Risk Evaluation Rule User Guide – Primary Authorized Official

Environmental Protection Agency

Office of Pollution Prevention and Toxics

EPA# EPA 705-G-2021-3733

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

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

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

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List of Exhibits

1 Introduction

This document presents the user guide for the Office of Pollution Prevention and Toxics (OPPT) Risk Evaluation Rule application submission process. This document is the user guide for the Primary Authorized Official (AO) of the Risk Evaluation Rule application.

The Risk Evaluation Rule application is the electronic, web-based tool provided by the United States Environmental Protection Agency (EPA) for the submission of Risk Evaluation data and responses to FR Notices. As a Primary AO, you can create, modify, and/or submit a Manufacturer Risk Evaluation request, EPA Initiated Risk Evaluation, and an Initial Response. You can also pay invoices and receive EPA communications. You can also delete request and responses, submit a Withdrawal Request, create amendments, and download the Copy of Record (CoR).

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0038, 0012, 0208). Responses to this collection of information are mandatory for certain persons, as specified at 40 CFR 713.7. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be 30 hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

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

For questions concerning the Toxic Substances Control Act (TSCA) Risk Evaluation software requirements, please contact the Central Data Exchange (CDX) Help Desk at helpdesk@epacdx.net or call 1-888-890-1995 between the hours of 8 am - 6 pm Eastern Standard Time (EST).

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

2 System Requirements

To use the Risk Evaluation Rule application to submit a Risk Evaluation request, the following are required:

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

2.1 Supported Browsers

One of the following supported browsers is required to access the Risk Evaluation Rule application:

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

  Go to the following link to download:

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

- Vendor supported versions of Mozilla Firefox

  Go to the following link to download:

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

- Vendor supported versions of Safari

  Go to the following link to download:

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

- Vendor supported versions of Google Chrome

  Go to the following link to download:

  http://www.google.com/chrome

2.2 Screen Resolution

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

3 Primary Authorized Official (AO) Functions

This section describes how to:

- Access the application
- Navigate the Risk Evaluation 'Home' screen
- Assign Supports to complete a form
- Start and complete the Risk Evaluation request
- Start and complete EPA's Initiated Risk Evaluation
- Start and complete the Withdrawal Request
- Start and complete an Initial Response
- Download a Copy of Record
- Create an amendment

The Primary AO is responsible for the submission of Risk Evaluation requests. As a Primary AO, you can create a new form. You are also responsible for submitting amendments, unlocking submissions, and deleting forms. You can assign Supports (or other authorized individuals) to edit and complete a form on your behalf.

You can save the form at any point during the data entry process. The save functionality allows you to return to that same form at any point in the future. Additionally, a PDF version of the form can be previewed at any point.

Exhibit 3-1 displays a table of the user role capabilities within the Risk Evaluation Rule application.

Exhibit 3-1 Risk Evaluation User Roles Matrix

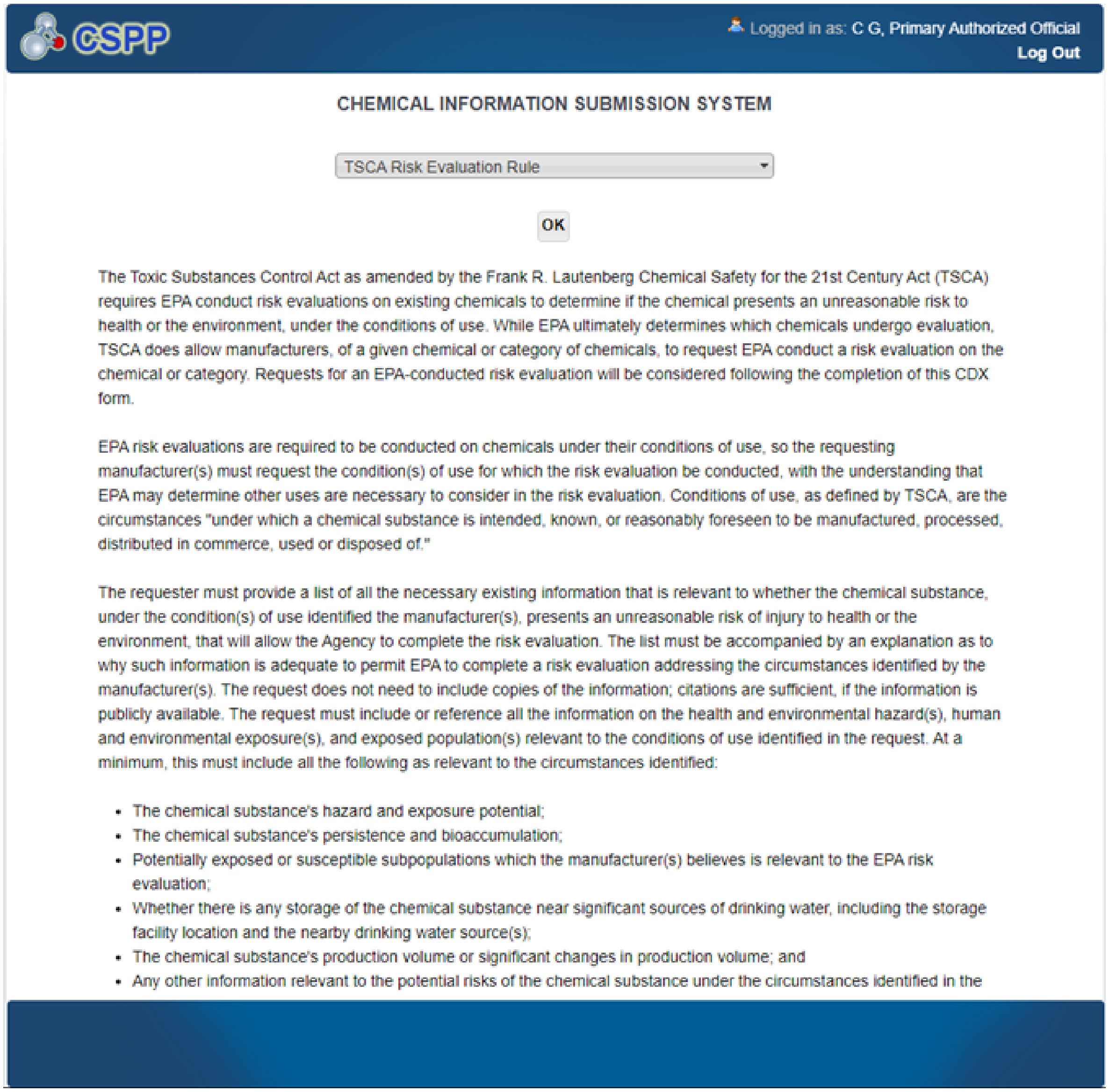
Legend X=Can Perform Function	Primary Authorized Official (Primary Company Authorized Official)		Primary Agent/Consultant (Primary Sponsored Authorized Official)		Primary Support	
	US	**non-US**	**US**	**non-US**	**US**	**non-US**
Risk Evaluation & Response Forms						
Create all original main forms	X	X	X	X		
Submit original main forms	X					
Submit amendments (by editing the main forms)	X		X			
Unlock all forms	X		X			
Edit unlocked forms	X		X		X	
Delete forms	X	X	X	X		
Assign Supports	X	X				
Recieve EPA Communications	X	X	X	X	X	X
Pay Invoices	X	X	X	X	X	X
Withdrawal Request						
Create all original main forms	X	X	X	X		
Submit original main forms	X					
Submit amendments (by editing the main forms)	X		X			
Unlock all main forms	X		X			
Edit unlocked main forms	X		X		X	X
Delete forms	X	X	X	X		
Assign Supports	X	X				

3.1 Log into Risk Evaluation Application

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

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

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



CSPP

Logged in as: C G, Primary Authorized Official

Log Out

CHEMICAL INFORMATION SUBMISSION SYSTEM

TSCA Risk Evaluation Rule

OK

The Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA) requires EPA conduct risk evaluations on existing chemicals to determine if the chemical presents an unreasonable risk to health or the environment, under the conditions of use. While EPA ultimately determines which chemicals undergo evaluation, TSCA does allow manufacturers, of a given chemical or category of chemicals, to request EPA conduct a risk evaluation on the chemical or category. Requests for an EPA-conducted risk evaluation will be considered following the completion of this CDX form.

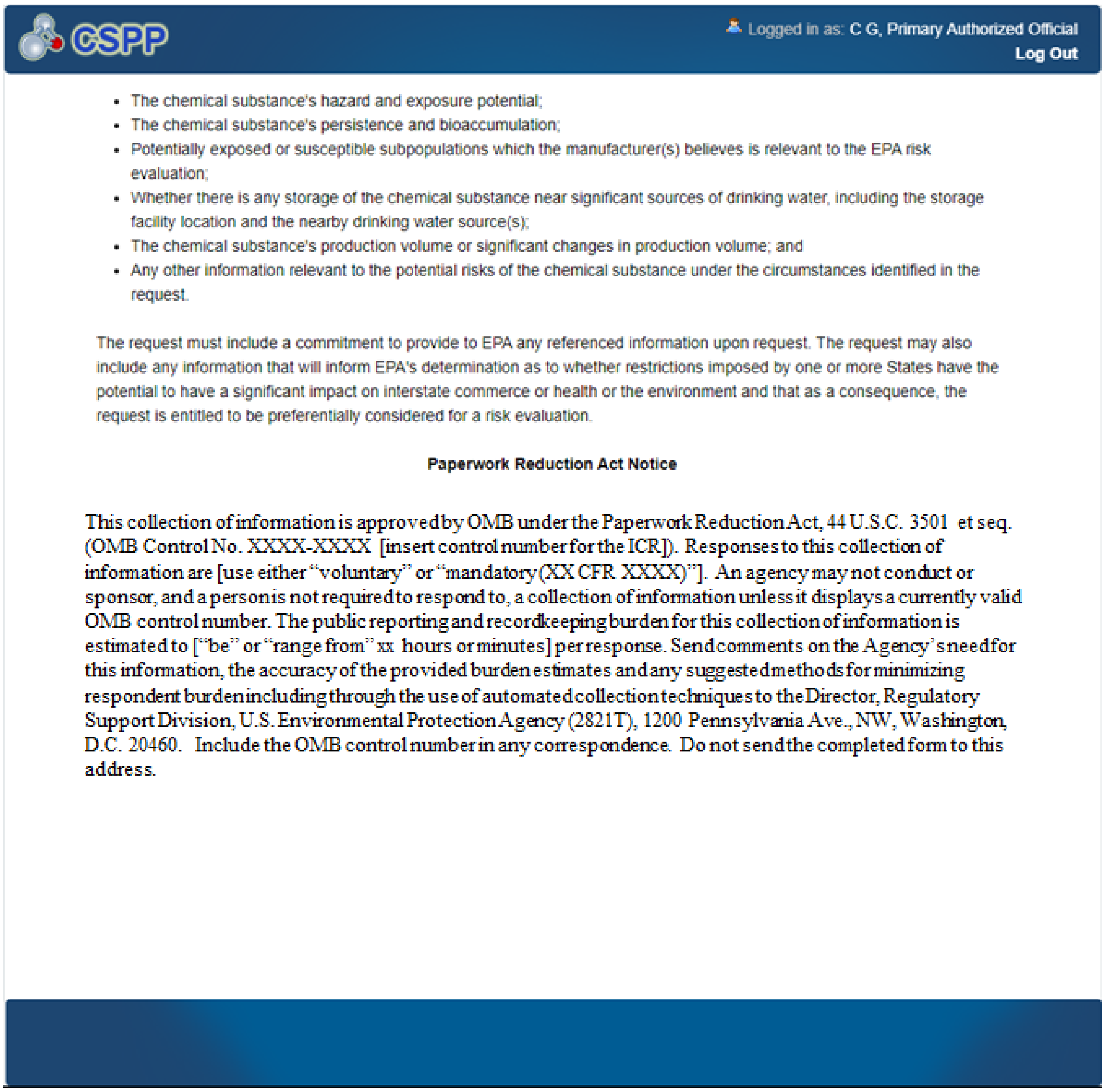
EPA risk evaluations are required to be conducted on chemicals under their conditions of use, so the requesting manufacturer(s) must request the condition(s) of use for which the risk evaluation be conducted, with the understanding that EPA may determine other uses are necessary to consider in the risk evaluation. Conditions of use, as defined by TSCA, are the circumstances "under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of."

The requester must provide a list of all the necessary existing information that is relevant to whether the chemical substance, under the condition(s) of use identified the manufacturer(s), presents an unreasonable risk of injury to health or the environment, that will allow the Agency to complete the risk evaluation. The list must be accompanied by an explanation as to why such information is adequate to permit EPA to complete a risk evaluation addressing the circumstances identified by the manufacturer(s). The request does not need to include copies of the information; citations are sufficient, if the information is publicly available. The request must include or reference all the information on the health and environmental hazard(s), human and environmental exposure(s), and exposed population(s) relevant to the conditions of use identified in the request. At a minimum, this must include all the following as relevant to the circumstances identified:

- The chemical substance's hazard and exposure potential;
- The chemical substance's persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations which the manufacturer(s) believes is relevant to the EPA risk evaluation;
- Whether there is any storage of the chemical substance near significant sources of drinking water, including the storage facility location and the nearby drinking water source(s);
- The chemical substance's production volume or significant changes in production volume; and
- Any other information relevant to the potential risks of the chemical substance under the circumstances identified in the

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

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


CSPP

Logged in as: C G, Primary Authorized Official

Log Out

- The chemical substance's hazard and exposure potential;
- The chemical substance's persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations which the manufacturer(s) believes is relevant to the EPA risk evaluation;
- Whether there is any storage of the chemical substance near significant sources of drinking water, including the storage facility location and the nearby drinking water source(s);
- The chemical substance's production volume or significant changes in production volume; and
- Any other information relevant to the potential risks of the chemical substance under the circumstances identified in the request.

The request must include a commitment to provide to EPA any referenced information upon request. The request may also include any information that will inform EPA's determination as to whether restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment and that as a consequence, the request is entitled to be preferentially considered for a risk evaluation.

Paperwork Reduction Act Notice

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. XXXX-XXXX [insert control number for the ICR]). Responses to this collection of information are [use either “voluntary” or “mandatory (XX CFR XXXX)”]. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to [“be” or “range from” xx hours or minutes] per response. Send comments on the Agency’s need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden including through the use of automated collection techniques to the Director, Regulatory Support Division, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

Navigation: To access the Risk Evaluation ‘Home’ screen, select ‘TSCA Risk Evaluation Rule’ from the submission type drop-down menu and click the ‘OK’ button.

3.2 Risk Evaluation Home Screen Navigation

You can access the Risk Evaluation 'Home' screen by selecting 'TSCA Risk Evaluation Rule' from the submission type drop-down menu on the 'Chemical Information Submission System' screen and clicking the 'OK' button.

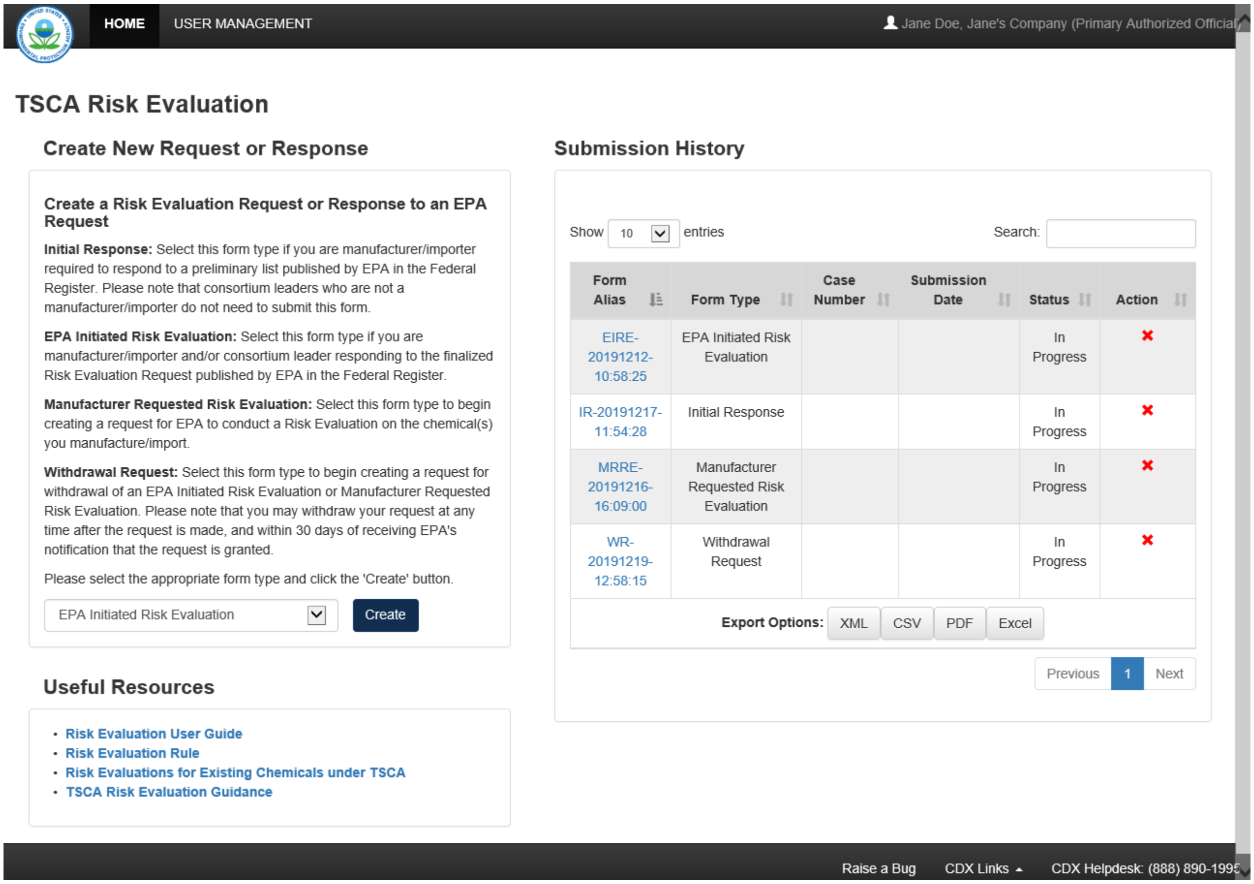
The Risk Evaluation 'Home' screen is the first screen within the Risk Evaluation application. It displays the 'Create New Request or Response,' 'Useful Resources,' and 'Submission History' sections and displays a link to the 'User Management' page.

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

- **Create New Request or Response:** Click the 'Create' button to navigate to the 'Create Passphrase' screen to create the form selected from the 'Form Type' drop-down menu.
- **Useful Resources:** Click the links within the 'Useful Resources' section.
- **Submission History:** Modify or delete a Risk Evaluation request using the 'Submission History' section. For additional details about the 'Submission History' section, please refer to **Section 3.3**.
- **User Management:** Click the 'User Management' link to navigate to the 'User Management' screen. You can manage the access rights of Supports per form alias using the 'User Management' screen. For additional details about the 'User Management' screen, refer to **Section 3.4**.

Exhibit 3-4 shows a screen capture of the Risk Evaluation ‘Home’ screen:

Exhibit 3-4 Risk Evaluation Home Screen



3.3 Submission History

Only one Risk Evaluation request is created per form alias, which helps differentiate between forms. Each column within the table of the ‘Submission History’ section can be sorted by clicking the individual column headers.

Start New Form: To create a new EPA Initiated Risk Evaluation, Initial Response, Manufacturer Requested Evaluation, or Withdrawal Request select the form type from the ‘Form Type’ drop-down menu and click the ‘Create’ button. You are required to create a passphrase that will be associated with that particular form. Make sure to create a passphrase that you will remember, as it cannot be retrieved or reset. Refer to **Section 3.5** for further instructions on creating a passphrase.

Edit an ‘In Progress’ Form: To modify an existing Risk Evaluation request, click the ‘Form Alias’ link for a form with a status of ‘In Progress.’ You are required to enter the passphrase associated with that particular form to access and edit the form. It is possible for more than one user to modify a form simultaneously; the user that clicks the 'Save' button first will have his/her changes saved.

Amend a submitted form: To edit an already submitted Risk Evaluation request (i.e., to create an amendment), you must first unlock the particular submission by clicking the 'Lock' icon ( ) under the 'Action' column. You will be required to enter the passphrase associated with that particular submission to gain access and continue amending the submission. All further changes that are made will be submitted as an amendment. Refer to **Section 13** for further instructions on creating an amendment.

Pay an invoice: To pay an invoice for a Risk Evaluation request, click the 'Unpaid Invoice' icon ($) to begin the process of accessing the 'Copy of Record' screen to pay an invoice.

