Please provide the mixture, compound, or product name: Enter the mixture, compound, or product's name.
- Add: Clicking the 'Add' button will generate a chemical substance field set.
- **Search SRS:** Clicking the 'Search SRS' button will generate a pop-up window to perform an SRS search. Refer to **Section 3.4.9.1** for further details.
- Chemical Identifying Number: Displays the chemical identifying number for the specified chemical substance.
- Chemical Name: Displays the chemical name of the specified substance.
- **Synonym:** Displays the chemical synonym(s) identified by the user. Clicking the 'Add' icon ( ) will allow you to enter up to three synonyms for the identified chemical substance. Click the 'Delete' icon ( ) to delete a synonym.
- **Mixture** (%): Enter the percent composition of each chemical within a mixture. This displays only when you have identified the submission is for a mixture.
- **Mixture** % **CBI**: Checking this checkbox will claim all mixture percent information as CBI.

Exhibit 3-17 shows the screen capture of the 'Chemical Identification' screen for a user reporting for a mixture:



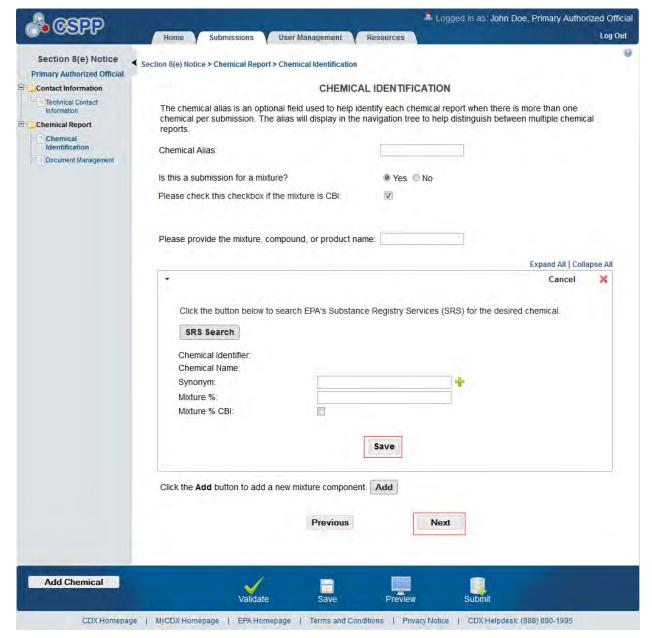


Exhibit 3-17: Chemical Identification Screen: Submission Is for a Mixture

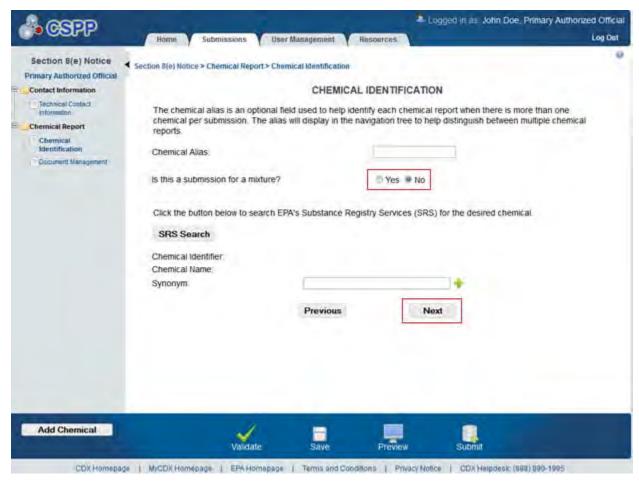
- **CBI:** Checking the CBI checkbox will claim the chemical as CBI. The CBI checkbox only appears if the chemical is not found on the TSCA inventory list.
- This is a submission for a mixture: Selecting the 'No' radio button captures that the user is not reporting for a mixture.
- **Search SRS:** Clicking the 'Search SRS' button will generate a pop-up window to perform an SRS search. Refer to **Section 3.4.9.1** for further details.
- Chemical Identifier: Displays the chemical identifying number for the specified chemical substance.
- Chemical Name: Displays the chemical name of the specified substance.



• Synonym: Displays the chemical synonym(s) identified by the user. Clicking the 'Add' icon ( ) will allow you to enter up to three synonyms for the identified chemical substance. Click the 'Delete' icon ( ) to delete a synonym.

Exhibit 3-18: shows the screen capture for the 'Chemical Identification' screen for reporting for a single chemical substance:

Exhibit 3-18: Chemical Identification Screen: Submission Is Not For a Mixture



**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.

#### 3.4.9.1 Search Substance Registry Services

Click the 'Search SRS' button to generate the 'Substance Registry Services' pop-up window. You can search for the chemical(s) being reported by the 'Chemical Abstract Service Registry Number (CASRN),' 'CA Index Name or Other Synonym,' 'Accession Number,' or 'Generic Name.' After you have searched for and selected a chemical and clicked the 'OK' button, the selected chemical information will populate the 'Chemical Identification' screen. See Section 3.4.9.2 below if you don't know the CAS or Accession Number.

• **CASRN:** Enter the CASRN of the chemical.



- CA Index Name or Other Synonym: Enter the CA Index Name or Other Synonym of the chemical. Displays the following search options: 'Contains,' 'Begins With,' and 'Matches Exactly.'
- Accession Number: Enter the accession number of the chemical. Displays the following search options: 'Contains,' 'Begins With,' and 'Matches Exactly.'
- **Generic Name:** Enter the generic name of the chemical. Displays the following search options: 'Contains,' 'Begins With,' and 'Matches Exactly.'

Exhibit 3-19 shows the screen capture for the 'Search Substance Registry Services' pop-up window:

Exhibit 3-19: Search Substance Registry Services Pop-Up Window



**Navigation:** Click the 'X' button in the upper-right hand corner of the 'SRS Search' window to close the 'Substance Registry Services Search' pop-up window and return to the 'Chemical Identification' screen.