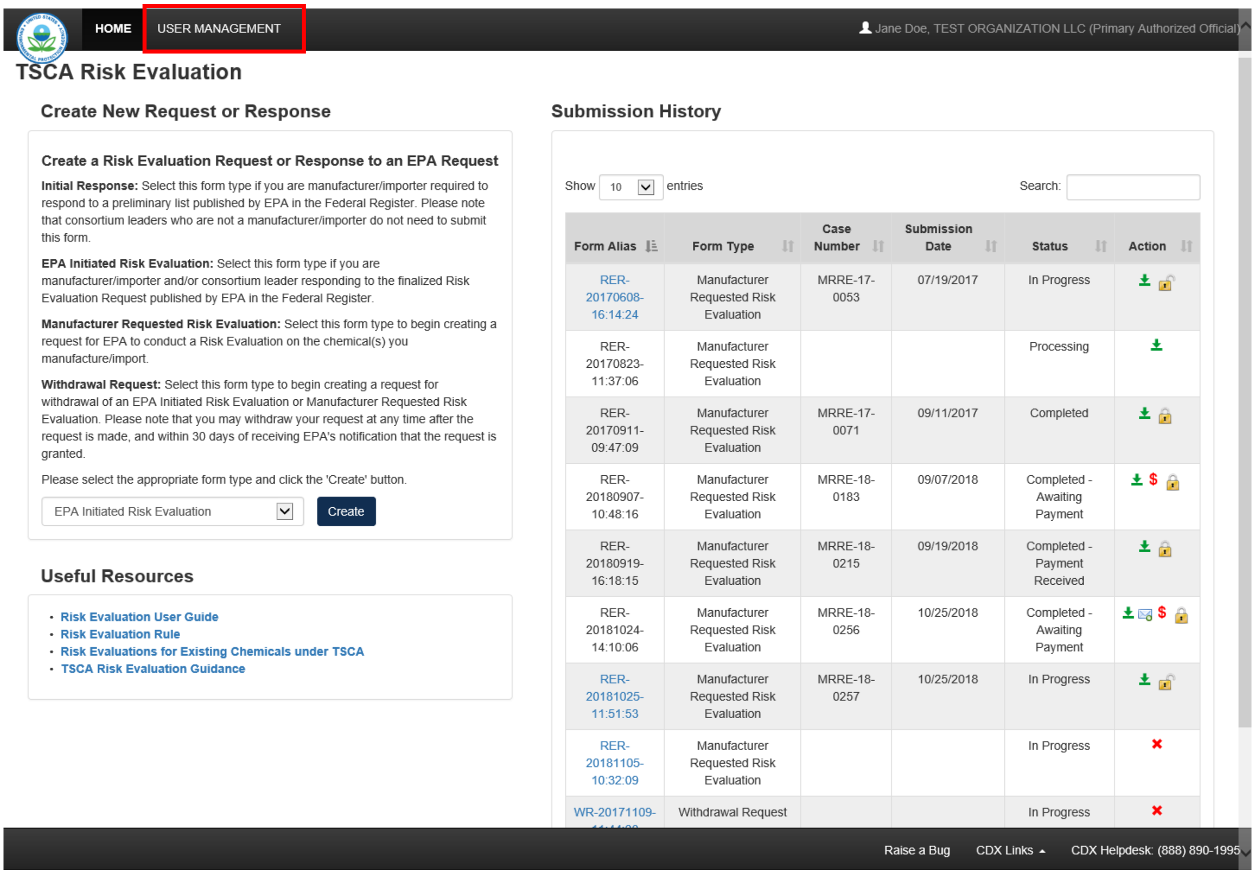
The 'Submission History' table displays the following fields and columns of information:

- **Show Entries:** Select a value from the 'Entries' drop-down menu to specify the number of entries that display on the current page.
- **Search:** Enter search criteria to filter the submissions within the 'Submission History' table.
- **Form Alias:** Displays the form alias of a Risk Evaluation request. Click the form alias link to navigate to the 'Enter Passphrase' page and complete/edit a request.
- **Form Type:** Displays 'EPA Initiated Risk Evaluation', 'Initial Response', 'Manufacturer Requested Evaluation', and 'Withdrawal Request.'
- **Case Number:** Displays the case number of a completed submission in the following format: <IR-YY-XXXX>, <EIRE-YY-XXXX>, and <MRRE-YY-XXXX>. The 'YY' represents the calendar year in which the request was submitted, and the 'XXXX' represents the order in which the request was received. Each submitted request generates a single case number.
- **Submission Date:** Displays the date that a form was successfully submitted to EPA via CDX. This date populates only after the request has been submitted.
- **Status:** Displays the status of a Risk Evaluation request (e.g., 'In Progress,' 'Submitted,' 'Completed,' 'Completed – Awaiting Payment,' or 'Completed – Payment Received').
- **Action:** Click the 'Copy of Record' icon ( ) to navigate to the 'Enter Passphrase' screen to continue to the 'Copy of Record' screen. The 'Copy of Record' icon displays only after the request has been completed. Click the 'Delete' icon ( ) to delete an in-progress request. Click the 'Lock' icon ( ) to unlock a request for an amendment. The request remains unlocked and will display the 'Unlocked' icon ( ) until the request is resubmitted by the AO. Click the red 'Unpaid Invoice' icon ($) to access the 'Copy of Record' screen to pay a fee, when applicable. The 'Unpaid Invoices' icon displays only after personnel sends an invoice. After a user pays the invoice, the icon disappears.

- **Export Options:** Click the ‘XML,’ ‘CSV,’ ‘PDF,’ or ‘Excel’ button to download the ‘Submission History’ table as an .xml, .csv, .pdf, or .xlsx file, respectively.
- **Previous:** Click the ‘Previous’ button to navigate to the previous set of submissions currently displayed (if applicable).
- **Next:** Click the ‘Next’ button to navigate to the subsequent set of submissions (if applicable).

Exhibit 3-5 shows a screen capture of the Risk Evaluation ‘Submission History’ section:

Exhibit 3-5 Risk Evaluation Submission History Section



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

3.4 User Management

You can access the ‘User Management’ screen by clicking the ‘User Management’ link on the application header of the Risk Evaluation ‘Home’ screen.

On the ‘User Management’ screen, you have the ability to assign/un-assign one or more Primary Supports or Primary Agents/Consultants to have access to modify any of the Risk Evaluation requests you have created.

Form Alias: A form alias is unavailable in this drop-down menu until one has been created. Select a form alias from the drop-down menu to begin assigning Supports or Primary Agents/Consultants. Once a form alias has been selected, the ‘Assign Users’ group box will update to display only the Supports or Primary Agents/Consultants who have identified you as their AO during CDX registration, or a user you have specified that is able to submit on your behalf.

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

Form Alias: Displays the form alias that a Risk Evaluation request is given.

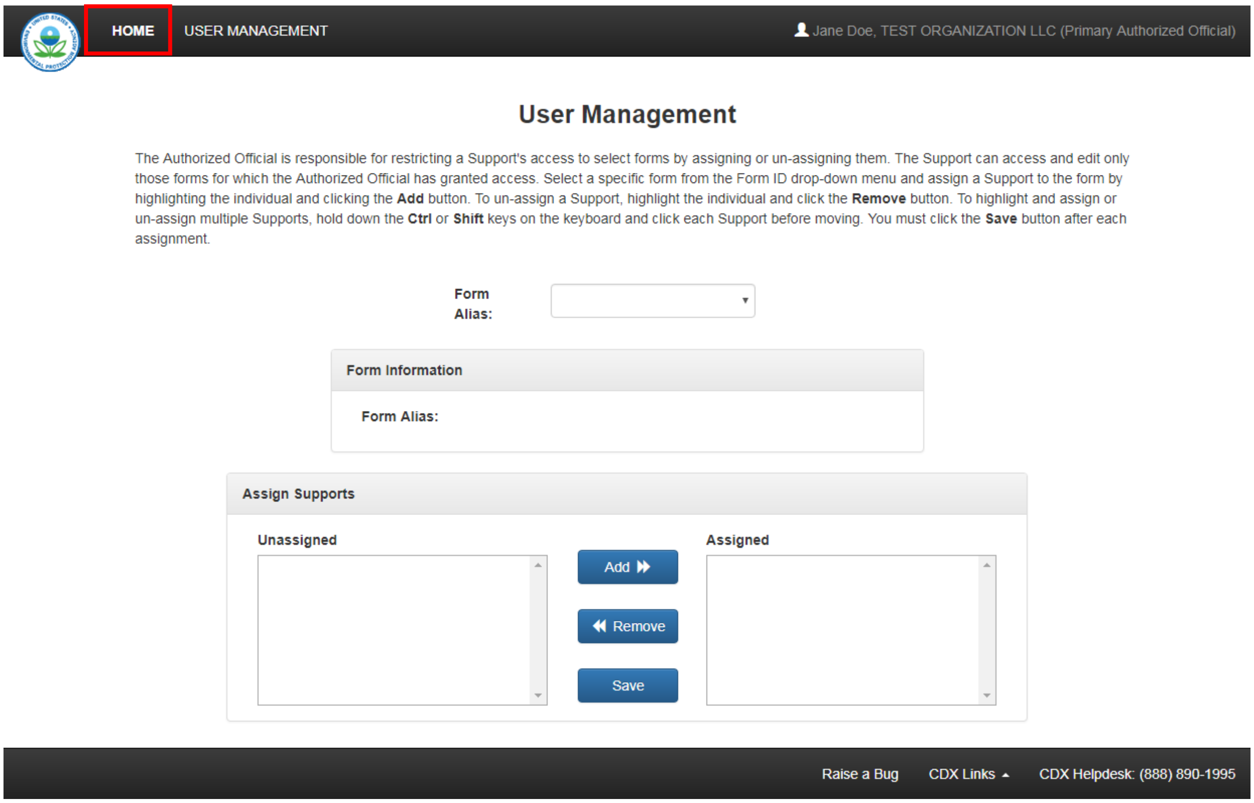
Assign Supports: This box shows all the Supports or Primary Agents/Consultants you can assign/un-assign to complete a Risk Evaluation request for the form alias selected. To move support persons from the ‘Unassigned’ group box to the ‘Assigned’ group box, highlight an individual or multiple Support(s)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

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

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

Exhibit 3-6 shows a screen capture of the ‘User Management’ screen:

Exhibit 3-6 User Management Screen



Navigation: Click the ‘Home’ link located within the application header to navigate to the Risk Evaluation ‘Home’ screen.

3.5 Create Passphrase

To start a new Request or Response, select ‘EPA Initiated Risk Evaluation,’ ‘Initial Response,’ ‘Manufacturer Requested Evaluation,’ or ‘Withdrawal Request’ from the ‘Form Type’ drop-down menu, and click the ‘Create’ button on the Risk Evaluation ‘Home’ screen to navigate to the ‘Create Passphrase’ screen, which allows you to create a passphrase and associate that passphrase with your newly created request.

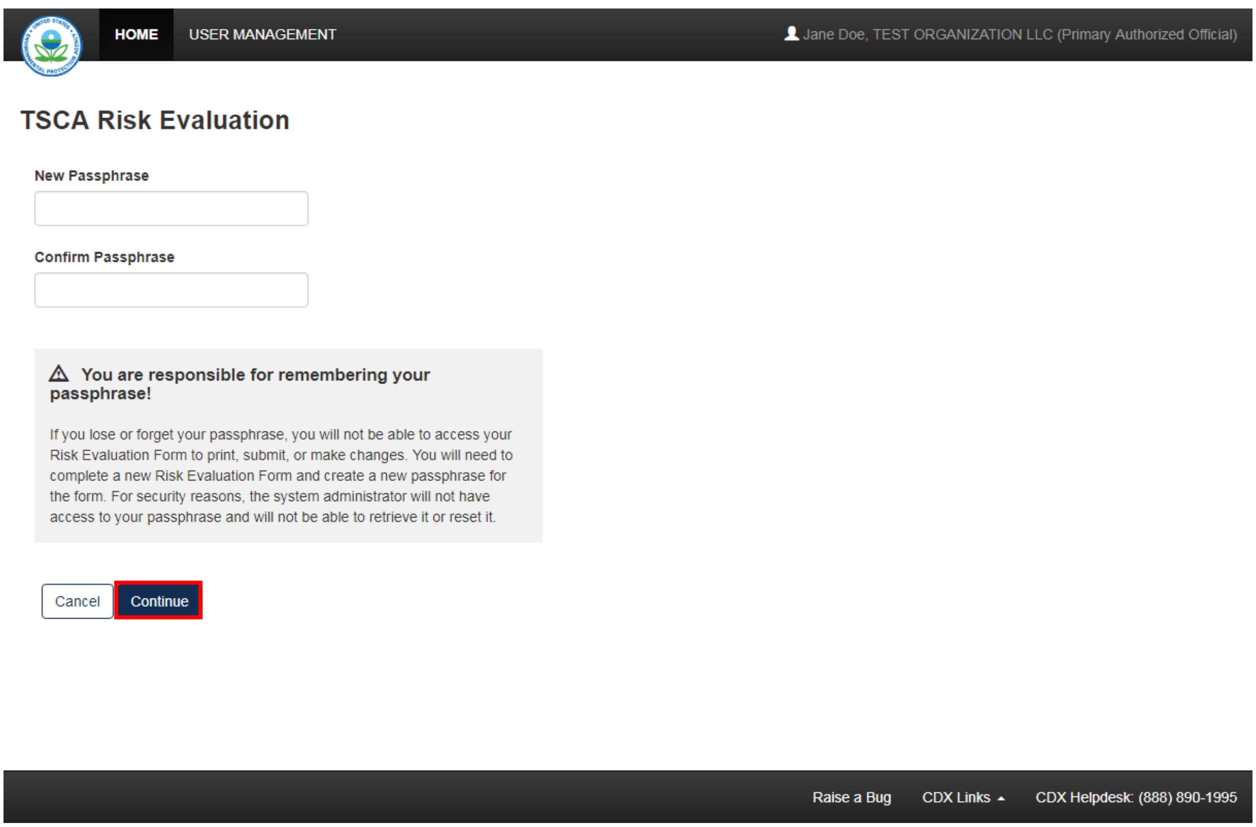
The application uses the passphrase as an encryption key to protect the contents of the request. You are responsible for remembering the passphrase and distributing it to the appropriate individuals.

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

- **New Passphrase:** Enter a passphrase that is between 8 to 20 characters. For maximum security, your passphrase should contain a combination of letters and numbers. Your passphrase should not contain special characters (for example, +, ?, and *). As a Primary user, you are responsible for remembering your passphrase and distributing it to only authorized individuals. The passphrase is used as an encryption key to protect the contents of the form data.
- **Confirm Passphrase:** Enter the same passphrase that was entered into the 'New Passphrase' field. The same passphrase may be associated with multiple forms. The user can choose to have the same passphrase for all forms. Supports do not have the ability to start a new form or create a passphrase for a form.

Exhibit 3-7 shows a screen capture of the 'Create Passphrase' screen:

Exhibit 3-7 Create Passphrase Screen



Navigation: For a new EPA Initiated Risk Evaluation, Initial Response, Manufacturer Requested Evaluation, or Withdrawal Request, create a passphrase and click the 'Continue' button to navigate to the 'Contact' screen.

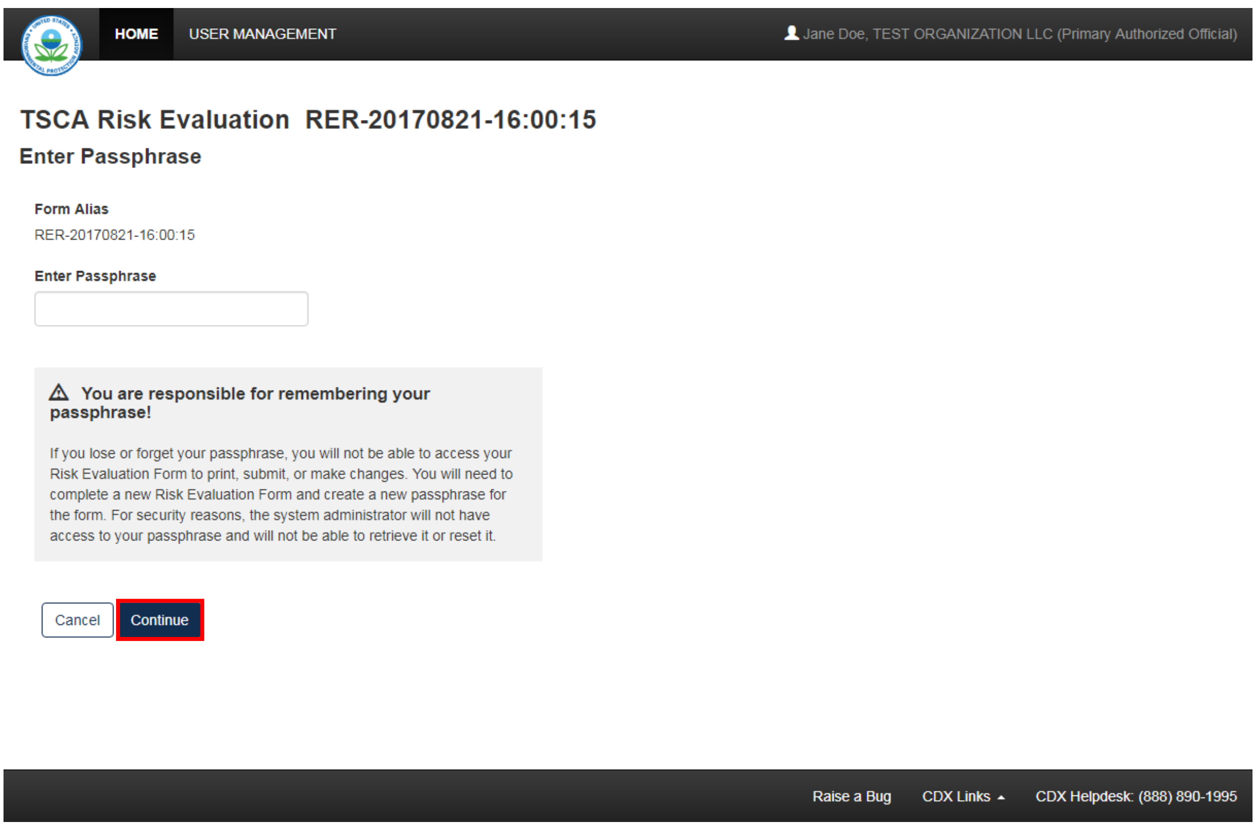
3.6 Enter Passphrase

To edit a form, click the 'Form Alias' link for a Risk Evaluation request with a status of 'In Progress.' The 'Enter Passphrase' screen requires you to enter the passphrase that is associated with the request.

- **Form Alias:** Displays the form alias that is used to identify the request.
- **Enter Passphrase:** Enter the same passphrase that was used to originally create the request. For security reasons, the system administrator does not have access to the passphrase and cannot retrieve it or reset it to a new one. If a user has forgotten the passphrase, a new request will need to be created with a new passphrase.

Exhibit 3-8 shows a screen capture of the 'Enter Passphrase' screen:

Exhibit 3-8 Enter Passphrase Screen



Navigation: Enter the passphrase that you originally created and associated with the request and click the 'Continue' button to navigate to the 'Contact' screen in a Manufacturer Requested Risk Evaluation form.

3.7 Action Bar

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

- **Home:** Click the 'Home' link to navigate to the Risk Evaluation 'Home' screen.
- **User ID:** Click the user ID link in the top right-hand corner to log out of the application.

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

- **Save:** Click the 'Save' link at any stage of completing a Risk Evaluation request to save the form. To generate and access links to other pages of the request within the navigation header, you must click the 'Save' link within the action bar. After you click the 'Save' link, you will receive a message indicating that all data entered in the request has been saved successfully. The save function does not validate any entered data. Click the 'Previous' and 'Next' buttons on a form to save the data entered within a request. Click the 'X' button in the upper right-hand corner of the form in your browser to close the request without saving.

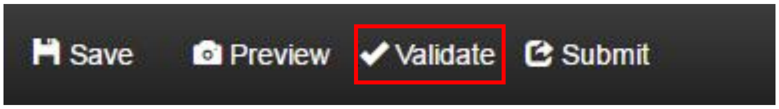
Exhibit 3-9 Action Bar – Save

- **Preview:** Click the 'Preview' link to preview the request. After you click the 'Preview' link, you will be given the option to view a regular version of the PDF(s) or a sanitized version of the PDF(s). Choosing either option will generate a watermarked PDF containing each chemical substance identified within the request. Refer to **Section 5** for more information on previewing a request.

Exhibit 3-10 Action Bar – Preview

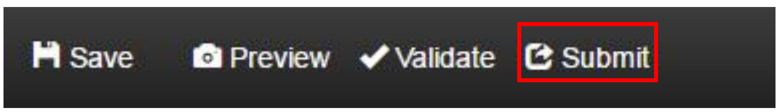
- **Validate:** Click the 'Validate' link at any stage of completing a Risk Evaluation request. A 'TSCA Risk Evaluation' window generates when you click the 'Validate' link if you disable the pop-up blocker within your internet browser. The 'TSCA Risk Evaluation' pop-up window displays a report of all warning messages. Refer to **Section 9** for more information on validating a request.

Exhibit 3-11 Action Bar – Validate



- **Submit:** Click the 'Submit' link to submit a Risk Evaluation request after completing all sections of a Risk Evaluation request. After you click the 'Submit' link a pop-up message displays to confirm the submission process. The request validates during the submission process and displays any applicable warning or error messages. Refer to **Section 9** for further instructions on validation errors. You can continue with the submission process only after clearing all validation errors. Upon successful submission of the request, the application generates and sends an email indicating the successful submission of the request to the submitter's email address. Refer to **Section 10** for more information on submitting a Risk Evaluation request.

Exhibit 3-12 Action Bar – Submit



- **CDX Links:** Click any of the 'CDX Links,' located at the bottom of each screen within the 'CDX Links' drop-down menu, at any stage of completing a Risk Evaluation request.
    - Click the 'CDX Homepage' link to navigate to the 'CDX' homepage.
    - Click the 'MyCDX Homepage' link to navigate to the 'MyCDX' page.
    - Click the 'EPA Homepage' link to navigate to EPA's Homepage.
    - Click the 'Terms and Conditions' link to navigate to the 'CDX Terms and Conditions' screen.
    - Click the 'Privacy Notice' link to navigate to the 'CDX Privacy and Security Notice' screen.

Exhibit 3-13 shows a screen capture of the action bar 'CDX Links':

Exhibit 3-13 CDX Links

4 Chemical Substance Risk Evaluation Request

The purpose of the Risk Evaluation request is to determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. Users can complete the request to solicit a Risk Evaluation for their manufactured chemical(s).

Each risk evaluation request must include a list of all the existing information that is relevant to whether the chemical substance, under the conditions of use identified by the manufacturer, presents an unreasonable risk of injury to health or the environment. The request does not need to include copies of the information; citations are sufficient, if the information is publicly available. The request must include or reference all available information on health and environmental hazard(s) of the chemical substance, human and environmental exposure(s), and exposed population(s), as relevant to the conditions of use identified in the request.

At a minimum this information must include: hazard and exposure potential, persistence and bioaccumulation, potentially exposed or susceptible subpopulations the requestor believes to be relevant, whether there is any storage of the chemical substance near significant sources of drinking water (this could include a storage facility), production volume or significant changes to production volume, and any other information relevant to the potential risks of the chemical substance.

4.1 Create a Manufacturer Requested Risk Evaluation

To create a new Risk Evaluation request, navigate to the Risk Evaluation ‘Home’ screen and select ‘Manufacturer Requested Evaluation’ from the ‘Form Type’ drop-down menu. Refer to **Section 3.2** for additional details regarding the Risk Evaluation ‘Home’ screen.

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

4.2 Contact

You can navigate to the ‘Contact’ screen by clicking the ‘Create’ button and creating a new passphrase, or by accessing a Risk Evaluation request that is ‘In Progress’ and entering the passphrase associated with the selected request.

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

- **Submission Alias:** Enter the submission alias. Upon navigating to the screen, the application displays an auto-generated editable submission alias in the following format: <Form Type-YYYYMMDD-HH:MM:SS >. This is a required field.

- **N/A:** Select the 'N/A' radio button to indicate that the form will be submitted on behalf of the reporting organization. Selecting this radio button generates the 'Fees Certification' page.
- **This is a submission on behalf of a consortium:** Select the 'This is a submission on behalf of a consortium to indicate that the request is submitted on behalf of a consortium. Selecting this radio button generates the 'Submitting on Behalf of Consortium' screen.
- **CBI:** Check the 'CBI' checkbox to claim the contact information as confidential.
- **Copy from CDX:** Click the 'Copy from CDX' link to copy CDX registration information.
- **First Name:** Enter the first name of the contact. This is a required field.
- **Last Name:** Enter the last name of the contact. This is a required field.
- **Position:** Enter the job title of the contact.
- **Company Name:** Enter the company name of the contact. This is a required field.
- **Additional Companies:** Enter an additional company in this field, if applicable.
- **Add:** Click the button to add the company entry into the 'Additional Companies' table.
- **Additional Company Name:** Displays the additional company name(s) associated with the contact.
- **Action:** Click the 'Delete' icon () to remove an additional company name.
- **Phone Number:** Enter the phone number of the contact. This is a required field.
- **Phone Number Extension:** Enter the extension to the phone number, if applicable.
- **Email Address:** Enter the email address of the contact.
- **Mailing Address 1:** Enter the mailing address of the contact. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the contact, if applicable.
- **City:** Enter the city of the mailing address of the contact. This is a required field.
- **State:** Select the state of the mailing address of the contact. This is a required field if 'United States' is identified as the country.
- **Postal Code:** Enter the postal code of the mailing address of the contact. This is a required field.
- **Country:** Select the country of the mailing address of the contact from the drop-down menu. Selecting a non-US country generates the 'United States Agent' screen. This is a required field.

Exhibit 4-1 shows a screen capture of the 'Contact' screen (Scroll 1):

Exhibit 4-1 Contact Screen (Scroll 1)

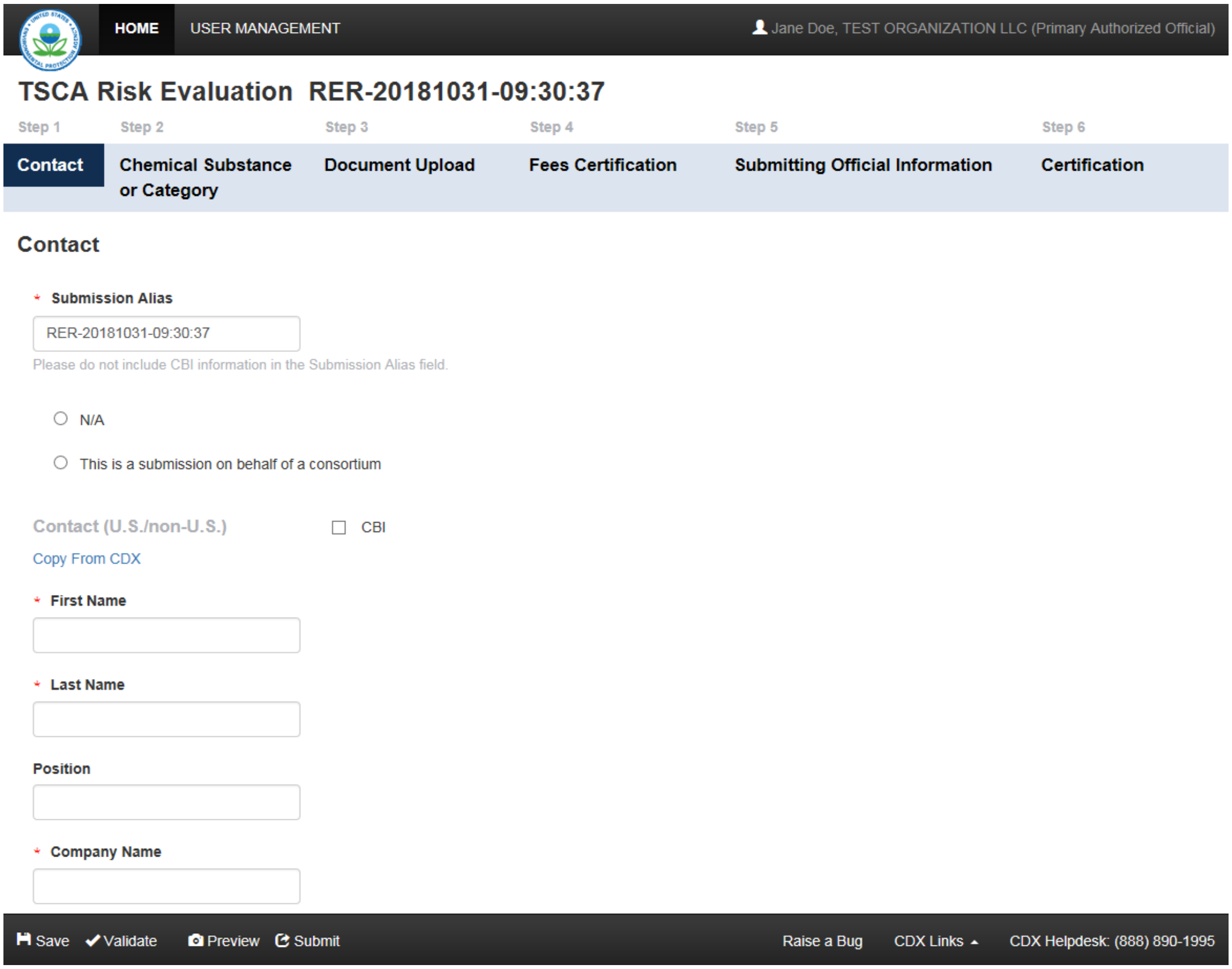


Exhibit 4-2 shows a screen capture of the ‘Contact’ screen (Scroll 2):

Exhibit 4-2 Contact Screen (Scroll 2)

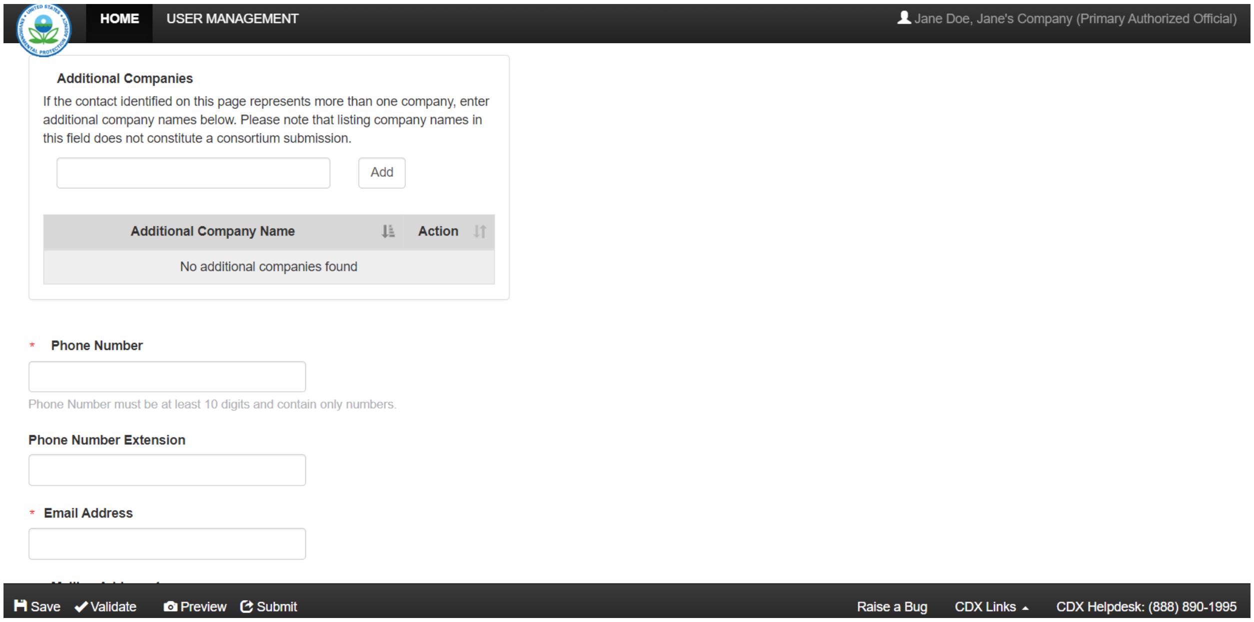
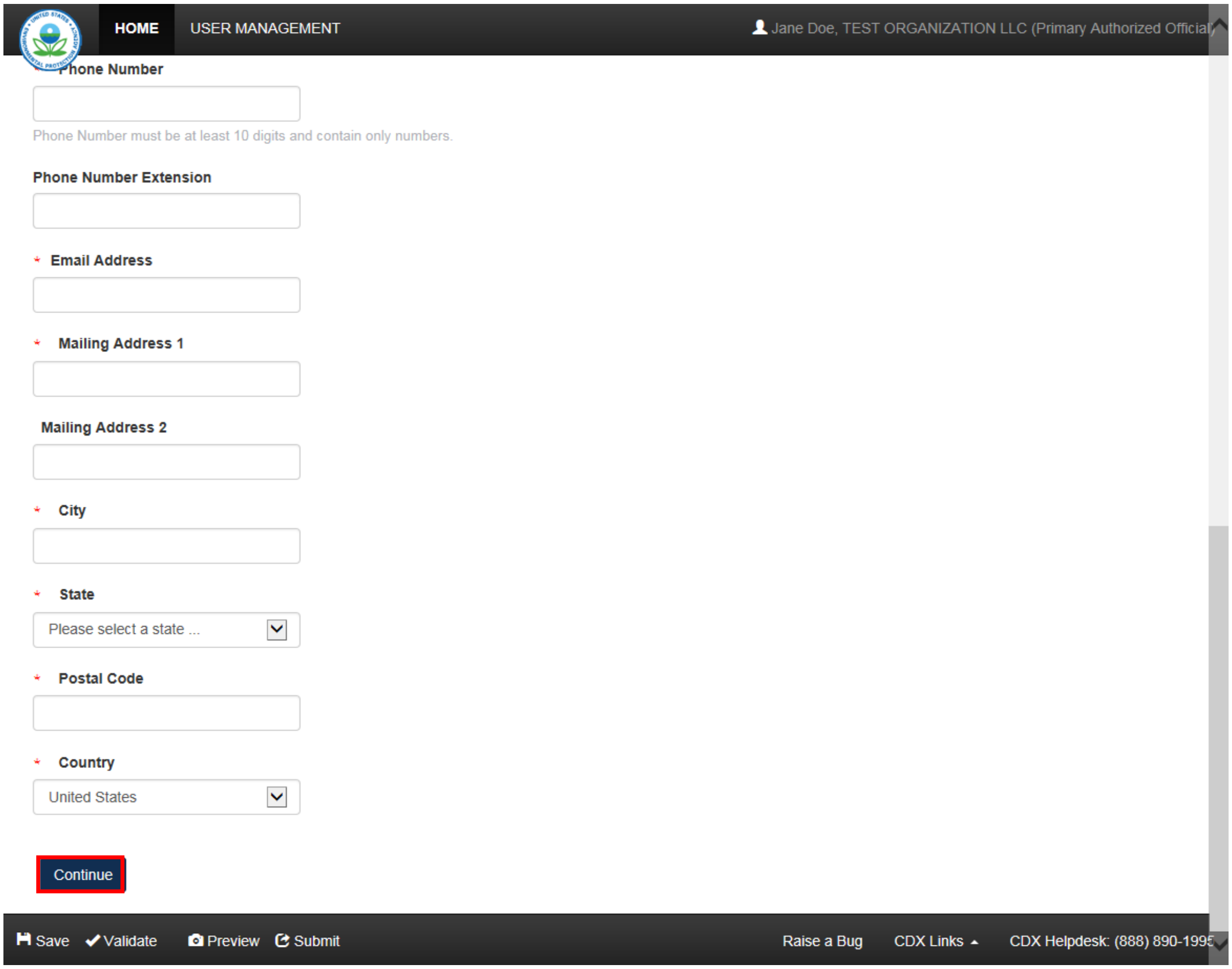


Exhibit 4-3 shows a screen capture of the ‘Contact’ screen (Scroll 3):

Exhibit 4-3 Contact Screen (Scroll 3)



Navigation: Click the ‘Continue’ button to navigate to the ‘Chemical Substance or Category’ screen if a U.S. contact is identified and the request is submitted on behalf of the reporting organization. Click the ‘Continue’ button to navigate to the ‘Submitting on Behalf of Consortium’ screen if the request is submitted on behalf of a consortium. You can also access this screen by clicking the ‘Chemical Substance or Category’ or ‘Submitting on Behalf of Consortium’ link, respectively, within the navigation header. Click the ‘Continue’ button to navigate to the ‘United States Agent’ screen if a non-U.S. contact is identified. You can also access this screen by clicking the ‘U.S. Agent’ link within the navigation header.

4.3 Submitting on Behalf of Consortium

You can navigate to the ‘Submitting on Behalf of Consortium’ screen by selecting the ‘This is a submission on behalf of a consortium’ radio button and clicking the ‘Continue’ button on the ‘Contact’ screen.

The ‘Submitting on Behalf of Consortium’ screen provides fields to capture consortium information and individual consortium members. The user populating the form is identified as a consortium member by default upon navigating to the ‘Submitting on Behalf of Consortium’ page. A minimum of two consortium members is required.

- **Consortium Name:** Enter the name of the consortium. This is a required field.
- **Consortium CBI:** Check the ‘CBI’ checkbox to claim the consortium as confidential.
- **Add Consortium Member:** Click the ‘Add Consortium Member’ button to generate an additional set of consortium input fields. At least two (2) consortium members are required to be identified.
- **First Name:** Enter the first name of the consortium member. This is a required field.
- **Last Name:** Enter the last name of the consortium member. This is a required field.
- **Position:** Enter the job title of the consortium member.
- **Company Name:** Enter the company name of the consortium member. This is a required field.
- **Phone Number:** Enter the phone number of the consortium member. This is a required field.
- **Phone Number Extension:** Enter the extension to the phone number, if applicable.
- **Email Address:** Enter the email address of the consortium member. This is a required field.
- **Mailing Address 1:** Enter the mailing address of the consortium member. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the consortium member, if applicable.
- **City:** Enter the city of the mailing address of the consortium member. This is a required field.
- **State:** Select the state of the mailing address of the consortium member. This is a required field.
- **Postal Code:** Enter the postal code of the mailing address of the consortium member. This is a required field.
- **Country:** Select the country of the mailing address of the consortium member. This is a required field.

- **My company is a "small business concern" as defined under 40 CFR 700.43:** Select the radio button to indicate that the consortium is a small business concern. A fee certification statement is required to be selected.
- **My company is not a "small business concern" as defined under 40 CFR 700.43:** Select the radio button to indicate that the consortium member does not represent a small business concern. A fee certification statement is required to be selected.

Exhibit 4-114 shows a screen capture of the 'Submitting on Behalf of Consortium' screen (Scroll 1):

Exhibit 4-4 Submitting on Behalf of Consortium Screen (Scroll 1)

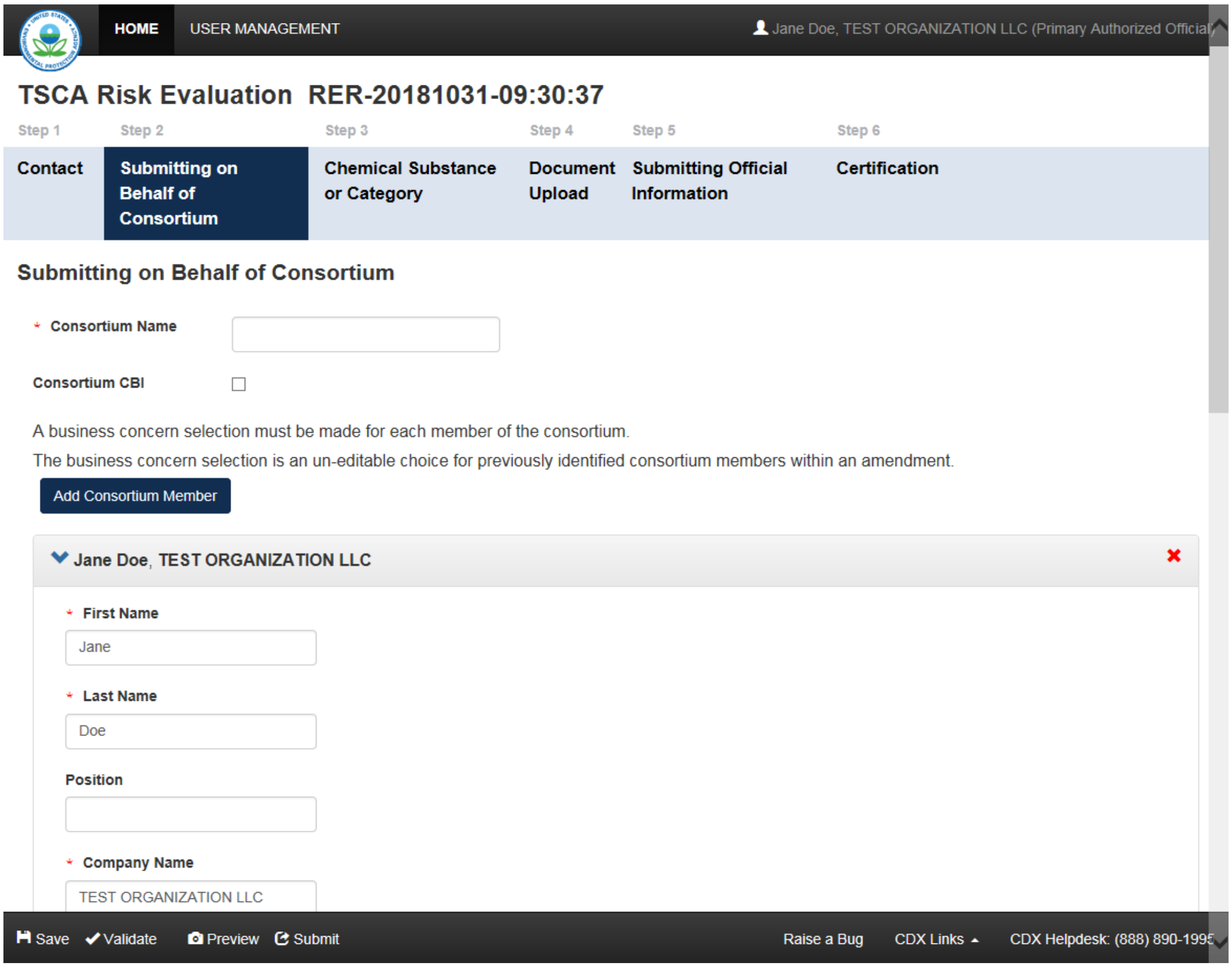


Exhibit 4-125 shows a screen capture of the ‘Submitting on Behalf of Consortium’ screen (Scroll 2):

Exhibit 4-5 Submitting on Behalf of Consortium Screen (Scroll 2)