#### 3.4.9.2 Chemical Not Found in Substance Registry Services

You can access the 'Chemical Not Found in Substance Registry Services' screen by entering known information into the SRS window and performing a search. If there are no results, a message will be returned stating 'There were no results returned.' If you are sure the chemical does not exist in SRS, please click the 'Create New Chemical' button to enter the chemical information. Clicking the 'Create New Chemical' button on the 'Search Substance Registry Services' screen takes you to the 'Chemical Not Found in Substance Registry Services' screen. Click the 'Cancel' button to go back to the 'Search Substance Registry Services' screen. When entering information into the 'Chemical Not Found in Substance Registry Services' screen at least one of the following four fields is required; 'Accession Number,' 'CASRN,' 'Premanufacture Notice (PMN) Number,' or 'International Union of Pure and Applied Chemistry (IUPAC) Name'

If you do not know the accession number, CASRN, PMN number, or IUPAC number, check the 'Unknown' checkbox. Once you check the 'Unknown' checkbox, the above mentioned fields are disabled and you are only required to enter a chemical name (or descriptor).

- Unknown: Checking the 'Unknown' checkbox disables the 'Accession Number,' 'CASRN,' 'PMN Number,' and 'IUPAC Name' fields and requires you to enter the chemical name in the 'Chemical Name (descriptor)' field.
- Accession Number: If known, enter the accession number of the chemical.
- **CASRN:** If known, enter the CASRN of the chemical.
- PMN Number: If known, enter the PMN number of the chemical.
- IUPAC Name: If known, enter the IUPAC name of the chemical.
- Chemical Name (descriptor): Enter the chemical name/descriptor of the chemical being reported. This is a required field when the 'Unknown' checkbox is checked.

Exhibit 3-20 shows the screen capture for the 'Chemical Not Found in Substance Registry Services' pop-up window:



Exhibit 3-20: Chemical Not Found in Substance Registry Services Search Pop-Up Window



**Navigation:** Click the 'OK' button to populate the entered information and navigate to the 'Chemical Identification' screen. Click the 'Cancel' button to navigate to the 'Search Substance Registry Services' screen.

The following fields are displayed on the 'Chemical Identification' screen if a chemical is not found in SRS Search:

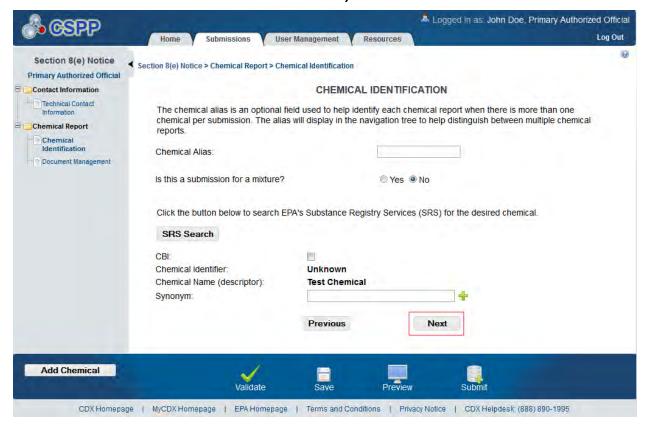
- **CBI:** Checking this checkbox will claim the chemical identity as CBI.
- Chemical Identifier: Displays which identifier you used to label the chemical. The chemical identifier will vary depending on the data entered in the 'Chemical Not Found In Substance Registry Services' screen.
- Chemical Name (descriptor): Displays the chemical name (or descriptor) of the chemical being reported entered in the 'Chemical Not Found In Substance Registry Services' screen.



• Synonym: Enter the chemical synonym(s).. Clicking the 'Add' icon ( †) will allow you to enter up to three synonyms for the identified chemical substance. Click the 'Delete' icon ( ) to delete a synonym.

Exhibit 3-21 shows the screen captures for the 'Chemical Identification' screen when it is populated with a chemical not found in SRS Search:

Exhibit 3-21: Chemical Identification Screen (Populated with chemical not found in SRS Search)



**Navigation:** Click the 'Next' button to navigate to the 'Document Management' screen.

#### 3.4.10 Document Management Screen

You can access the 'Document Management' screen by clicking the 'Next' button from the 'Chemical Identification' screen. You can also access this screen by clicking the 'Document Management' link within the navigation tree.

The 'Document Management' screen allows you to upload documents related to Section 8(e) Notice reporting requirements. To add Section 8(e) Notice documents, click the 'Add Document' button. Clicking the 'Add Document' button generates the 'Document Management' pop-up window.

The 'Document Management' pop-up window allows you to attach the submission types: 'Initial Submission,' 'Follow-up Submission, and 'Final Report Submission.'

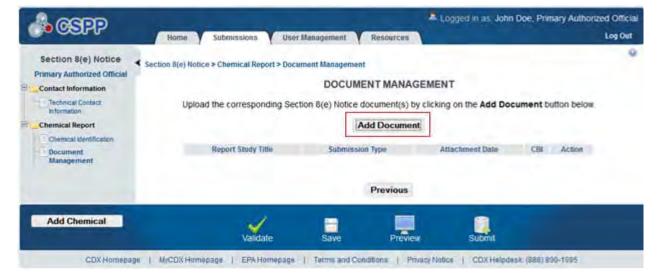
The 'Document Management' table displays the 'Report Study Title' of the document, the document type, the date the document was attached, and the CBI status of the document. The system allows you to delete unwanted documents by clicking the 'Delete' icon ( $\stackrel{>}{\sim}$ ) located



under the 'Action' column. Clicking the report study title link generates the 'Document Management' pop-up window. This allows you to view and edit the attached documents.

- Add Document: Clicking the 'Add Document' button generates the 'Document Management' pop-up window.
- **Report Study Title:** Displays the file name and file extension of the attached file. Clicking the file name link displays the 'Document Management' pop-up window and allows you to view and edit the attached document.
- **Submission Type:** Displays the submission type chosen in the 'Document Management' pop-up window.
- Attachment Date: Displays the date the document was attached.
- **CBI:** Displays 'N' or 'Y' depending on if the CBI checkbox was checked.
- Action: Clicking the 'Delete' icon (💥) will delete the specified row and all contents within. A warning message displays to confirm the deletion of the document.

Exhibit 3-22 shows the screen capture of the 'Document Management' screen:



**Exhibit 3-22: Document Management Screen** 

The 'Document Management' pop-up window allows you to browse for a document from your local hard drive and attach one document at a time. You must enter a report study title and attach one document. Clicking the 'Browse' button will generate the 'File Upload' window on your local hard drive. Select the document you wish to attach and click the 'Open' button. If a document is marked as 'CBI' then a sanitized copy of the document must be attached. To save the attached document to the 'Document Management' screen, click the 'OK' button within the 'Document Management' pop-up window.

- **Report Study Title**: Enter the report study title that is unique to this chemical report. This field is required. This study title must be non-confidential.
- **CBI:** Checking the 'CBI' checkbox will claim the uploaded document as CBI.



- **Submission Type**: Allows you to select the submission type for the attachments. Displays the following options: 'Initial Submission,' 'Follow-up Submission,' and 'Final Submission.'
- **Original Document:** Clicking the 'Browse' button will generate the 'File Upload' window for you to search for a particular file on your hard drive.
- **CBI:** Checking the 'CBI' checkbox will claim the uploaded summary/abstract document as CBI.
- **Summary/Abstract:** Displays 'Yes' and 'No' radio buttons. If you select the 'Yes' radio button a document upload will generate. Click the 'Browse' button to generate the 'File Upload' window for you to search for a particular file on your hard drive.
- **Effects:** Allows you to select the effect specific to the chemical report. Displays the following options: 'Health Effects,' 'Environmental Fate,' 'Ecotoxicity,' and 'Physical Chemical Properties.'
- **Endpoints:** Allows you to select an endpoint that is specific to the chemical report. The endpoints will be specific to the effect chosen from the 'Effects' drop-down menu. If no effect is chosen, no endpoints will display.

Refer to Error! Reference source not found. for a complete list of values that are found within each of the drop-down menus on the 'Document Management' pop-up window. If you have multiple documents that share the same effects and/or endpoints, you must upload each individual document separately and select values from the drop-down menus.

Exhibit 3-23 shows the screen capture of the 'Document Management' pop-up window:



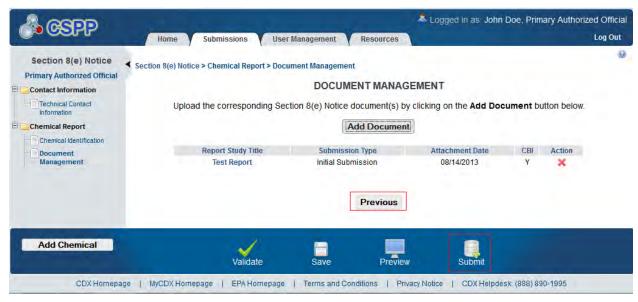
**Exhibit 3-23: Document Management Pop-Up Window** 



**Navigation:** Upload all required documentation and click the 'OK' button to save all data to the 'Document Management' table.

Exhibit 3-24 shows the screen capture for the 'Document Management' screen when a document is uploaded:





**Exhibit 3-24: Document Management Screen (Populated)** 

**Navigation:** Click the 'Next' button to navigate to the 'Substantiation' screen if a chemical or document was claimed as CBI. If no chemical or document was claimed as CBI click the 'Submit' button to begin your submission process.

# 3.4.11 TSCA Health and Safety Filing Substantiation Questions

Users completing submissions within the Section 8(e) Notice application may claim confidentiality for information within the TSCA Section 8(e) submission. If you are claiming CBI within the TSCA Section 8(e) Notice submission, you must complete substantiation questions and submit detailed written explanations to substantiate all CBI claims. Sanitized copies of all documents claimed as CBI must be submitted to be placed in the TSCA public docket.

The system allows you to complete Section 8(e) Notice substantiation for chemicals claimed as CBI as well as documents claimed as CBI. If you only claim the submitting official information, or the technical contact information as CBI, the system does not require the submitter to complete substantiation.

The system takes you to the substantiation sections of the application. Each time you claim an item as CBI that allows substantiation; the system generates an alert that informs you substantiation must be completed for items claimed as CBI.

The system will auto-populate substantiation questions for which the information has already been provided within the Section 8(e) Notice application. The substantiation questions are logically separated into sections within the application to streamline the substantiation process. Each question has functionality built into the system dependent upon your responses.

# 3.4.12 Substantiation Screen

The 'Substantiation' screen presents you with substantiation questions that pertain to the chemical substance(s) and document(s) claimed as CBI. The 'Substantiation' screen presents you with substantiation questions that allow answers to be entered as free text in text fields or by selecting 'Yes' or 'No' radio buttons.



You can access the 'Substantiation' screen by clicking the 'Next' button from the 'Document Management' screen if the chemical substance(s) has been claimed as CBI or document has been claimed as CBI. You can also access the screen by clicking the 'Substantiation' link within the navigation tree. All of the fields on the 'Substantiation' screens are required.

## **Substantiation Question 1:**

Is the subject chemical on the TSCA Inventory or otherwise available in commerce in the United States? If it is a mixture, is the mixture in commerce?

- Yes/No: Allows you to identify if the substance is commercially available.
- **CBI:** Checking this checkbox will claim the answer as CBI.

## **Substantiation Question 2:**

Is the subject chemical or mixture expected to be subject to TSCA or is it expected to be used for a non-TSCA purpose?

- **Yes/No:** Allows you to identify if the substance is expected to be used for a non-TSCA purpose.
- **CBI:** Checking this checkbox will claim the answer as CBI.

#### **Substantiation Question 3:**

Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public. In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitor's access to your customers. Address each piece of information claimed CBI separately.

- **CBI:** Checking this checkbox will claim the answer as CBI
- A text field is available for you to answer the question.

#### **Substantiation Question 4**:

For what period do you assert your claim of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period.

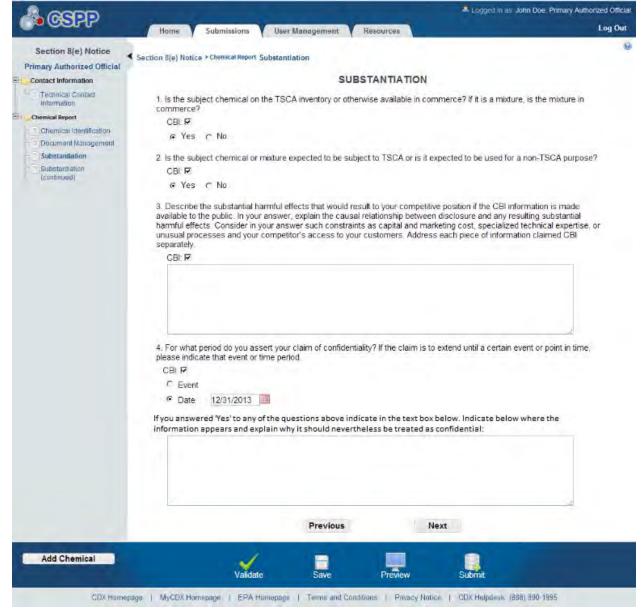
- **CBI:** Checking this checkbox will claim the answer as CBI.
- **Event:** Allows you to enter the appropriate information to complete the question.
- **Date:** Provides a calendar widget for you to specify the date to which the claim of confidentiality extends.