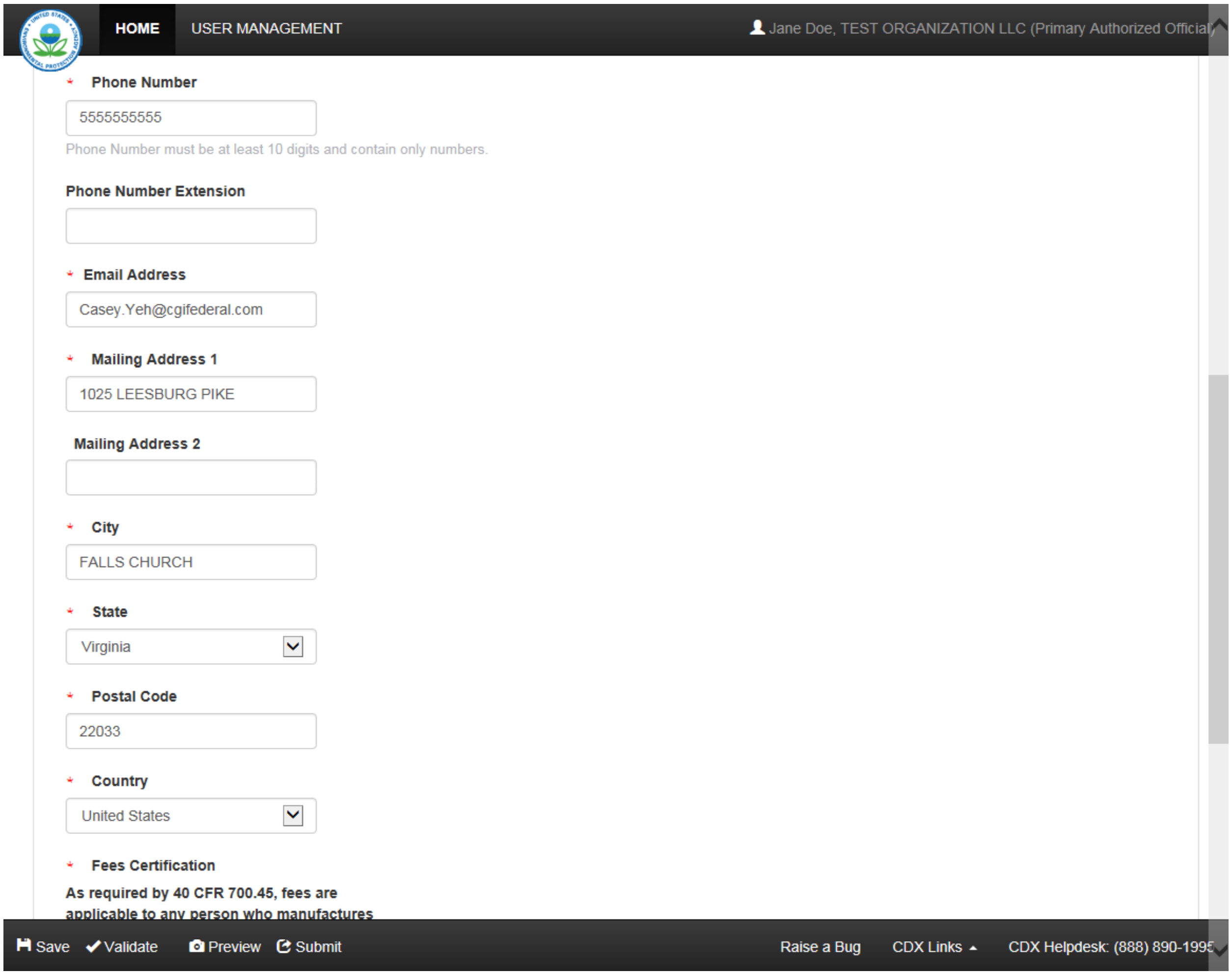
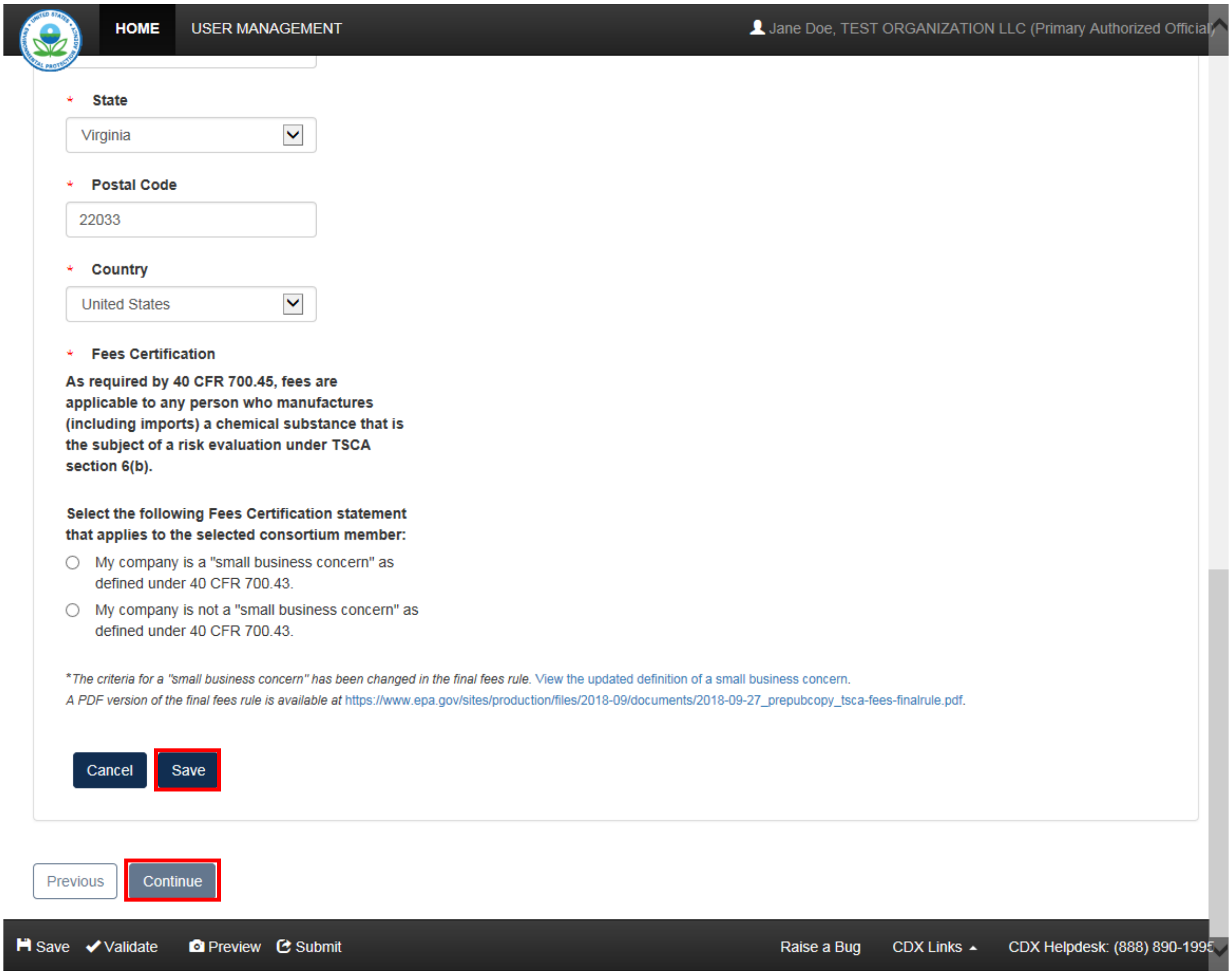


Exhibit 4-6 shows a screen capture of the 'Submitting on Behalf of Consortium' screen (Scroll 3):

Exhibit 4-6 Submitting on Behalf of Consortium Screen (Scroll 3)



Navigation: Click the 'Save' button to save the consortium member information. Click the 'Continue' button to navigate to the 'Chemical Substance or Category' screen if the request is submitted on behalf of the reporting organization. You can also access this screen by clicking the 'Chemical Substance or Category' link within the navigation header. Click the 'Continue' button to navigate to the 'U.S. Agent' screen if a non-U.S. contact is identified. You can also access this screen by clicking the 'U.S. Agent' link within the navigation header.

4.3.1 Small Business Concern Definition

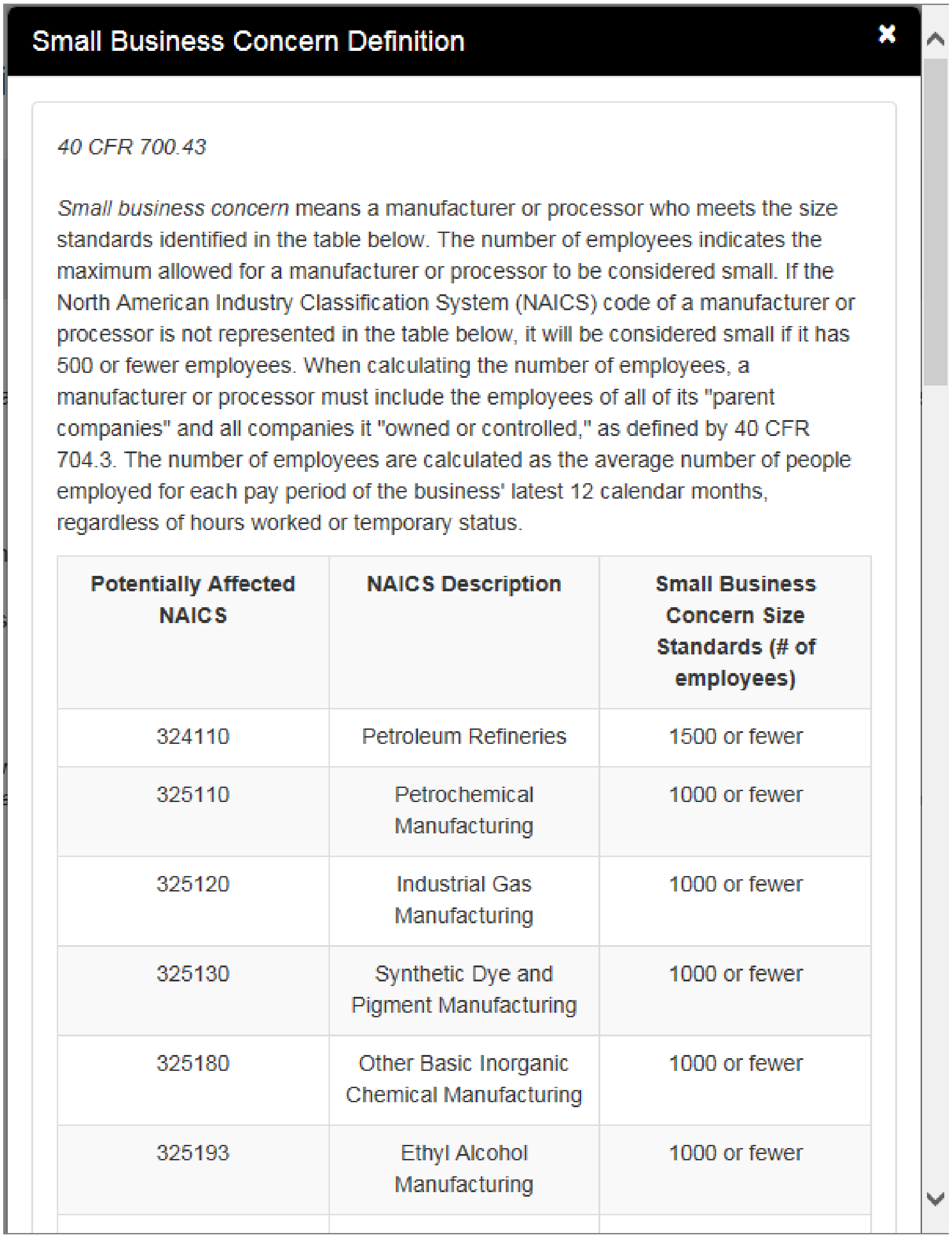
Click the 'View the updated definition of a small business concern' link to generate the 'Small Business Concern Definition' window. This window displays a table of the North American

Industry Classification System (NAICS) codes, NAICS descriptions, and applicable small business concern size in number of employees.

As noted in the definition, if there are codes that are not listed within the NAICS table, a small business definition applies to 500 or fewer employees that a company "owns or controls."

Exhibit 4-7 shows a screen capture of the 'Small Business Concern Definition' window (Scroll 1):

Exhibit 4-7 Small Business Concern Definition Window (Scroll 1)



Small Business Concern Definition

40 CFR 700.43

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

Potentially Affected NAICS	NAICS Description	Small Business Concern Size Standards (# of employees)
324110	Petroleum Refineries	1500 or fewer
325110	Petrochemical Manufacturing	1000 or fewer
325120	Industrial Gas Manufacturing	1000 or fewer
325130	Synthetic Dye and Pigment Manufacturing	1000 or fewer
325180	Other Basic Inorganic Chemical Manufacturing	1000 or fewer
325193	Ethyl Alcohol Manufacturing	1000 or fewer

Exhibit 4-8 shows a screen capture of the 'Small Business Concern Definition' window (Scroll 2):

Exhibit 4-8 Small Business Concern Definition Window (Scroll 2)

325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	1250 or fewer
325199	All Other Basic Organic Chemical Manufacturing	1250 or fewer
325211	Plastics Material and Resin Manufacturing	1250 or fewer
325212	Synthetic Rubber Manufacturing	1000 or fewer
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	1000 or fewer
325311	Nitrogenous Fertilizer Manufacturing	1000 or fewer
325312	Phosphatic Fertilizer Manufacturing	750 or fewer
325314	Fertilizer (Mixing Only) Manufacturing	500 or fewer
325320	Pesticide and Other Agricultural Chemical Manufacturing	1000 or fewer
325411	Medicinal and Botanical Manufacturing	1000 or fewer
325412	Pharmaceutical Preparation Manufacturing	1250 or fewer
325413	InVitro Diagnostic Substance	1250 or fewer

Exhibit 4-9 shows a screen capture of the 'Small Business Concern Definition' window (Scroll 3):

Exhibit 4-9 Small Business Concern Definition Window (Scroll 3)

325414	Biological Product (except Diagnostic) Manufacturing	1250 or fewer
325510	Paint and Coating Manufacturing	1000 or fewer
325520	Adhesive Manufacturing	500 or fewer
325611	Soap and Other Detergent Manufacturing	1000 or fewer
325612	Polish and Other Sanitation Good Manufacturing	750 or fewer
325613	Surface Active Agent Manufacturing	750 or fewer
325620	Toilet Preparation Manufacturing	1250 or fewer
325910	Printing Ink Manufacturing	500 or fewer
325920	Explosives Manufacturing	750 or fewer
325991	Custom Compounding of Purchased Resins	500 or fewer
325992	Photographic Film, Paper, Plate and Chemical Manufacturing	1500 or fewer
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	500 or fewer

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

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

325613	Surface Active Agent Manufacturing	750 or fewer
325620	Toilet Preparation Manufacturing	1250 or fewer
325910	Printing Ink Manufacturing	500 or fewer
325920	Explosives Manufacturing	750 or fewer
325991	Custom Compounding of Purchased Resins	500 or fewer
325992	Photographic Film, Paper, Plate and Chemical Manufacturing	1500 or fewer
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	500 or fewer
424690	Other Chemical and Allied Products Merchant Wholesalers	150 or fewer
424710	Petroleum Bulk Stations and Terminals	200 or fewer
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	200 or fewer

Navigation: Click the 'X' icon in the upper right-hand corner to close the 'Small Business Concern Definition' window.

4.4 United States Agent

You can navigate to the 'United States Agent' screen by identifying a non-U.S. contact and clicking the 'Continue' button on the 'Contact' screen.

The 'United States Agent' screen provides fields to input identifying information for a U.S. agent.

- **CBI:** Check the 'CBI' checkbox to claim the agent information as confidential.
- **First Name:** Enter the first name of the agent. This is a required field.
- **Last Name:** Enter the last name of the agent. This is a required field.
- **Position:** Enter the job title of the agent.
- **Company Name:** Enter the company name of the agent. This is a required field.
- **Phone Number:** Enter the phone number of the agent. This is a required field.
- **Phone Number Extension:** Enter the extension to the phone number, if applicable.
- **Email Address:** Enter the email address of the agent. This is a required field.
- **Mailing Address 1:** Enter the mailing address of the agent. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the agent, if applicable.
- **City:** Enter the city of the mailing address of the agent. This is a required field.
- **State:** Select the state of the mailing address of the agent. This is a required field.
- **Postal Code:** Enter the postal code of the mailing address of the agent. This is a required field.
- **Country:** Displays 'United States.'

Exhibit 4-11 shows a screen capture of the 'United States Agent' screen (Scroll 1):

Exhibit 4-11 United States Agent Screen (Scroll 1)

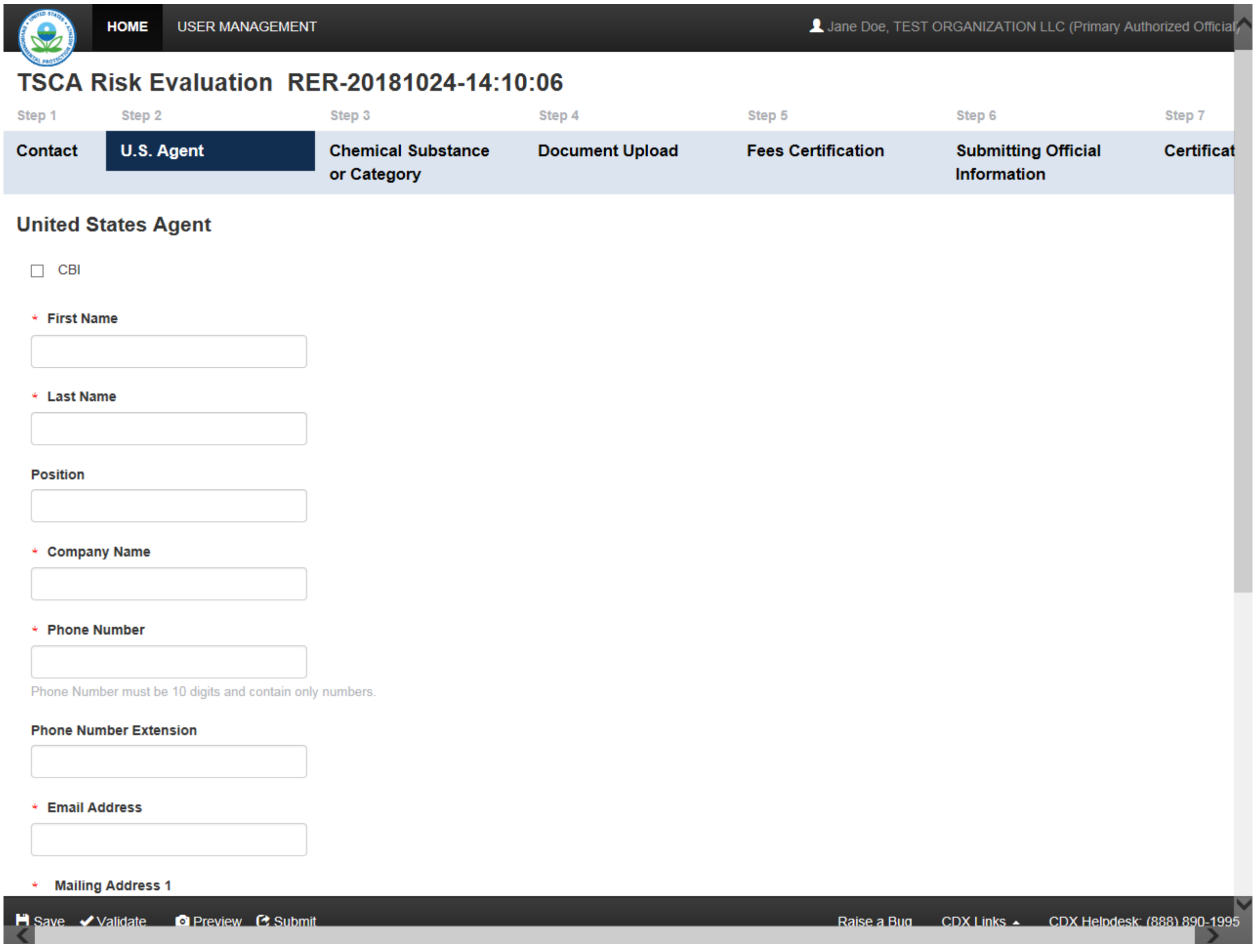
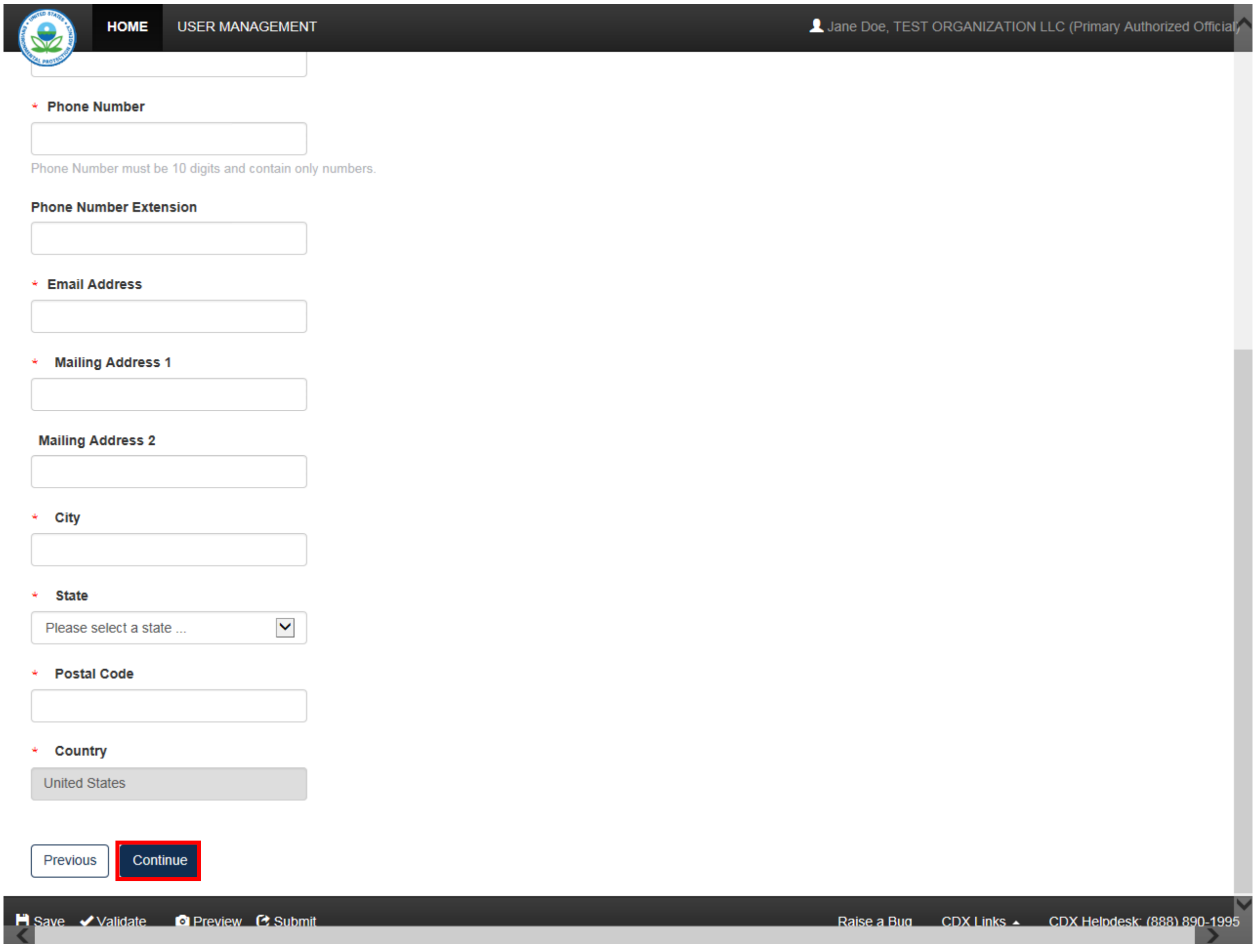


Exhibit 4-12 shows a screen capture of the ‘United States Agent’ screen (Scroll 2):

Exhibit 4-12 United States Agent Screen (Scroll 2)



Navigation: Click the 'Continue' button to navigate to the 'Chemical Substance or Category' screen if the request is submitted on behalf of the reporting organization. You can also access this screen by clicking the 'Chemical Substance or Category' link within the navigation header.

4.5 Chemical Substance or Category

You can access the 'Chemical Substance or Category' screen by clicking the 'Continue' button from the 'Contact' screen if identifying a U.S. contact. If identifying a non-U.S. contact within the 'Contact' screen, you can access this screen by clicking the 'Continue' button from the 'United States Agent' screen. You can also access this screen by clicking the 'Chemical Substance or Category' link within the navigation header.

The 'Chemical Substance or Category' screen displays the following fields and columns of information:

- **Chemical Type:** Select 'Chemical Category' from the 'Chemical Type' drop-down menu to indicate that the chemical substances included will be classified under a single chemical category. Select 'Chemical Substance' to identify one chemical substance for evaluation.
- **Chemical Category Description:** Enter a description of the chemical category; either chemicals or a chemical category must be identified. 'Chemical category' means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances. This is a required field (if displayed).
- **Search:** Enter criteria to filter the attached documents.
- **Document Type:** Displays the document type of the uploaded chemical category attachment. A chemical category rationale document and either chemicals or a chemical category substance list document is required if the user is reporting a chemical category.
- **File Name:** Displays the file name of the uploaded chemical category attachment. Click the link to navigate to the 'Attach Document' window with uploaded document information.
- **File Description:** Displays the description of the uploaded chemical category attachment.
- **Page Count:** Displays the number of pages the uploaded chemical category attachment contains.
- **Date:** Displays the date the chemical category attachment is uploaded.
- **CBI:** Displays a 'Y' or an 'N' to indicate the confidentiality status of the uploaded attachment.
- **Action:** Click the 'Delete' icon (✖) to remove the uploaded chemical category document.
- **Attach Chemical Category Document:** Click this link to navigate to the 'Attach Document' pop-up window and upload a new document. You are required to upload a 'Chemical Category Rationale' document if you selected 'Chemical Category' from the 'Chemical Type' drop-down menu on the 'Chemical Substance or Category' screen. Refer to **Section 4.5.1** for further details on the 'Attach Document' window.
- **Search:** Enter criteria to filter the identified chemical substances.
- **CASRN:** Displays the Chemical Abstract Services Registry Number (CASRN) (if applicable) of the identified chemical substance.
- **PMN No.:** Displays the Premanufacture (PMN) Number (if applicable) of an identified chemical substance.
- **Acc. No.:** Displays the Accession Number (if applicable) of an identified chemical substance.

- **Chemical Name (TSCA Inventory):** Displays the chemical name of an identified chemical substance.
- **Chemical Name (Generic):** Displays the generic name of an identified chemical substance.
- **Action:** Click the 'Edit' icon ( ) to enable the chemical fields and modify the chemical information. Click the 'Delete' icon (**)** to remove the identified chemical substance.
- **Add Chemical:** Click the 'Add Chemical' button to enable the chemical information fields.
- **Search SRS:** Click the 'Search SRS' button to generate the 'Search Substance Registry Services (SRS)' window. See **Section 4.5.2** for additional details about the 'Search SRS' functionality.
- **CASRN:** Displays the Chemical Abstract Services Registry Number (CASRN) of the identified chemical substance.
- **Chemical Name:** Displays the chemical name of the identified chemical substance.
- **Trade Name:** Enter the trade name of the identified chemical substance. This is a required field.
- **Molecular Structure:** Enter the molecular structure of the identified chemical substance. This is a required field.
- **Cancel:** Click the 'Cancel' button to close the chemical information fields.
- **Save:** Click the 'Save' button to save the entered chemical substance information.

Exhibit 4-13 shows a screen capture of the ‘Chemical Substance or Category’ screen (Scroll 1):

Exhibit 4-13 Chemical Substance or Category Screen (Scroll 1)

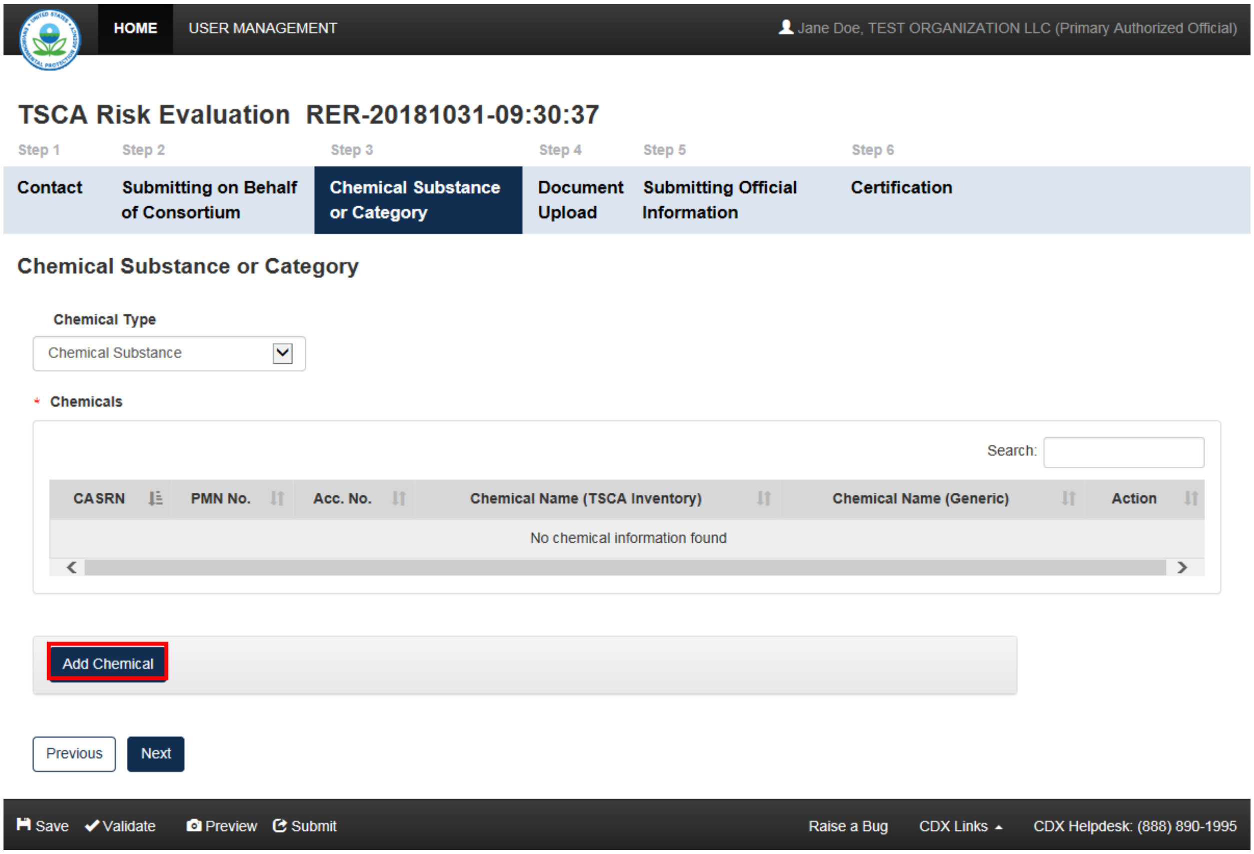


Exhibit 4-14 shows a screen capture of the ‘Chemical Substance or Category’ screen (Scroll 2):

Exhibit 4-14 Chemical Substance or Category Screen (Scroll 2)

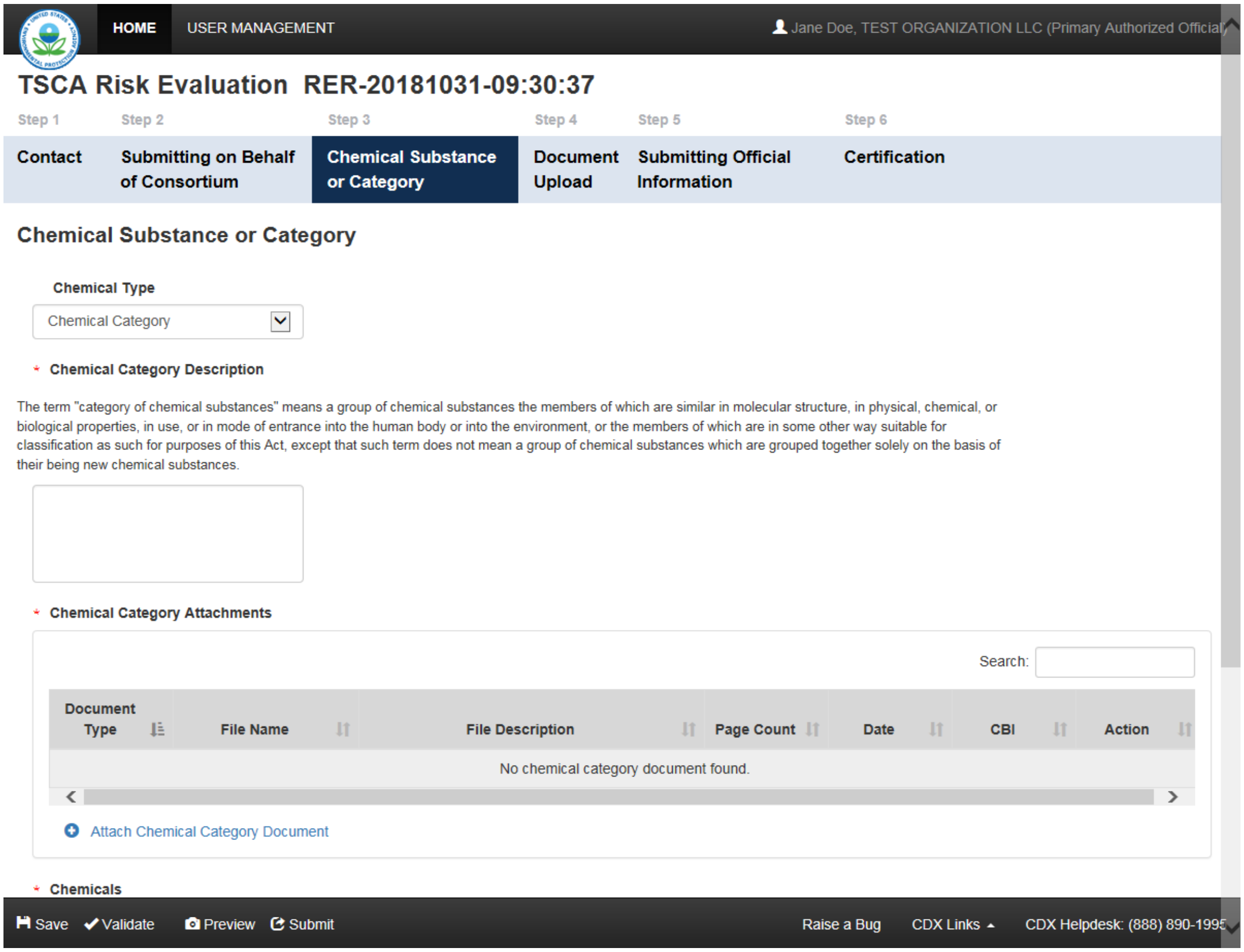
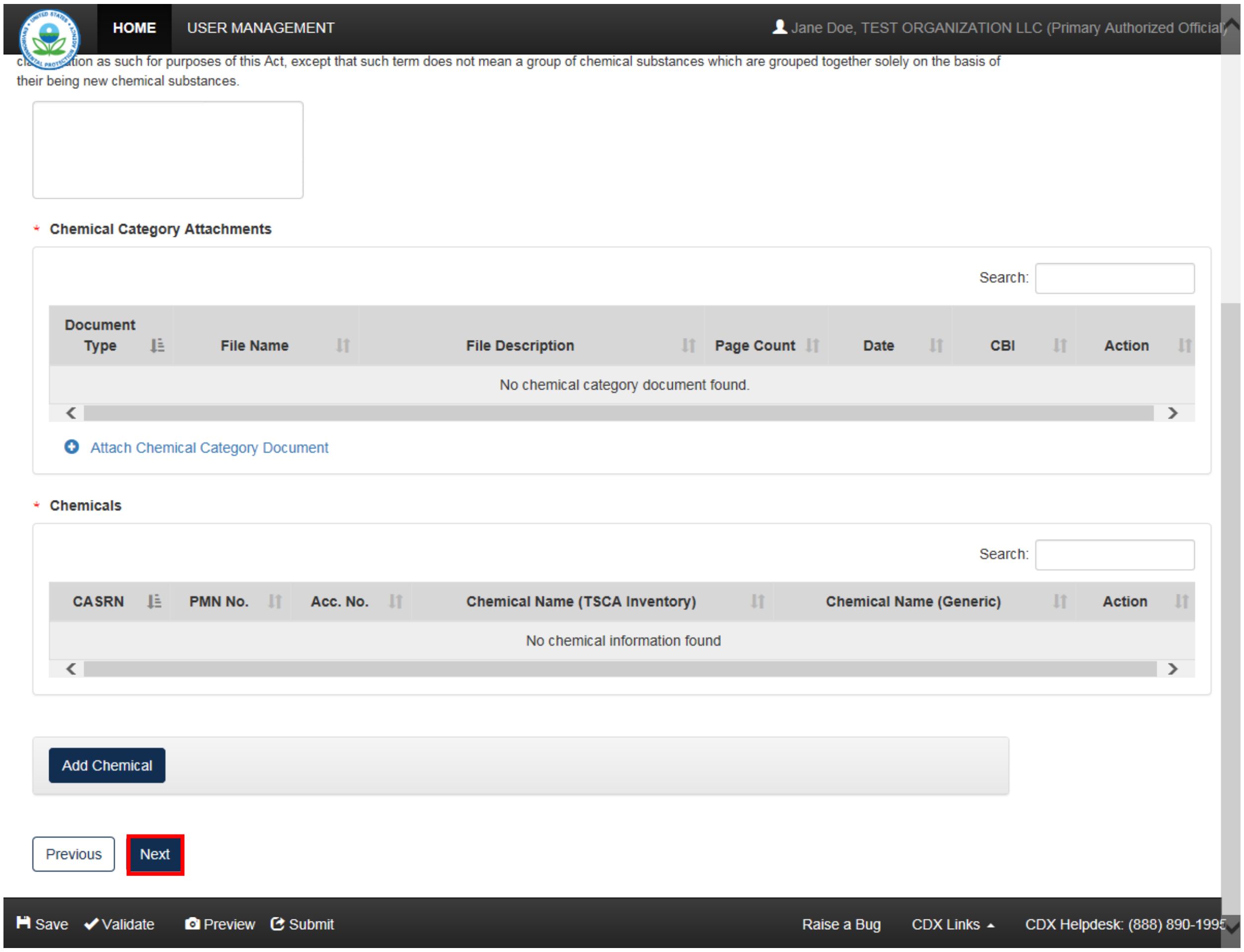


Exhibit 4-15 shows a screen capture of the 'Chemical Substance or Category' screen (Scroll 3):

Exhibit 4-15 Chemical Substance or Category Screen (Scroll 3)



Navigation: Click the 'Next' button to navigate to the 'Document Upload' screen. You can also access this screen by clicking the 'Document Upload' link within the navigation header.

4.5.1 Attach Document

The 'Attach Document' window displays the following fields of information:

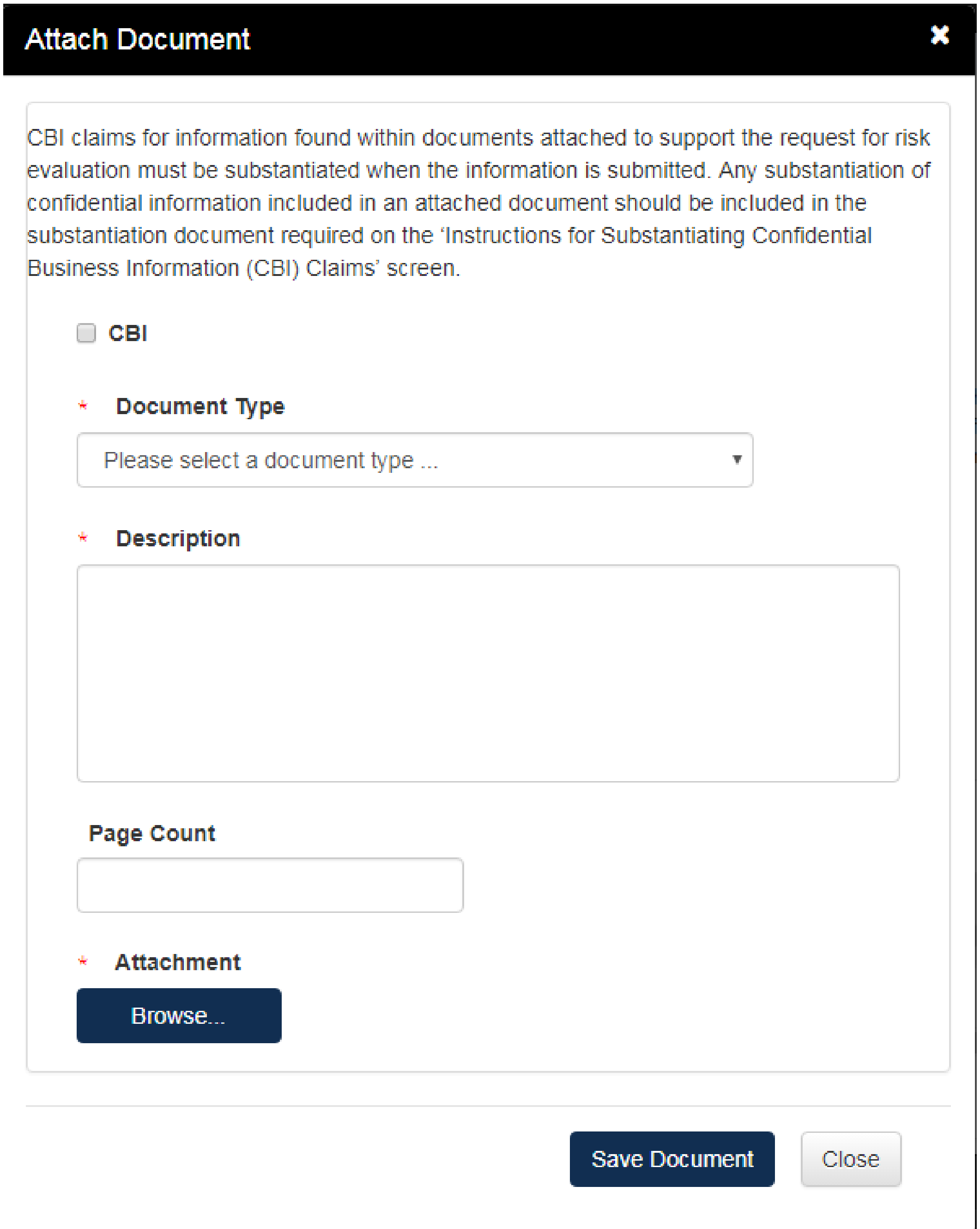
- **CBI:** Check this checkbox to claim the uploaded document as confidential.
- **Document Type:** Select the type of document you are uploading from this drop-down menu. Refer to **Appendix A**. Document Types and Subtypes for a list of all the document types available in this drop-down menu. This is a required field.
- **Document Subtype:** Select the subtype of the document you are uploading from this drop-down menu, if applicable. Refer to **Appendix A**. Document Types and Subtypes for a list of

all the document subtypes available in this drop-down menu. This is a required field, if shown.

- **Description:** Enter a description for the uploaded document. This is a required field.
- **Page Count:** Enter the number of pages the attached document contains.
- **Attachment:** Click the 'Browse' button to search for and select a document to attach.
- **Sanitized Attachment:** Click the 'Browse' button to search for and select a sanitized document to attach.
- **Save Document:** Click the button to save and upload the selected document.
- **Close:** Click this button to close the 'Attach Document' pop-up window and return to the 'Chemical Substance or Category' screen without saving any information.

Exhibit 4-16 shows a screen capture of the ‘Attach Document’ pop-up window within the ‘Chemical Substance or Category’ screen:

Exhibit 4-16 Attach Document Pop-Up Window (Chemical Substance or Category Screen)



4.5.2 Search Substance Registry Services (SRS)

The ‘Search SRS’ button displays on the ‘Chemical Substance or Category’ screen to identify chemicals in SRS.