If you answered 'Yes' to any of the questions above indicate why in the text box below. Indicate below where the information appears and explain why it should nevertheless be treated as confidential:

• A text box is displayed and allows you to enter any text.

Exhibit 3-25 shows the screen captures for the 'Substantiation' screen:





**Exhibit 3-25: Substantiation Screen** 

**Navigation:** Answer all substantiation questions and click the 'Next' button to navigate to the 'Substantiation (continued)' screen.

#### 3.4.13 Substantiation (continued) Screen

The 'Substantiation (continued)' screen presents you with substantiation questions that require answers to be entered as free text in text fields or by selecting 'Yes' or 'No' radio buttons.

You can access the 'Substantiation (continued)' screen by clicking the 'Next' button from the 'Substantiation'. All of the fields on the 'Substantiation (continued)' screen are required.

#### **Substantiation Question 5A:**

Do you assert that disclosure of this information you are claiming CBI would reveal any of the following?



Confidential processes used in manufacturing the substance?

Clicking the 'Yes' radio button will bring up another question:

• **CBI:** Checking this checkbox will claim the answer as CBI.

#### **Substantiation Question 5B:**

Do you assert that disclosure of this information you are claiming CBI would reveal any of the following?

If a mixture, the actual portions of the substance in the mixture?

Clicking the 'Yes' radio button will bring up another question:

• **CBI:** Checking this checkbox will claim the answer as CBI.

## **Substantiation Question 5C:**

Do you assert that disclosure of this information you are claiming CBI would reveal any of the following?

Information unrelated to the effects of the substance on human health or the environment?

Clicking the 'Yes' radio button will bring up another question:

• **CBI:** Checking this checkbox will claim the answer as CBI.

#### **Substantiation Question 6A:**

Does the information claimed as confidential appear or is it referred to in any of the following:

Advertising or promotional material for the chemical substance or the resulting end product?

Clicking the 'Yes' radio button brings up another set of questions:

- **CBI:** Checking this checkbox will claim the answer as CBI.
- Browse for the document(s) containing the materials as indicated above: Browse for the specified document and click the 'Upload' button.

#### **Substantiation Ouestion 6B:**

Does the information claimed as confidential appear or is it referred to in any of the following:

Non-confidential material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale)?

Clicking the 'Yes' radio button brings up another set of questions:

- **CBI:** Checking this checkbox will claim the answer as CBI.
- Browse for the document(s) containing the materials as indicated above: Browse for the specified document and click the 'Upload' button.



#### **Substantiation Question 6C:**

Does the information claimed as confidential appear or is it referred to in any of the following:

Professional or trade publications?

Clicking the 'Yes' radio button brings up another set of questions:

- **CBI:** Checking this checkbox will claim the answer as CBI.
- Browse for the document(s) containing the materials as indicated above: Browse for the specified document and click the 'Upload' button.

# **Substantiation Question 6D:**

Does the information claimed as confidential appear or is it referred to in any of the following:

Any other media or publications available to the public or to your competitors?

Clicking the 'Yes' radio button brings up another set of questions:

- **CBI:** Checking this checkbox will claim the answer as CBI.
- Browse for the document(s) containing the materials as indicated above: Browse for the specified document and click the 'Upload' button.

# **Substantiation Question 7:**

Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance?

Clicking the 'Yes' radio button brings up another question:

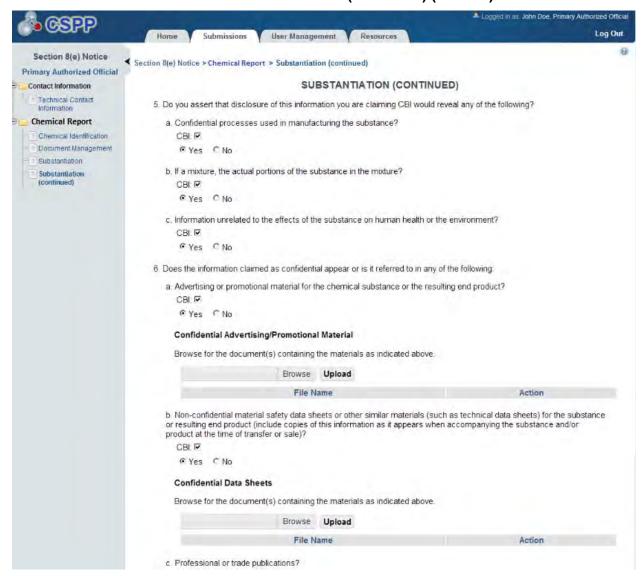
- **CBI:** Checking this checkbox will claim the answer as CBI.
- Browse for the document(s) containing the materials as indicated above: Browse for the specified document and click the 'Upload' button.

If you answered 'Yes' to any of the questions above indicate in the text box below. Indicate below where the information appears and explain why it should nevertheless be treated as confidential: Displays a text field for you to enter the appropriate information to complete the question.

Exhibit 3-26 and Exhibit 3-27 show the screen capture for the 'Substantiation (continued)' screen:



## Exhibit 3-26: Substantiation (continued) (Scroll 1)





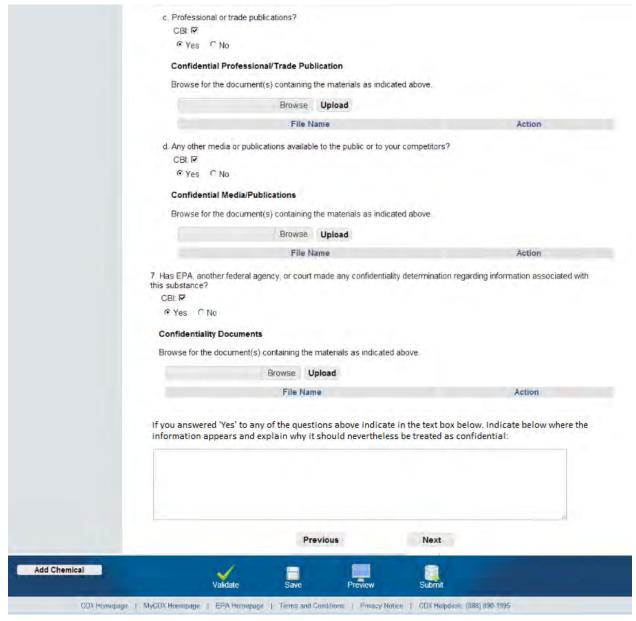


Exhibit 3-27: Mock-Up of Substantiation (continued) (Scroll 2)

**Navigation:** Answer all of the substantiation questions and click the 'Validate' button to navigate to the 'Section 8(e) Notice Validation' pop-up window.



# 4 Validate

You can click the 'Validate' icon () at any stage of completing a Section 8(e) Notice. The 'Section 8(e) Notice Validation' pop-up window is displayed when you click the 'Validate' icon () in the action bar. The 'Section 8(e) Notice Validation' pop-up window displays a report of all validation errors. During the validation process, the application validates each screen of the Section 8(e) Notice to find missing and invalid data. For example, if a document is claimed as CBI a sanitized version of the document must be uploaded. If a sanitized version if not uploaded, you will be unable to complete the submission.

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. For example, if you claimed an uploaded document as CBI and have not attached a sanitized copy prior to validation, the system would display a validation error similar to 'Document Management: ● You have uploaded a CBI document. A sanitized copy is required.' After you click a link, the main application screen will display the screen 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 8(e) Notice Validation' pop-up window. If the information you fixed passes validation, the error will be removed from the 'Section 8(e) Notice Validation' pop-up window. You must fix all validation errors to successfully submit to EPA via CDX.

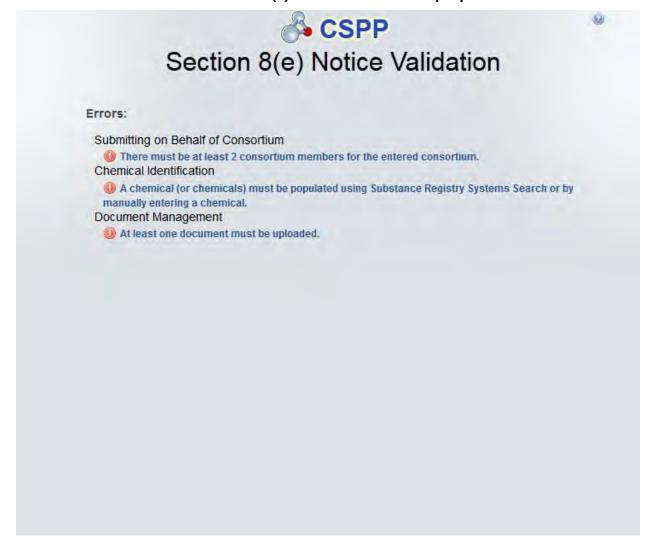
Warning Messages: Warnings are denoted by a 'Warning' icon (△) and can be fixed by clicking the warning link. The links will display the *Screen Title* and the associated warning. After you click a link, the main application screen will display the section where the warning occurred so you can easily fix the warning. Once you have fixed the warning(s), click the 'Validate' icon (✓) again to refresh the 'Section 8(e) Notice Validation' pop-up window. If the information you fixed passes validation, the warning will be removed from the 'Section 8(e) Notice 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 8(e) Notice Validation' pop-up window by clicking the 'X' button located at the top right of the 'Section 8(e) Notice Validation' pop-up window.



Exhibit 4-1 shows the screen capture for the 'Section 8(e) Notice Validation' pop-up window:

Exhibit 4-1: Section 8(e) Notice Validation Pop-Up Window





#### 5 Submit to EPA via CDX

As the Primary AO, you have the ability to sign and submit Section 8(e) Notice submissions to EPA. Any assigned Supports for your submissions do not have access rights to submit to EPA via CDX.

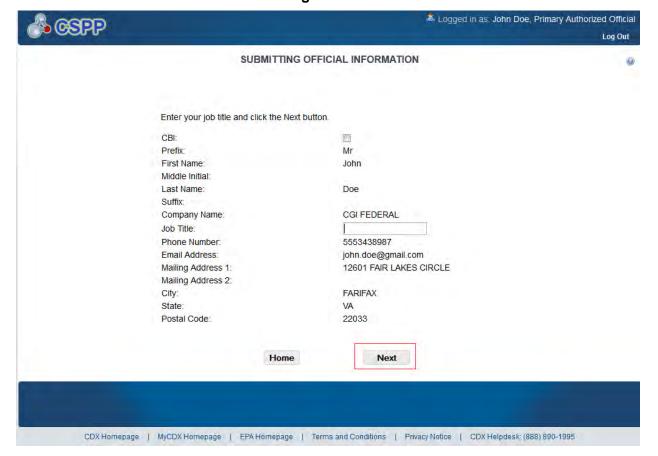
Once you complete all required information and correct all items failing validation, the system will allow you to successfully submit.

# 5.1 Submitting Official Information Screen

Click the 'Submit' icon ( ) that is located in the bottom action bar of the Section 8(e) Notice application to access the 'Submitting Official Information' screen. This screen only displays to the Primary 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.

Exhibit 5-1 shows the screen capture of the 'Submitting Official Information' screen:



**Exhibit 5-1: Submitting Official Information Screen** 

**Navigation:** Click the 'Next' button to continue the submission process and proceed to the 'Submission Process: Validation' screen.



## 5.2 Submission Process: Validation Screen

You can access the 'Submission Process: Validation' screen by clicking the 'Next' button from the 'Submitting Official Information' screen.

The 'Submission Process: Validation' screen will validate the information entered within the Section 8(e) Notice submission.

Exhibit 5-2 shows the screen capture of the 'Submission Process: Validation' screen:

Exhibit 5-2: Submission Process: Validation Screen





After the Section 8(e) Notice submission being submitted is verified, a PDF is generated for you to view.

Exhibit 5-3 shows the screen capture of the 'Submission Process: PDF Generation' screen:



SUBMISSION PROCESS: PDF GENERATION

Your PDF preview transaction was successful!