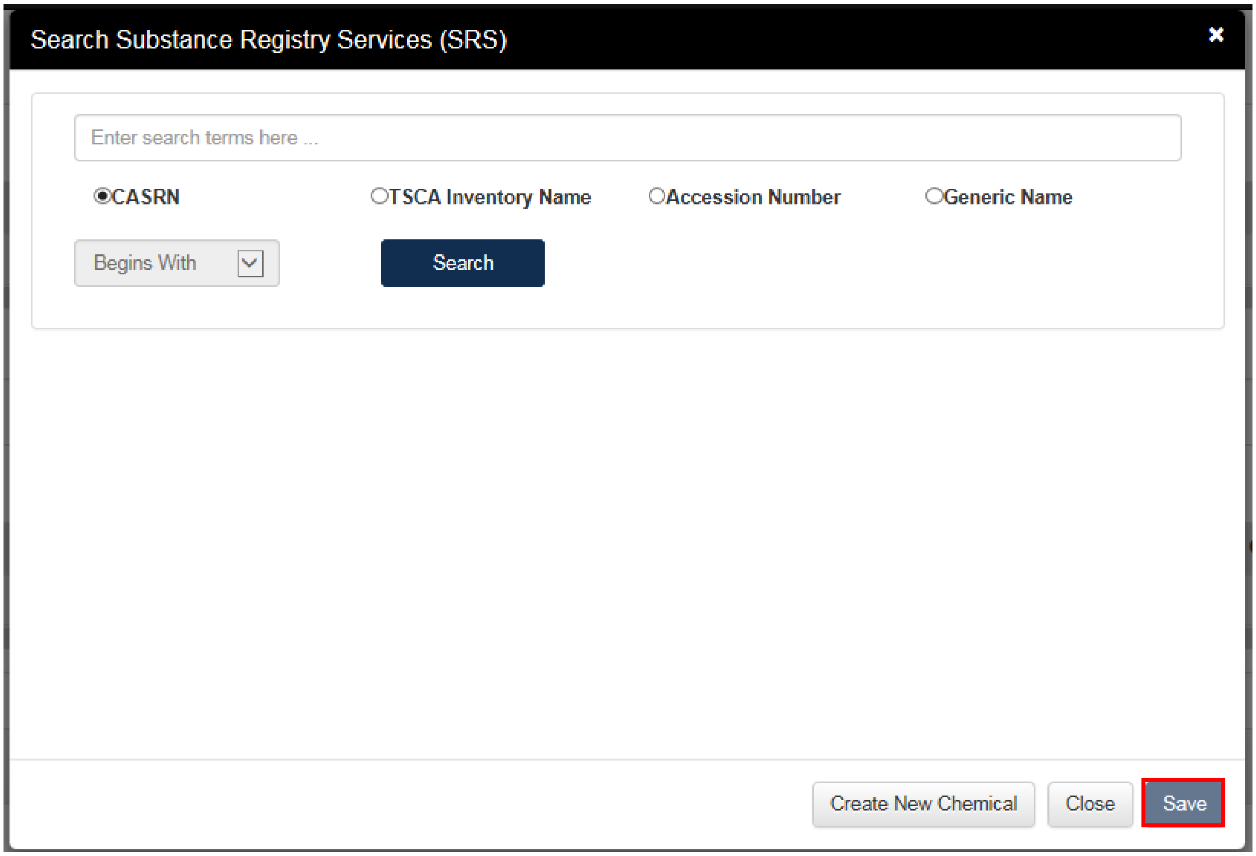
Search SRS: Click the ‘Search SRS’ button to generate the ‘Search Substance Registry Services (SRS)’ pop-up window. You can search for the reported chemical(s) by either the ‘CASRN,’ ‘TSCA Inventory Name,’ ‘Accession Number,’ or ‘Generic Name.’

The system allows you to save each chemical by clicking the ‘Save’ button located at the bottom of the ‘Search Substance Registry Services (SRS)’ pop-up window. Once you select the specified chemical substance and click the ‘Save’ button, the chemical information saves and populates into the chemical substance fields.

- **CASRN:** Select the ‘CASRN’ radio button to search by the Chemical Abstracts Service Registry Number of the chemical; this field accommodates dashes.
- **TSCA Inventory Name:** Select the ‘TSCA Inventory Name’ radio button to search by the inventory name of the chemical.
- **Accession Number:** Select the ‘Accession Number’ radio button to search by the accession number of the chemical.
- **Generic Name:** Select the ‘Generic Name’ radio button to search by the generic chemical name.
- **Begins With/Matches Exactly/Contains:** Select an option to apply a specific filter to the entered search criteria.
- **Search:** Click the ‘Search’ button to search SRS using the entered search criteria.
- **Create New Chemical:** To identify a new chemical, click the ‘Create New Chemical’ button. Refer to **Section 4.5.3** for further details on the process of creating a new chemical.
- **Close:** Click this button to close the ‘Search Substance Registry Services (SRS)’ window and return to the ‘Chemical Substance or Category’ screen without saving any information.
- **Save:** Click the ‘Save’ button to return to the ‘Chemical Substance or Category’ screen and populate the selected chemical into the chemical substance fields.

Exhibit 4-17 shows a screen capture of the ‘Search Substance Registry Services (SRS)’ window:

Exhibit 4-17 Search Substance Registry Services (SRS) Window



Navigation: Click the 'Save' button to return to the 'Chemical Substance or Category' screen and populate the selected chemical into the chemical substance fields.

4.5.3 Create New Chemical

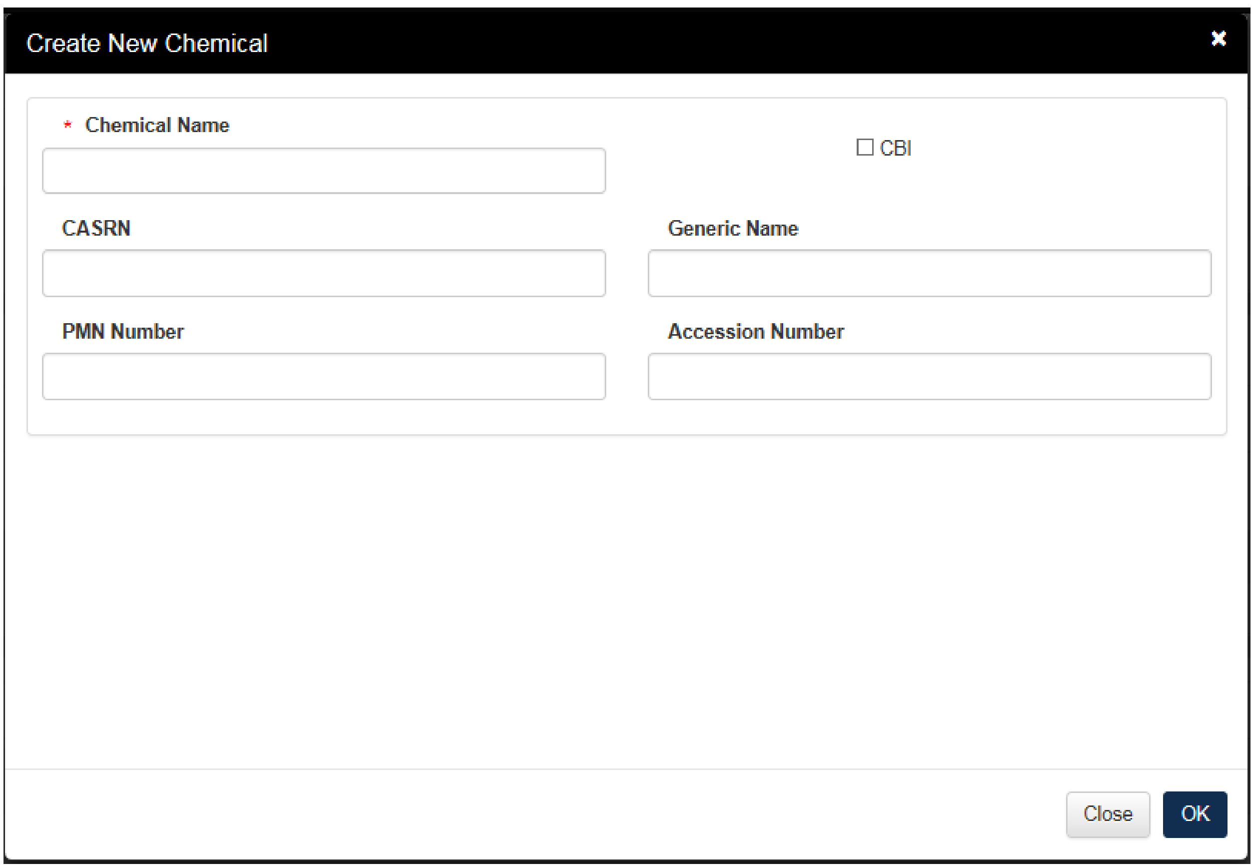
The 'Create New Chemical' button displays on the 'Search Substance Registry Services (SRS)' window to identify new chemicals.

- **Create New Chemical:** Click the 'Create New Chemical' button to generate the 'Create New Chemical' window. You can enter chemical information into the 'Chemical Name,' 'CASRN,' 'PMN Number,' 'Generic Name,' 'PMN Number,' and/or 'Accession Number' fields.
- **Chemical Name:** Enter the name of the identified chemical substance.
- **CBI:** Check the 'CBI' checkbox to claim the chemical name as confidential; this is disabled if a CASRN is entered.

- **CASRN:** Enter the CASRN of the entered chemical substance; either the 'CASRN,' 'PMN Number,' or 'Accession Number' must be entered. The 'CBI' checkbox is disabled if a CASRN is identified.
- **Generic Name:** Enter the generic name of the entered chemical substance.
- **PMN Number:** Enter the PMN Number of the entered chemical substance; either the 'CASRN,' 'PMN Number,' or 'Accession Number' must be entered.
- **Accession Number:** Enter the Accession Number of the entered chemical substance; either the 'CASRN,' 'PMN Number,' or 'Accession Number' must be entered.
- **OK:** Click the 'OK' button to return to the 'Chemical Substance or Category' screen and populate the entered chemical information into the chemical substance fields.
- **Close:** Click the 'Close' button to close the 'Create New Chemical' window and return to the 'Search Substance Registry Services (SRS)' window without saving the entered data.

Exhibit 4-18 shows a screen capture of the 'Create New Chemical' window:

Exhibit 4-18 Create New Chemical Window



4.6 Document Upload

You can access the 'Document Upload' screen by clicking the 'Next' button from the 'Chemical Substance or Category' screen. You can also access this screen by clicking the 'Document Upload' link within the navigation header.

A condition of use rationale document is required to be uploaded within a Risk Evaluation request.

- **Condition of Use:** Enter text including a rationale for the conditions of use. The term 'condition of use' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, or distributed in commerce, used or disposed of. This is a required field.
- **Search:** Enter criteria to filter the uploaded document(s).
- **Document Type:** Displays the document type of the uploaded document.
- **File Name:** Displays the file name of the uploaded document.
- **File Description:** Displays the description of the uploaded document.
- **Page Count:** Displays the number of pages in the uploaded document.
- **Date:** Displays the date that the uploaded document was attached.
- **CBI:** Displays a 'Y' or an 'N' to indicate the confidentiality status of the uploaded document.
- **Action:** Click the 'Delete' icon (**)** to remove the uploaded document.
- **Attach Document:** Click the 'Attach Document' link to generate the 'Attach Document' window. Refer to **Section 4.5.1** for further details on the 'Attach Document' window.

Exhibit 4-19 shows a screen capture of the 'Document Upload' screen (Scroll 1):

Exhibit 4-19 Document Upload Screen (Scroll 1)

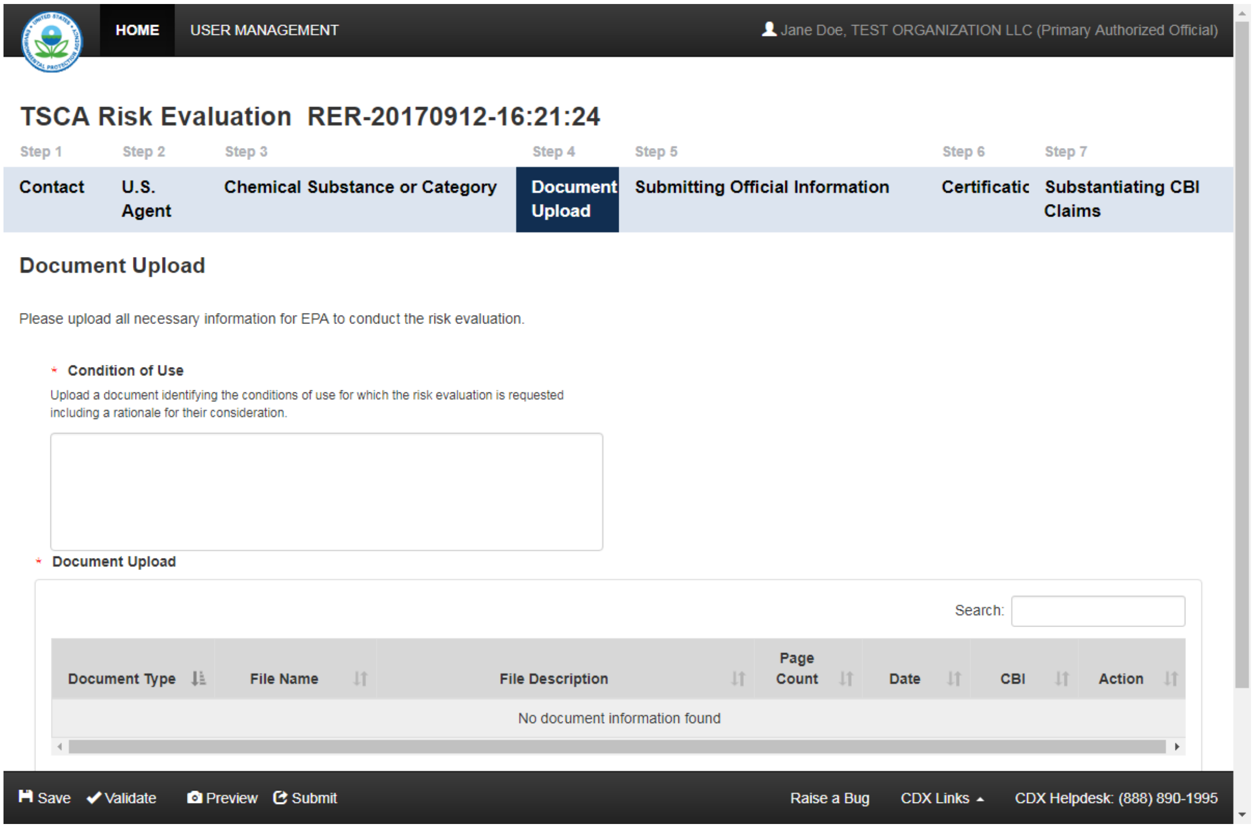
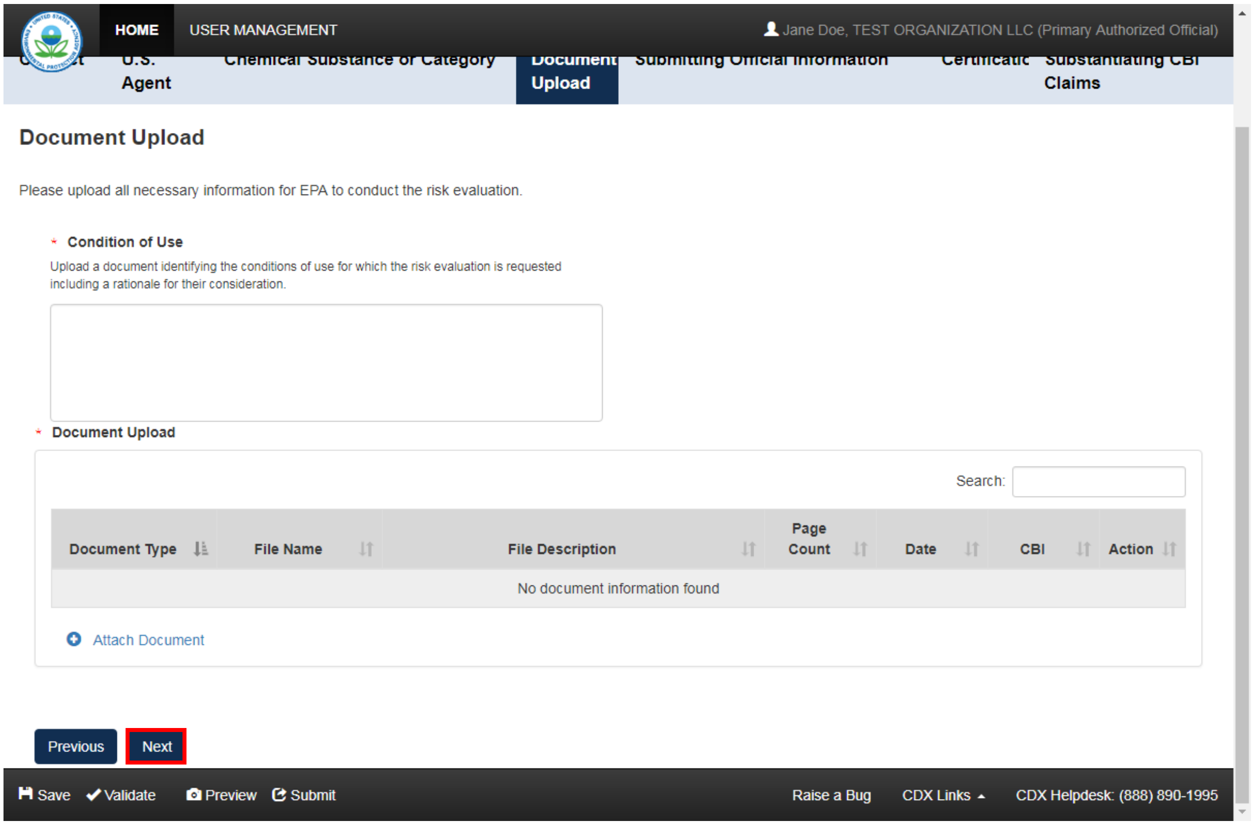


Exhibit 4-20 shows a screen capture of the ‘Document Upload’ screen (Scroll 2):

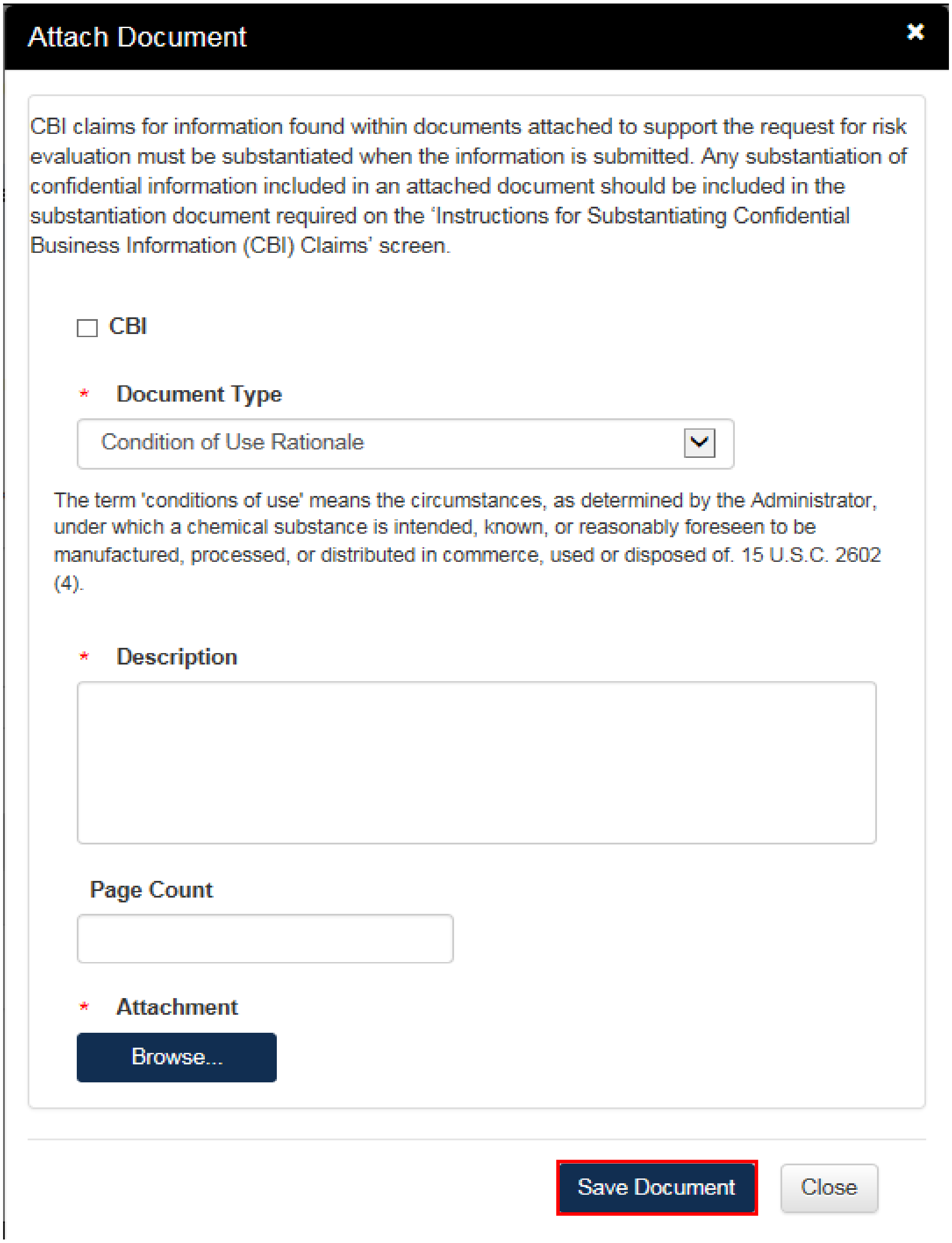
Exhibit 4-20 Document Upload Screen (Scroll 2)



Navigation: Click the ‘Next’ button to navigate to the ‘Submitting Official Information’ screen if this form is submitted on behalf of a consortium. You can also access this screen by clicking the ‘Submitting Official Information’ link within the navigation header. Click the ‘Next’ button to navigate to the ‘Fees Certification’ screen if this form is submitted on behalf of the reporting organization. You can also access this screen by clicking the ‘Fees Certification’ link within the navigation header.

Exhibit 4-21 shows a screen capture of the ‘Attach Document’ window:

Exhibit 4-21 Attach Document Window



Navigation: Click the ‘Save Document’ button to upload the selected attachment to the ‘Documents’ table.

4.7 Fees Certification

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

You can access the ‘Fees Certification’ screen by selecting the ‘N/A’ radio button within the ‘Contact’ screen and clicking the ‘Continue’ button from the ‘Chemical Substance or Category’ screen.

The purpose of the ‘Fees Certification’ screen is to inform EPA of the fee amount that a primary submitter pays on behalf of the reporting organization based on the business size. The certification statement selected on the ‘Fees Certification’ screen is non-editable when amending a Risk Evaluation Request. See **Section 4.3.1** for additional information regarding the definition of a small business concern.