View PDF Continue

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

Exhibit 5-3: Submission Process: PDF Generation Screen

**Navigation:** Click the 'Continue' button to continue the submission process and proceed to the 'Cross-Media Electronic Reporting Regulation (CROMERR) Certification' screen. Click the 'View PDF' button to view a copy of the Section 8(e) Notice submission.

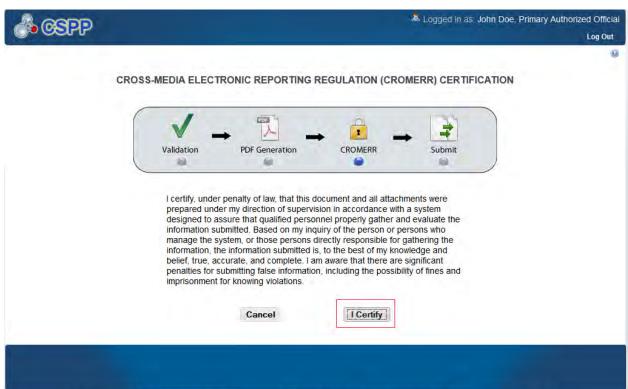
# 5.3 Cross-Media Electronic Reporting Regulation (CROMERR) Certification Screen

Click the 'Continue' button on the 'Submission Process: PDF Generation' screen to access the 'Cross-Media Electronic Reporting Regulation (CROMERR) Certification' screen.

After clicking the 'Continue' button on the 'Submission Process: PDF Generation' screen, the system requires you to certify that the submission is CROMERR compliant. By clicking the 'I Certify' button on the 'CROMERR Certification' screen, you authenticate all of the information entered in the submission. Clicking the 'Cancel' button will allow you to navigate back to the Section 8(e) Notice application.

Exhibit 5-4 shows the screen capture for the 'CROMERR Certification' screen:





**Exhibit 5-4: CROMERR Certification Screen** 

**Navigation:** Click the 'I Certify' button to continue the submission process and proceed to the 'CROMERR Login' screen.

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

# 5.4 CROMERR Login Screen

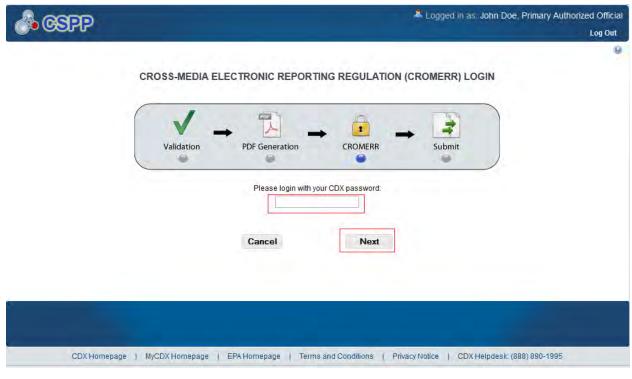
You can access the 'CROMERR Login' screen by clicking the 'I Certify' button on the 'CROMERR Certification' screen.

To submit the Section 8(e) Notice submission, log in to CDX using the credentials you provided during CDX registration:

• Please login with your CDX password: Enter your CDX registration password.

Exhibit 5-5 shows the screen capture of the 'CROMERR Login' screen:





**Exhibit 5-5: CROMERR Login Screen** 

**Navigation:** Enter your CDX registration password and click the 'Next' button to navigate to the 'CROMERR Security Question' screen.

# 5.5 CROMERR Security Question Screen

You can access the 'CROMERR Security Question' screen by entering your CDX registration password and clicking the 'Next' button on the 'CROMERR Login' 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.

Exhibit 5-6 shows the screen capture of the 'CROMERR Security Question' screen:





**Exhibit 5-6: CROMERR Security Question Screen** 

**Navigation:** Answer the security question and click the 'Next' button to navigate to the 'Submit to CDX' screen.

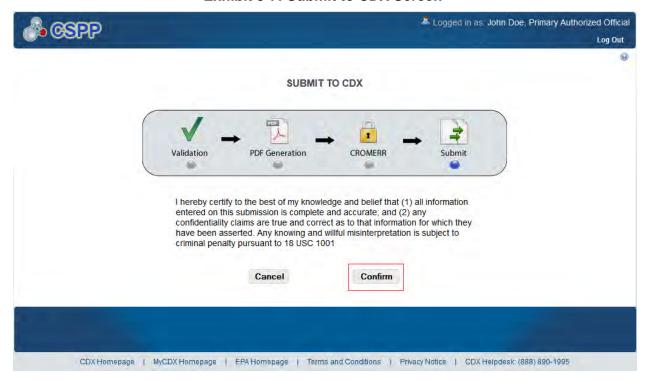
#### 5.6 Submit to CDX Screen

You can access the 'Submit to CDX' screen after answering the 20-5-1 security question and clicking the 'Next' button on the 'CROMERR Security Question' screen.

On the 'Submit to CDX' screen, you will see a certification message. Read the message and acknowledge it by clicking the 'Confirm' button. Once you have clicked the 'Confirm' button, your submission will be submitted to EPA via CDX.

Exhibit 5-7 shows the screen capture of the 'Submit to CDX' screen:





**Exhibit 5-7: Submit to CDX Screen** 

Navigation: Click the 'Confirm' button to navigate to the 'CROMERR Submission' screen.

#### 5.7 CROMERR Submission Screen

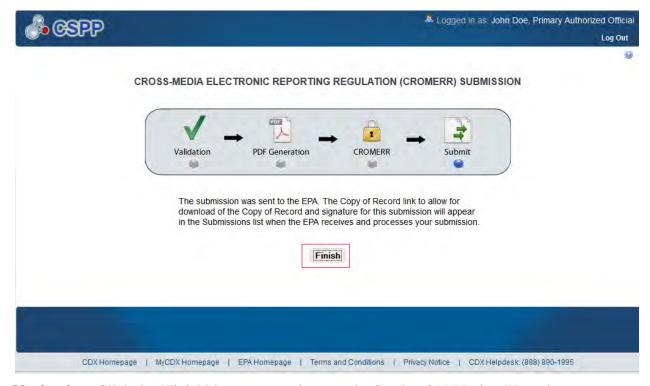
You can access the 'CROMERR Submission' screen by acknowledging the certification to submit to EPA via CDX by clicking the 'Confirm' button on the 'Submit to CDX' screen.

On the 'CROMERR Submission' screen, you will see a message indicating the submission was successfully submitted to EPA via CDX.

Exhibit 5-8 shows the screen capture of the 'CROMERR Submission' screen:



**Exhibit 5-8: CROMERR Submission Screen** 



**Navigation:** Click the 'Finish' button to navigate to the Section 8(e) Notice 'Home' screen. Then click the 'Submissions' link or tab to find your locked submission. The 'Section 8(e) Notice' submissions screen will display the submission with a lock icon ( ) under the 'Action' column and will display a status of 'Submitted.'



# 6 Download Copy of Record

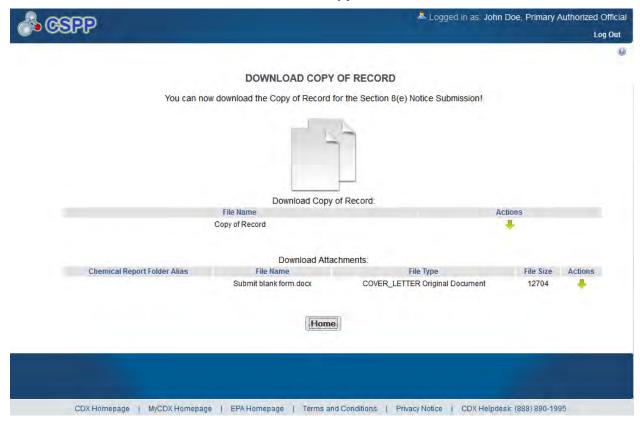
To download a copy of record, navigate to the 'Section 8(e) Notice' submissions screen and locate a successfully completed submission with a status of 'Submitted.' Note that if you have just submitted to EPA via CDX, the 'Copy of Record' icon may take 15-20 minutes to display. In addition, you must refresh the 'Section 8(e) Notice' submissions screen by clicking your browser's refresh button for the 'Copy of Record'icon to display.

After you click the 'Copy of Record'icon, enter the passphrase associated with the submission, and click the 'Next' button. The 'Enter Passphrase' screen requires you to enter the passphrase originally associated with the submission. If your passphrase is entered correctly, you will be taken to the 'Cross-Media Electronic Reporting Regulation (CROMERR) Login' screen where you are required to enter the credentials you provided during CDX registration. Once you have provided the correct CDX password, click the 'Next' button to navigate to the 'Cross-Media Electronic Reporting Regulation (CROMERR) Security Question' screen. The '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 correct, you will be taken to the 'Download Copy of Record' screen.

The 'Download Copy of Record' screen displays the 'Chemical Report Folder Alias,' 'File Name,' 'File Type,' 'File Size,' and 'Actions' columns in a table format. You can click the copy of record icon to download a PDF version of the submitted Section 8(e) Notice submission and a XML version of the Section 8(e) Notice submission. 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.

Exhibit 6-1 shows the screen capture of the 'Download Copy of Record' screen:

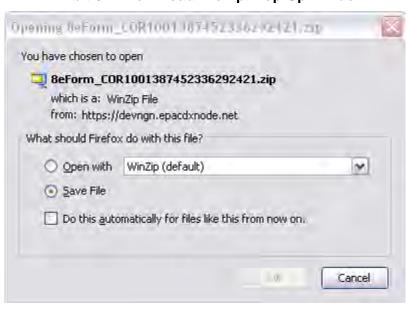




**Exhibit 6-1: Download Copy of Record Screen** 

Exhibit 6-2 shows a screen capture of the download prompt pop-up window:

Exhibit 6-2: Download Prompt Pop-Up Window



If you click the copy of record icon you will download the zip file of the Section 8(e) Notice submission that contains the following:

• A PDF version of the Section 8(e) Notice submission



• An XML version of the Section 8(e) Notice submission



# 7 Create an Amendment

To amend a submitted Section 8(e) Notice submission, navigate to the 'Section 8(e) Notice' submissions screen and locate a submission 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 7-1 shows the screen capture of the 'Section 8(e) Notice' submissions screen:

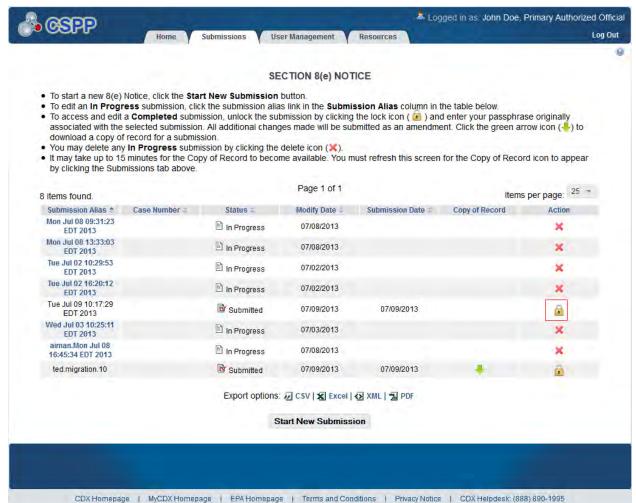


Exhibit 7-1: Section 8(e) Notice Submissions – Amendment

**Navigation:** After clicking the 'Lock' icon ( ), you will receive a prompt to confirm the unlock process. Once your submission is unlocked, you will have the ability to update the information within your document. If you do not want to continue with the amendment, click the 'Cancel' button to cancel the amendment process and return to the 'Section 8(e) Notice' submissions screen. Click the 'OK' button to close the prompt and continue with the amendment process.

Exhibit 7-2 shows the screen capture of the 'Unlock Prompt' message:



**Exhibit 7-2: Unlock Prompt Message** 



After you click the 'OK' button, you will be taken to the 'Enter Passphrase' screen. You must enter the passphrase originally associated with the submission to start the amendment process. After you enter the passphrase and click the 'Next' button, you will be taken to the 'Technical Contact Information' screen.

After a submission has been unlocked, the 'Section 8(e) Notice' submissions screen will display a status of 'In Progress' under the 'Status' column, and the 'Unlocked' icon ( ) will display under the 'Action' column; however, you will not see these changes until you navigate back to the 'Section 8(e) Notice' submissions screen.