Exhibit 4-22 shows the fee structure implemented for Risk Evaluation Requests:

Exhibit 4-22 Risk Evaluation Request Fee Structure

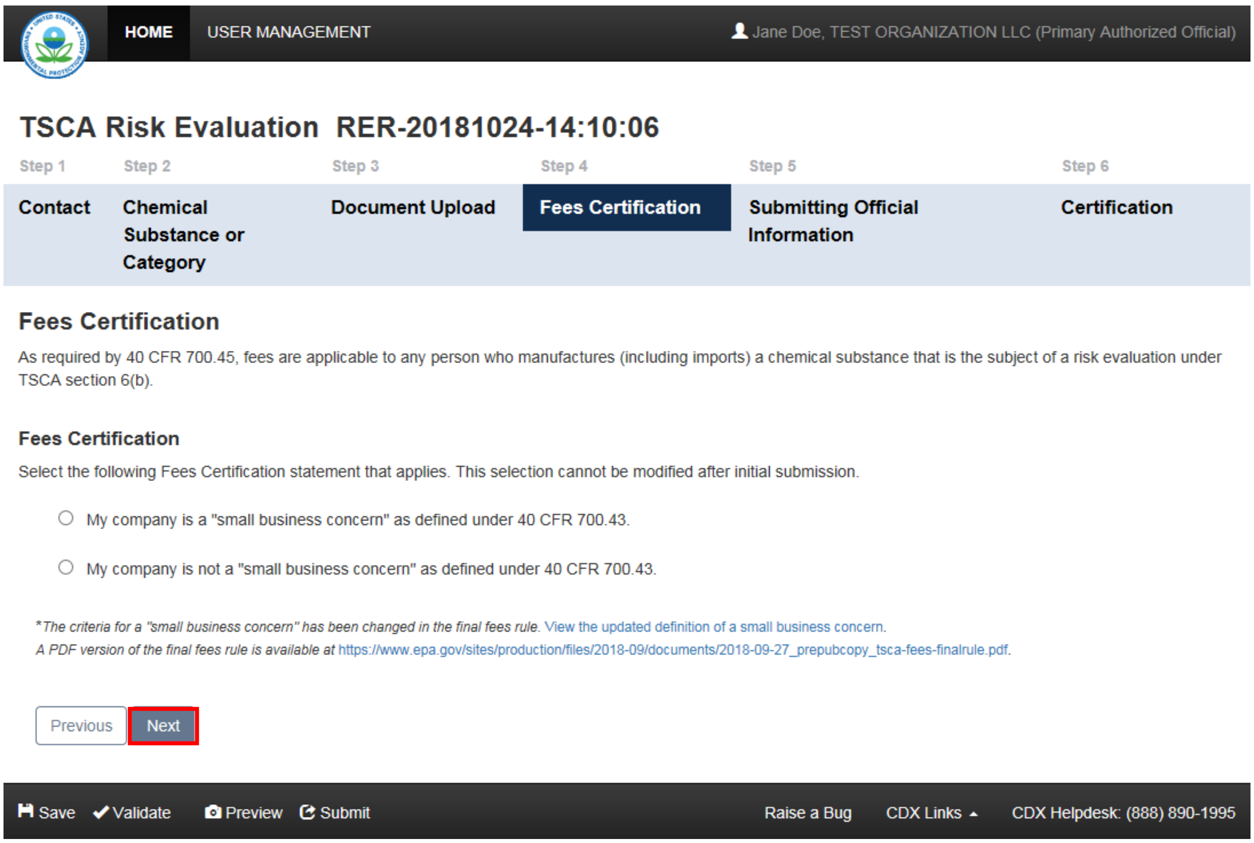
Business Concern	Fee Category	Fee Amount
Not a small business concern	EPA-initiated Risk Evaluation	• $1,350,000
	Manufacturer-requested risk evaluation on a chemical in the TSCA Work Plan	• Initial $1,250,000 payment + final invoice to recover 50% of Actual Costs
	Manufacturer-requested risk evaluation on a chemical <u>not</u> in the TSCA Work Plan	• Initial $2,500,000 payment+ final invoice to total 100% of Actual Costs
Small business	EPA-initiated Risk Evaluation	• $270,000
	Manufacturer-requested risk evaluation on a chemical in the TSCA Work Plan	• Initial $1,250,000 payment + final invoice to recover 50% of Actual Costs
	Manufacturer-requested risk evaluation on a chemical <u>not</u> in the TSCA Work Plan	• Initial $2,500,000 payment+ final invoice to total 100% of Actual Costs

The following certification statements display:

- **My company is a "small business concern" as defined under 40 CFR 700.43:** Select this radio button to indicate that the reporting organization is a small business concern.
- **My company is not a "small business concern" as defined under 40 CFR 700.43:** Select this radio button to indicate that the reporting organization is not a small business concern.

Exhibit 4-23 shows a screen capture of the 'Fees Certification' screen:

Exhibit 4-23 Fees Certification Screen



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

4.8 Submitting Official Information

You can access the 'Submitting Official Information' screen by clicking the 'Next' button from the 'Fees Certification' screen if the request is submitted on behalf of the reporting organization.You can also access this screen by clicking the 'Submitting Official Information' link within the navigation header.

The information below has been pre-populated from CDX registration. If the information listed is incorrect please make the appropriate edits to your user information in CDX registration.

- **Submitter is CBI:** Check the 'CBI' checkbox to claim the submitter information as confidential.
- **First Name:** Displays the first name of the submitter.
- **Middle Initial:** Displays the middle initial of the submitter.
- **Last Name:** Displays the last name of the submitter.
- **Company Name:** Displays the company name of the submitter.
- **Phone Number:** Displays the phone number of the submitter.
- **Email Address:** Displays the email address of the submitter.
- **Mailing Address 1:** Displays line 1 of the mailing address of the submitter.
- **City:** Displays the city of the mailing address of the submitter.
- **State:** Displays the state of the mailing address of the submitter.
- **Postal Code:** Displays the postal code of the mailing address of the submitter.
- **Country:** Displays the country of the mailing address of the submitter.
- **This confirmation is required to proceed with the submission process:** Check the legal verification checkbox to begin the submission process; this is required and gets reset when accessing the form.

Exhibit 4-24 shows a screen capture of the ‘Submitting Official Information’ screen (Scroll 1):

Exhibit 4-24 Submitting Official Information Screen (Scroll 1)

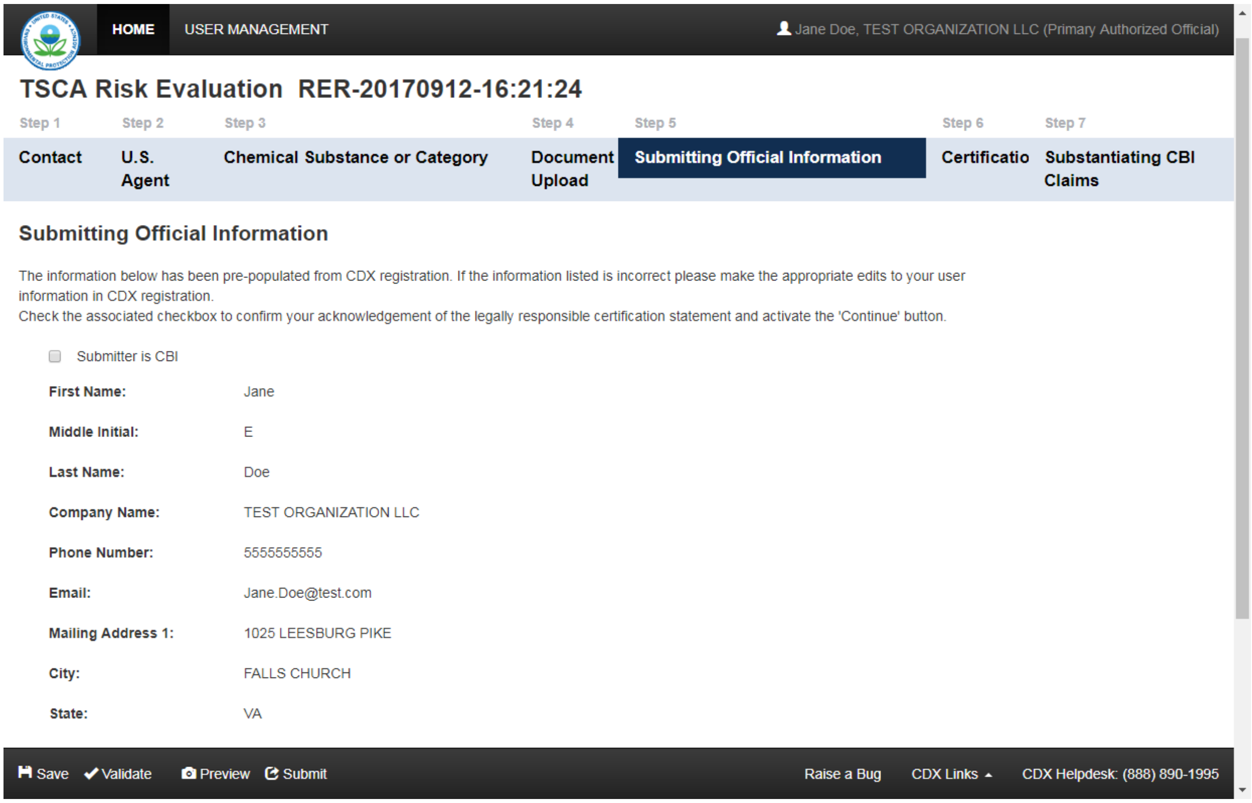
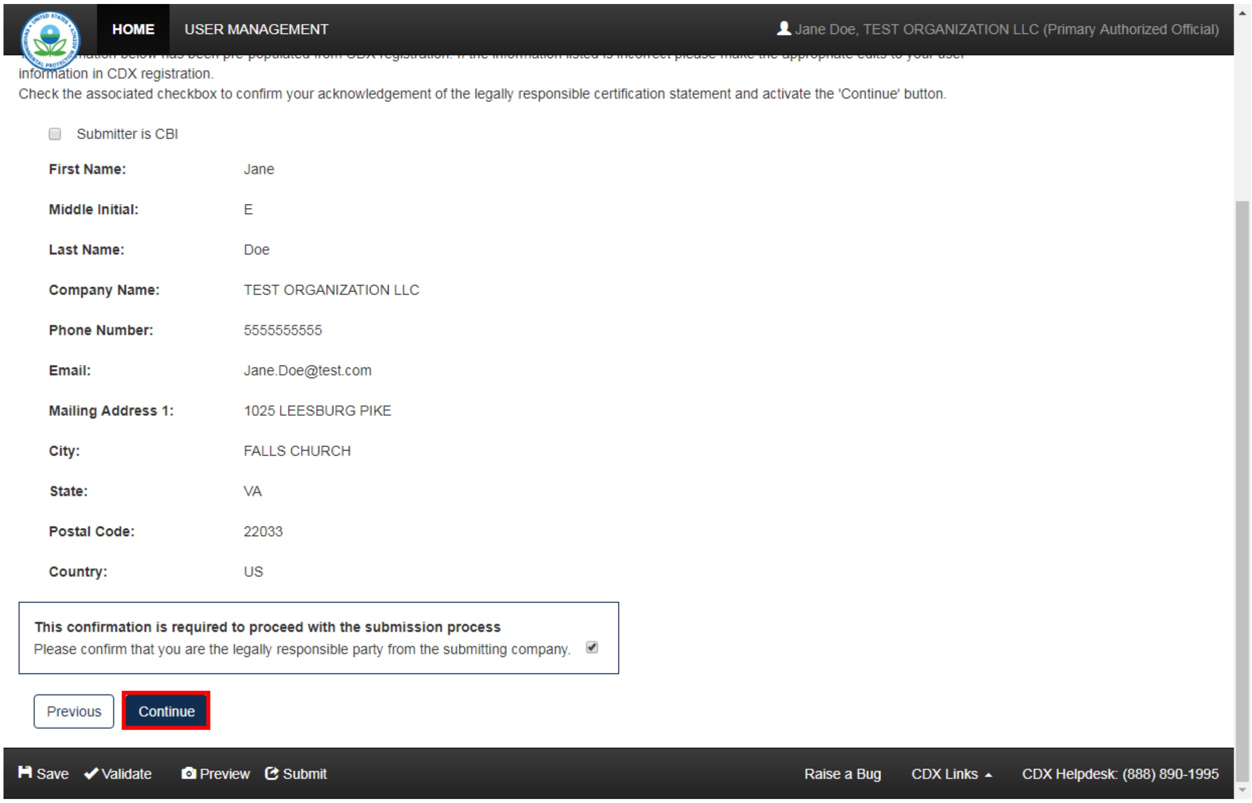


Exhibit 4-25 shows a screen capture of the 'Submitting Official Information' screen (Scroll 2):

Exhibit 4-25 Submitting Official Information Screen (Scroll 2)



Navigation: Click the 'Continue' button to navigate to the 'Submission of Referenced Information' screen. You can also access this screen by clicking the 'Certification' link within the navigation header.

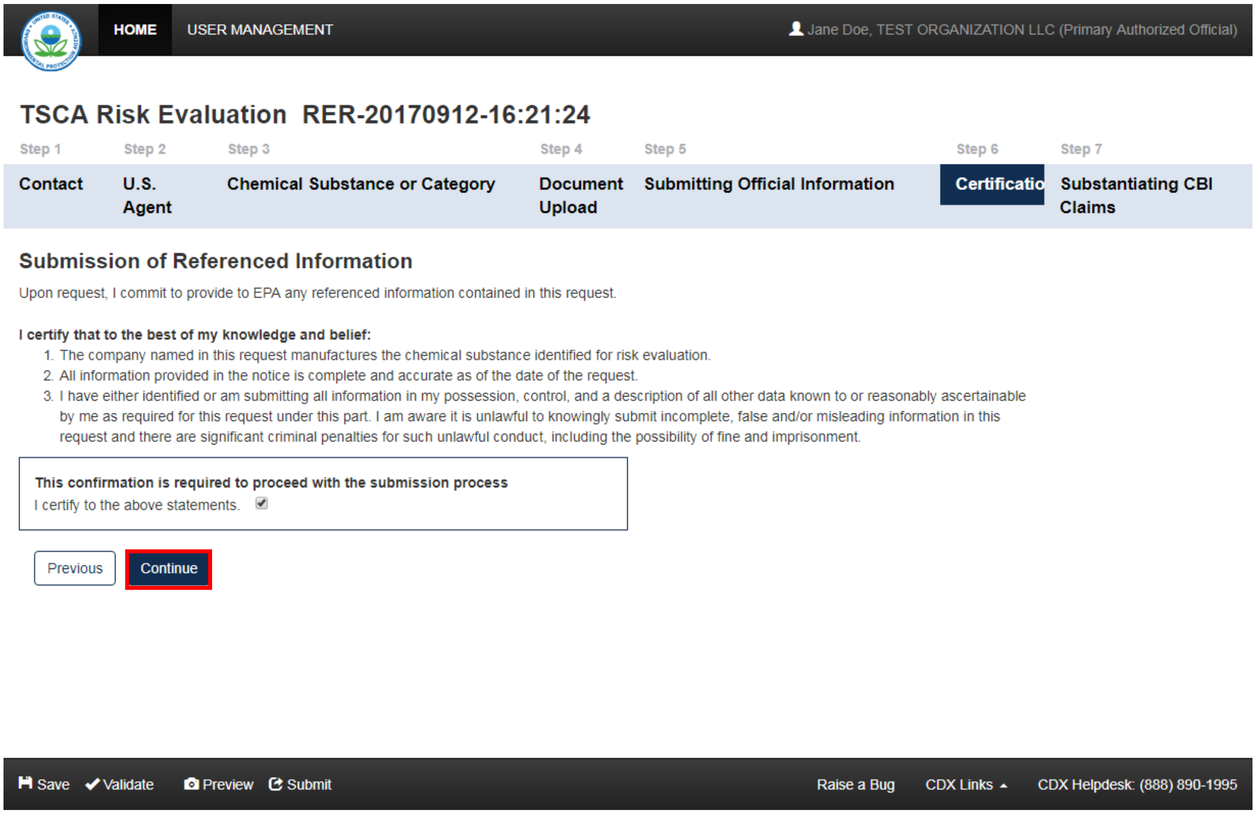
4.9 Submission of Referenced Information

You can access the 'Submission of Referenced Information' screen by clicking the 'Continue' button from the 'Submitting Official Information' screen. You can also access this screen by clicking the 'Certification' link within the navigation header.

The purpose of the 'Submission of Referenced Information' screen is for users to commit to providing EPA referenced information contained in this Risk Evaluation request.

Exhibit 4-26 shows a screen capture of the ‘Submission of Referenced Information’ screen:

Exhibit 4-26 Submission of Referenced Information Screen



Navigation: If any CBI claims were made, check the certification checkbox and click the ‘Continue’ button to navigate to the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen. You can also access this screen by clicking the ‘Substantiating CBI Claims’ link within the navigation header. If no CBI claims were made, check the certification checkbox and click the ‘Start Submission Process’ button to initiate the submission process.

4.10 Instructions for Substantiating Confidential Business Information (CBI) Claims

EPA modified the electronic reporting applications for TSCA submissions to accept CBI substantiations for CBI claims made during the creation of electronic submissions. Other than information exempt from substantiation under TSCA Section 14(c)(2), users who wish to assert CBI claims for data within a submission must substantiate those claims at the time of submission as required by TSCA Section 14(c)(3).

You can access the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen by claiming information as CBI within a form and clicking the ‘Continue’ button from the ‘Submission of Referenced Information’ screen. You can also access this screen by clicking the ‘Substantiating CBI Claims’ link within the navigation header. This screen will not generate until a CBI claim is made within a submission. Information claimed CBI must either be substantiated or claimed exempt pursuant to TSCA Section 14(c)(2) at the time of submission.

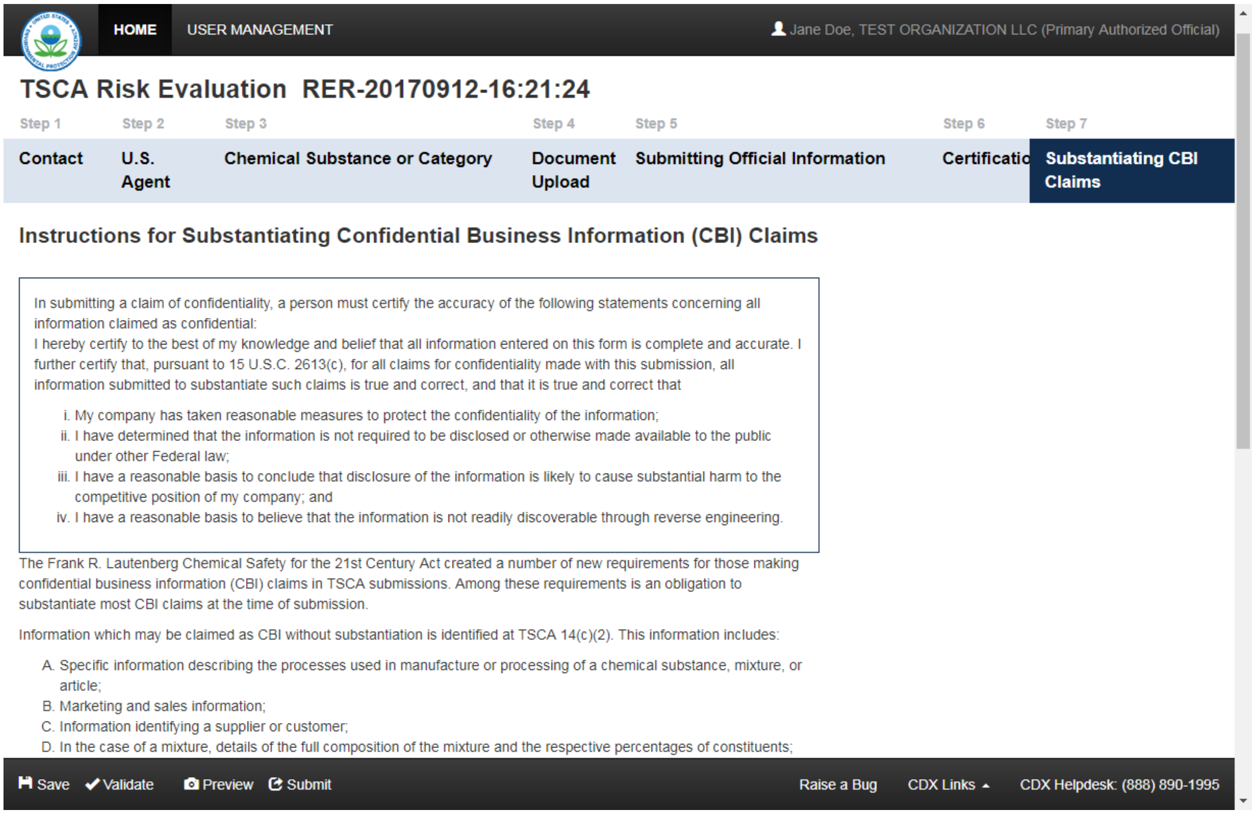
To substantiate a CBI claim, upload documentation asserting your claim(s) on the ‘Instructions for Substantiating CBI Claims’ screen within the form. You may also opt-out of substantiation on the ‘Instructions for Substantiating CBI Claims’ screen if, for example, you believe your CBI claim is exempt under TSCA Section 14(c)(2). Common exemption reasons can be found at https://www.epa.gov/tsca-cbi/what-information-include-cbi-substantiations. To opt-out of substantiation at the time of submission, all CBI claims within a submission must be exempt.

- **Substantiation Opt-Out:** Check this checkbox to opt out of providing CBI substantiation. You will be required to provide reasoning if you choose to opt out.
- **Substantiation Opt-Out Reason:** Enter reasoning for opting out of CBI substantiation. This is a required field.
- **Attach Document for CBI Substantiation:** Click the ‘Attach Document for CBI Substantiation’ link to generate the ‘Attach Documents for CBI Substantiation’ pop-up window.

If you are unfamiliar with substantiating CBI claims or require assistance preparing substantiation documents, EPA offers a link to templates and other information for substantiating CBI claims on the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen. It is suggested that you right-click the link and open in a new tab or new window so you do not leave your submission as this may affect your saved data.