#### 8 Resources

You can access the 'Resources' screen by clicking the 'Resources' link on the Section 8(e) Notice 'Home' screen or by clicking the 'Resources' tab located in the application header. The 'Resources' screen provides you with a link to the Section 8(e) Notice user guide as well as additional helpful links. Click the 'User Guide' link to access the Section 8(e) Notice user guide document.

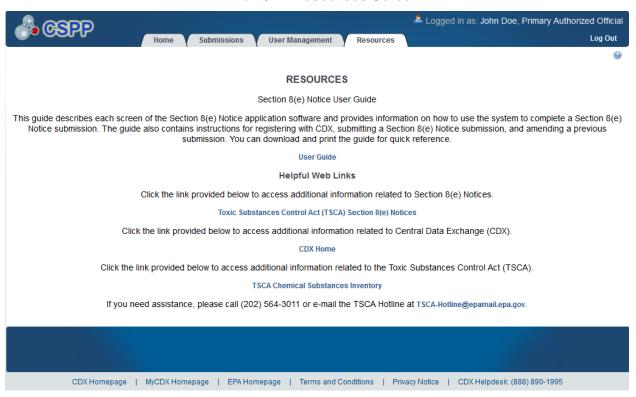
Toxic Substances Control Act (TSCA) Section 8(e) Notices: If you click this link, a new internet browser window will generate displaying EPA's TSCA Section 8(e) Notices screen.

**CDX Home:** 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 for EPA's TSCA Chemical Substances Inventory screen will be displayed.

Exhibit 8-1 shows the screen capture of the 'Resources' screen:

Exhibit 8-1: Resources Screen





# Appendix A. Definitions, Acronyms, and Abbreviations

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
AO	Authorized Official
CA	Chemical Abstract
CASRN	Chemical Abstract Service Registry Number
CBI	Confidential Business Information
CDX	Central Data Exchange
CoR	Copy of Record
CROMERR	Cross-Media Electronic Reporting Regulation Security System
CSPP	Submissions for Chemical Safety and Pesticide Programs
CSV	Comma-Separated Values
EPA	Environmental Protection Agency
EST	Eastern Standard Time
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
IUPAC	International Union of Pure and Applied Chemistry
OPPT	Office of Pollution Prevention and Toxics
PDF	Portable Document Format
PMN	Premanufacture Notices
SRS	Substance Registry Services
TSCA	Toxic Substances Control Act
UVCB	Unknown or Variable Composition or Complex Reaction Product or Biological Material
XML	Extensible Markup Language



# Appendix B. Submission Types, Effects, and Endpoints

The following appendix displays all possible options within each drop-down menu on the 'Document Management' pop-up window.

# First Dropdown:

- Title: Submission Type
- Contains the following values
  - o Initial Submission
  - o Follow-Up Submission
  - o Final Submission

## Second Dropdown

- Title: Summary/Abstract Submission
- Contains the following values
  - o Yes
  - o No

#### Third Dropdown

- Title: Effects
- Contains the following values
  - Health Effect
  - o Ecotoxicity
  - o Environmental Fate
  - o Physical-Chemical Properties

#### Fourth Dropdown

- Title: Endpoints
- Contains the following values
  - o For Health Effect (shows when Health Effect is selected from third dropdown)
    - Basic Toxic kinetics
    - Dermal Absorption
    - Acute Toxicity: oral
    - Acute Toxicity: inhalation
    - Acute Toxicity: dermal
    - Acute Toxicity: other routes
    - Skin irritation/corrosion
    - Eye irritation
    - Skin sensitization
    - Respiratory sensitization
    - Repeated Dose toxicity: oral
    - Repeated Dose toxicity: inhalation



- Repeated Dose Toxicity: dermal
- Repeated Dose Toxicity: other routes
- Genetic Toxicity in vitro
- Genetic Toxicity in vivo
- Carcinogenicity
- Toxicity to Reproduction
- Developmental Toxicity/teratogenicity
- Toxicity to reproduction: other studies
- Neurotoxicity
- Immunotoxicity
- Specific investigations: other studies
- Health surveillance data
- Epidemiological data
- Direct observations: clinical cases, poisoning incidents and other
- Sensitization data (humans)
- Exposure related observations in humans: other data
- Toxic effects on livestock and pets
- Additional toxicological information
- Other
- o For Ecotoxicity (shows when Ecotoxicity is selected from third dropdown)
  - Short-term toxicity to fish
  - Long-term toxicity to fish
  - Short-term toxicity to aquatic invertebrates
  - Long-term toxicity to aquatic invertebrates
  - Toxicity to aquatic algae and cyanobacteria
  - Toxicity to aquatic plants other than algae
  - Toxicity to microorganisms
  - Toxicity to other aquatic organisms
  - Sediment toxicity
  - Toxicity to soil macroorganisms except arthropods
  - Toxicity to terrestrial arthropods
  - Toxicity to terrestrial plants
  - Toxicity to soil microorganisms
  - Toxicity to birds
  - Toxicity to other above-ground organisms
  - Biological effects monitoring
  - Biotransformation and kinetics
  - Additional ecotoxicological information
  - Other



- o For Environmental Fate (shows when Environmental Fate is selected from third dropdown)
  - Photo transformation in air
  - Hydrolysis
  - Photo transformation in water
  - Photo transformation in soil
  - Biodegradation in water: screening test
  - Biodegradation in water and sediment: simulation tests
  - Biodegradation in soil
  - Mode of degradation in actual use
  - Bioaccumulation: aquatic/sediment
  - Bioaccumulation: terrestrial
  - Adsorption/desorption
  - Henry's Law constant
  - Distribution Modeling
  - Other Distribution Data
  - Monitoring Data
  - Field Studies
  - Additional Information on Environmental Fate and Behavior
  - Other
- o For Physical-Chemical Properties (shows when Physical-Chemical Properties is selected from third dropdown)
  - Appearance/Physical
  - Melting Point
  - Boiling Point
  - Density
  - Particle size distribution
  - Vapor Pressure
  - Partition Coefficient
  - Water Solubility
  - Solubility in Organic Solvent
  - Surface Tension
  - Flash Point
  - Auto Flammability
  - Flammability
  - Explosiveness
  - Oxidizing Properties
  - Oxidation Reduction Potential
  - Stability in organic solvents and identity of relevant degradation products
  - Storage stability and reactivity towards container material



- Stability: thermal, sunlight, metals
- рΗ
- Dissociation constant
- Viscosity
- Additional physic-chemical information