Exhibit 4-27 shows a screen capture of the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen (Scroll 1):

Exhibit 4-27 Instructions for Substantiating Confidential Business Information (CBI) Claims Screen (Scroll 1)



HOME USER MANAGEMENT Jane Doe, TEST ORGANIZATION LLC (Primary Authorized Official)

TSCA Risk Evaluation RER-20170912-16:21:24

Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7
Contact	U.S. Agent	Chemical Substance or Category	Document Upload	Submitting Official Information	Certificatio	Substantiating CBI Claims

Instructions for Substantiating Confidential Business Information (CBI) Claims

In submitting a claim of confidentiality, a person must certify the accuracy of the following statements concerning all information claimed as confidential:
I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

i. My company has taken reasonable measures to protect the confidentiality of the information;
ii. I have determined that the information is not required to be disclosed or otherwise made available to the public under other Federal law;
iii. I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and
iv. I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act created a number of new requirements for those making confidential business information (CBI) claims in TSCA submissions. Among these requirements is an obligation to substantiate most CBI claims at the time of submission.

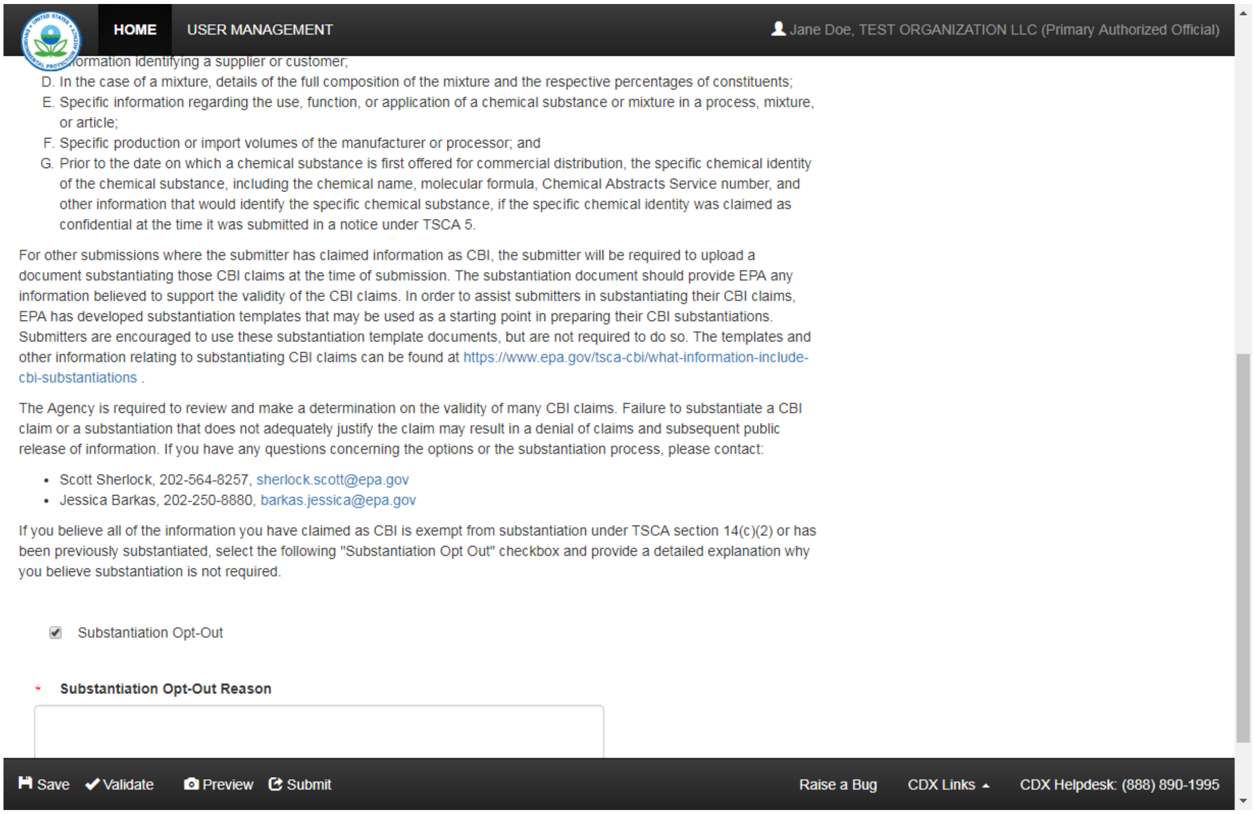
Information which may be claimed as CBI without substantiation is identified at TSCA 14(c)(2). This information includes:

A. Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article;
B. Marketing and sales information;
C. Information identifying a supplier or customer;
D. In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents;

Save Validate Preview Submit Raise a Bug CDX Links CDX Helpdesk: (888) 890-1995

Exhibit 4-28 shows a screen capture of the 'Instructions for Substantiating Confidential Business Information (CBI) Claims' screen (Scroll 2).

Exhibit 4-28 Instructions for Substantiating Confidential Business Information (CBI) Claims Screen (Scroll 2)



HOME USER MANAGEMENT Jane Doe, TEST ORGANIZATION LLC (Primary Authorized Official)

...formation identifying a supplier or customer;

D. In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents;
E. Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article;
F. Specific production or import volumes of the manufacturer or processor; and
G. Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under TSCA 5.

For other submissions where the submitter has claimed information as CBI, the submitter will be required to upload a document substantiating those CBI claims at the time of submission. The substantiation document should provide EPA any information believed to support the validity of the CBI claims. In order to assist submitters in substantiating their CBI claims, EPA has developed substantiation templates that may be used as a starting point in preparing their CBI substantiations. Submitters are encouraged to use these substantiation template documents, but are not required to do so. The templates and other information relating to substantiating CBI claims can be found at https://www.epa.gov/tsca-cbi/what-information-include-cbi-substantiations .

The Agency is required to review and make a determination on the validity of many CBI claims. Failure to substantiate a CBI claim or a substantiation that does not adequately justify the claim may result in a denial of claims and subsequent public release of information. If you have any questions concerning the options or the substantiation process, please contact:

- Scott Sherlock, 202-564-8257, sherlock.scott@epa.gov
- Jessica Barkas, 202-250-8880, barkas.jessica@epa.gov

If you believe all of the information you have claimed as CBI is exempt from substantiation under TSCA section 14(c)(2) or has been previously substantiated, select the following "Substantiation Opt Out" checkbox and provide a detailed explanation why you believe substantiation is not required.

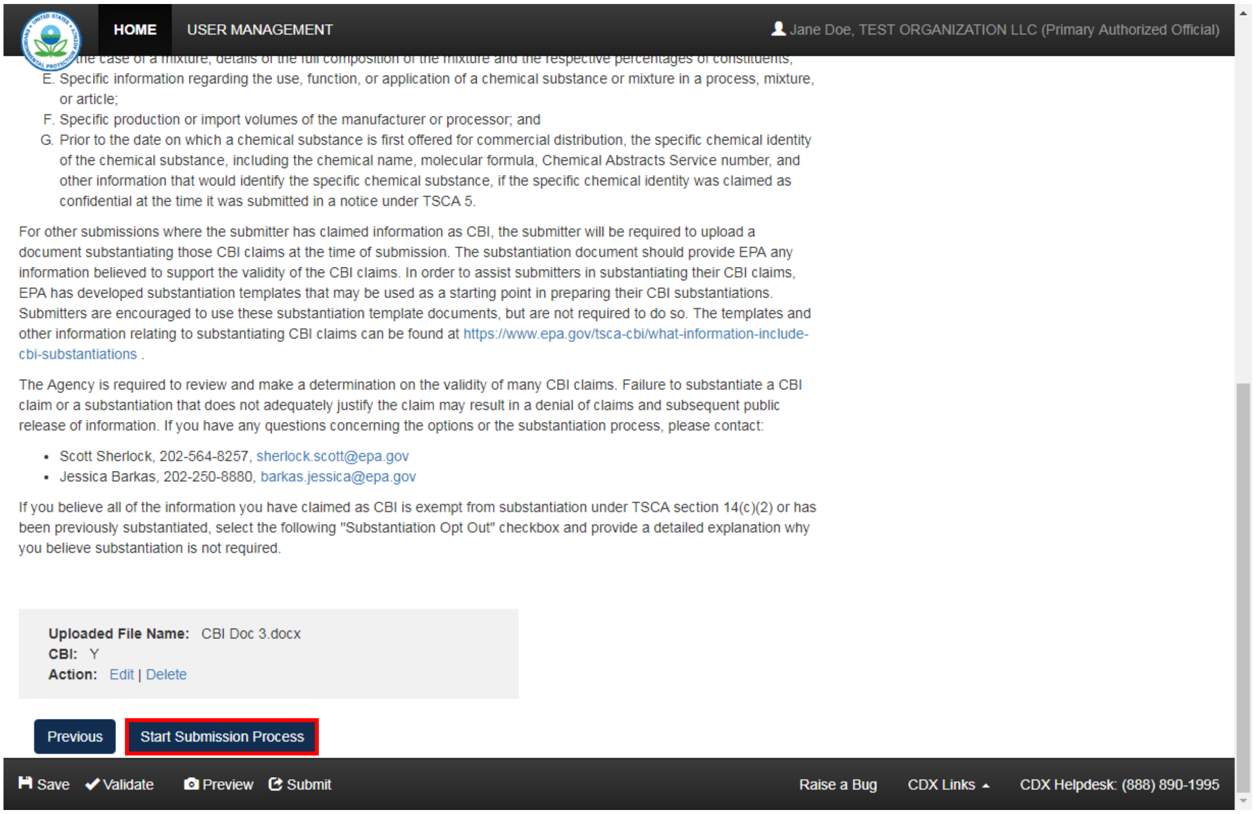
Substantiation Opt-Out

* **Substantiation Opt-Out Reason**

Save Validate Preview Submit Raise a Bug CDX Links CDX Helpdesk: (888) 890-1995

Exhibit 4-29 shows a screen capture of the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen (Scroll 3):

Exhibit 4-29 Instructions for Substantiating Confidential Business Information (CBI) Claims Screen (Scroll 3)



Navigation: Click the ‘Start Submission Process’ button to begin the submission process.

4.11 Attach Documents for CBI Substantiation

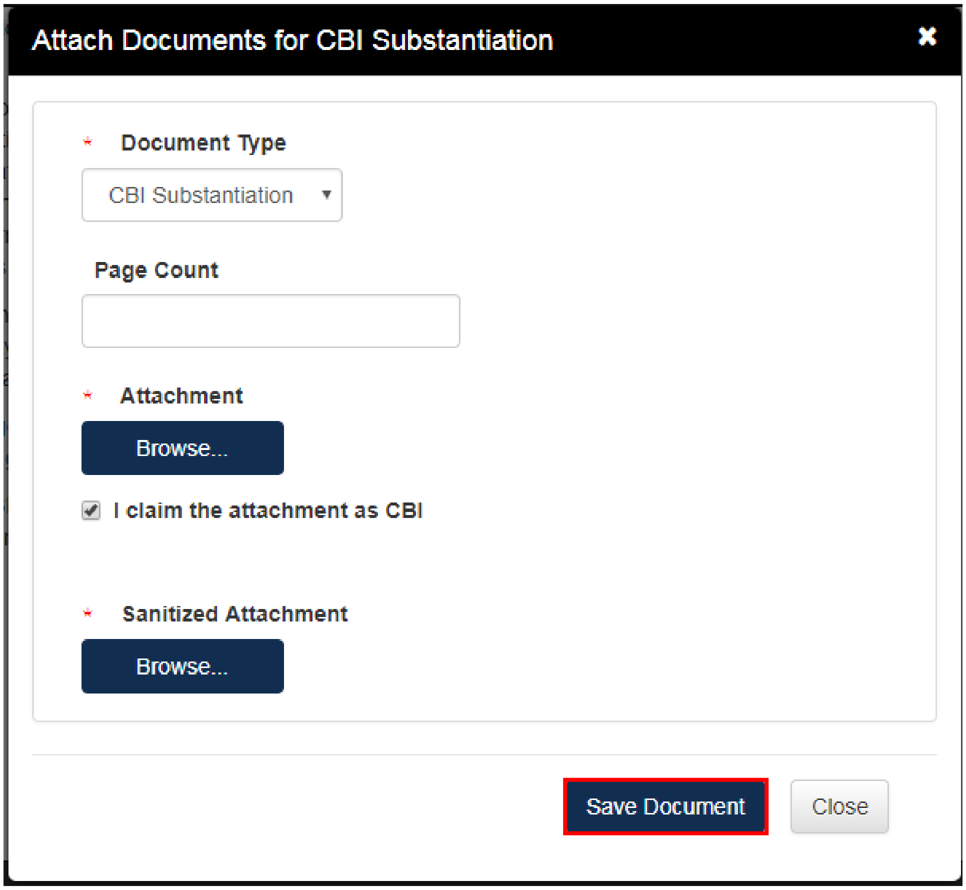
You can access the ‘Attach Documents for CBI Substantiation’ window by clicking the ‘Attach Document for CBI Substantiation’ link within the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen.

- **Document Type:** ‘CBI Substantiation’ is stored in the ‘Document Type’ drop-down menu.
- **Page Count:** Enter the number of pages in the attached document.
- **Attachment:** Click the ‘Browse’ button to search for and select a document to attach. This is a required field.
- **I claim the attachment as CBI:** Check the ‘I claim the attachment as CBI’ checkbox to claim the document as confidential.

- **Sanitized Attachment:** Click the 'Browse' button to search for and select a sanitized document to attach. This is a required field, if it displays.
- **Save Document:** Click the 'Save Document' button to save the uploaded CBI substantiation document(s).
- **Close:** Click the 'Close' button to close the 'Attach Documents for CBI Substantiation' window without saving any uploaded attachment information.

Exhibit 4-30 shows a screen capture of the 'Attach Documents for CBI Substantiation' window:

Exhibit 4-30 Attach Documents for CBI Substantiation Window



Navigation: Click the 'Save Document' button to upload the substantiation document and navigate back to the 'Instructions for Substantiating Confidential Business Information (CBI) Claims' screen.

5 Withdrawal Request

You can withdraw a manufacturer-requested risk evaluation at any time after the request is submitted, and within 30 days of receiving EPA's notification that the request is granted.

5.1 Create a Withdrawal Request

To create a new Withdrawal Request, navigate to the Risk Evaluation 'Home' screen and select 'Withdrawal Request' from the 'Form Type' drop-down menu. Refer to **Section 3.2** for additional details regarding the Risk Evaluation 'Home' screen.

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

5.2 Contact Information

You can navigate to the 'Contact Information' screen by clicking the 'Create' button and creating a new passphrase, or by accessing a Withdrawal Request that is 'In Progress' and entering the passphrase associated with the selected request.

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

- **Case Number:** Enter the case number of the Manufacturer-Requested Risk Evaluation that you would like to withdraw from EPA review. The case number must be in the format 'RER-YY-####.' Type-ahead suggestions will appear in a drop-down for any of your submitted Risk Evaluation requests. This is a required field.
- **Submission Alias:** Enter the submission alias. Upon navigating to the screen, the application displays an auto-generated editable submission alias in the following format: <Form Type-YYYYMMDD-HH:MM:SS >. This is a required field.
- **CBI:** Check the 'CBI' checkbox to claim the contact information as confidential.
- **Copy from CDX:** Click the 'Copy from CDX' link to copy CDX registration information.
- **First Name:** Enter the first name of the contact. This is a required field.
- **Last Name:** Enter the last name of the contact. This is a required field.
- **Position:** Enter the job title of the contact.
- **Company Name:** Enter the company name of the contact. This is a required field.
- **Phone Number:** Enter the phone number of the contact. This is a required field.
- **Phone Number Extension:** Enter the extension to the phone number, if applicable.
- **Email Address:** Enter the email address of the contact. This is a required field.

- **Mailing Address 1:** Enter the mailing address of the contact. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the contact, if applicable.
- **City:** Enter the city of the mailing address of the contact. This is a required field.
- **State:** Select the state of the mailing address of the contact. This is a required field if 'United States' is identified as the country.
- **Postal Code:** Enter the postal code of the mailing address of the contact. This is a required field.
- **Country:** Select the country of the mailing address of the contact from the drop-down menu. This is a required field.

Exhibit 5-1 shows a screen capture of the Withdrawal Request 'Contact Information' screen (Scroll 1):

Exhibit 5-1 Withdrawal Request - Contact Information Screen (Scroll 1)

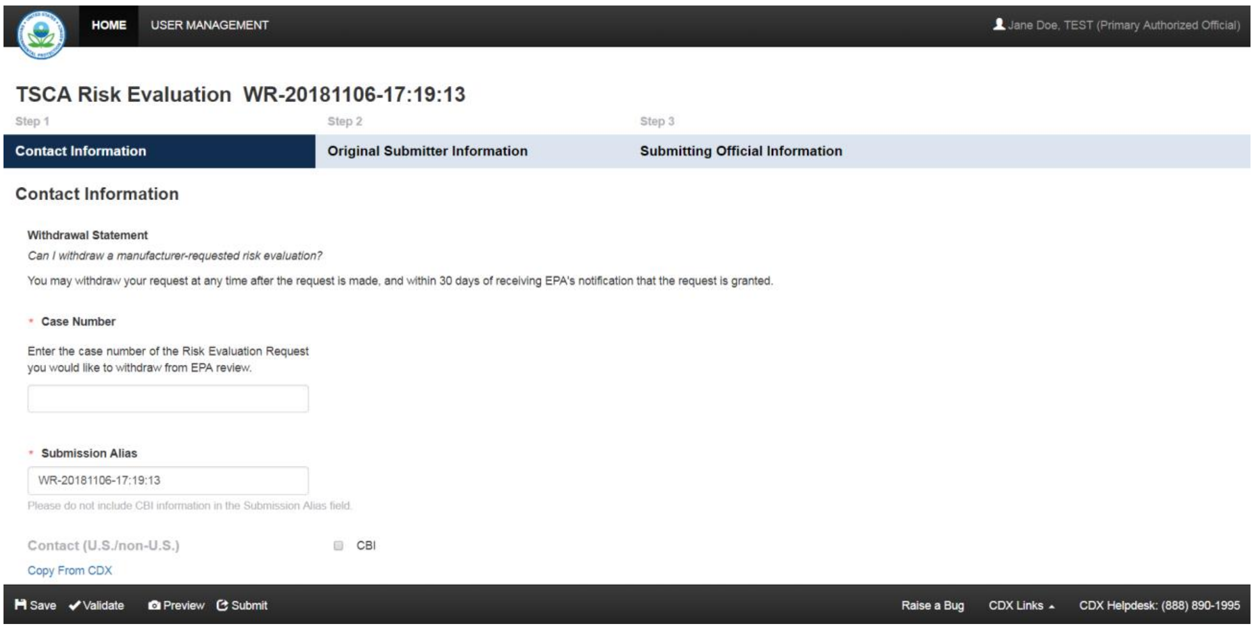


Exhibit 5-2 shows a screen capture of the Withdrawal Request 'Contact Information' screen (Scroll 2):

Exhibit 5-2 Withdrawal Request - Contact Information Screen (Scroll 2)

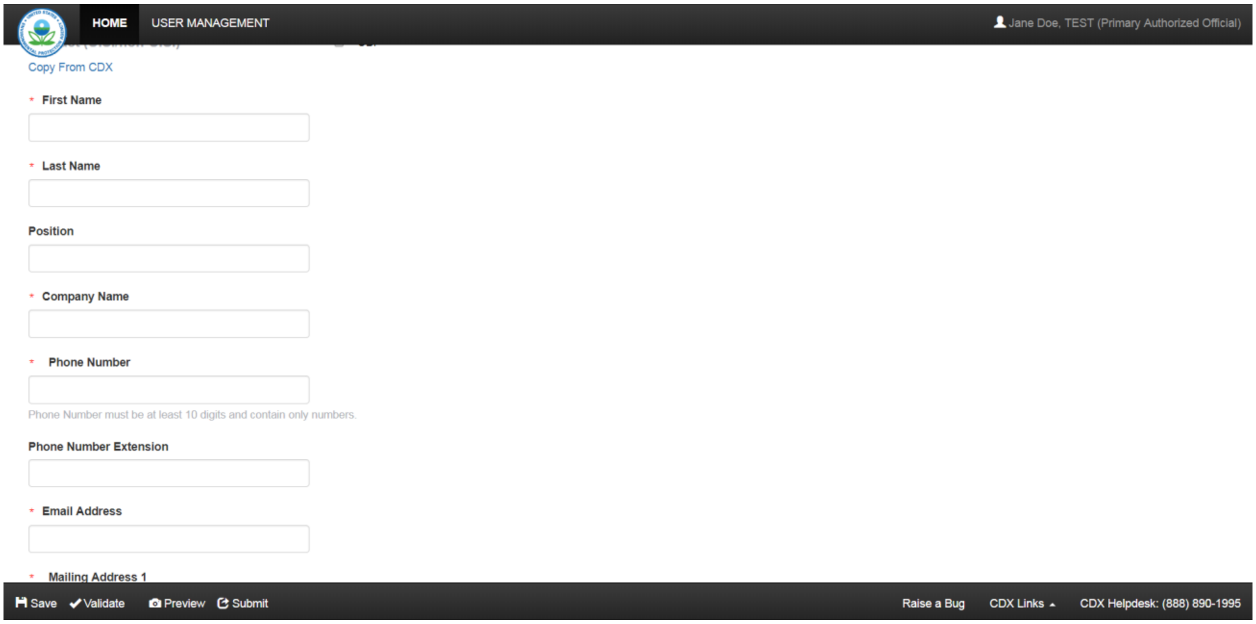


Exhibit 5-3 shows a screen capture of the Withdrawal Request 'Contact Information' screen (Scroll 3):

Exhibit 5-3 Withdrawal Request - Contact Information Screen (Scroll 3)

Navigation: Click the ‘Continue’ button to navigate to the ‘Original Submitter Information’ screen.

5.3 Original Submitter Information

You can navigate to the ‘Original Submitter Information’ screen by clicking the ‘Continue’ button within the ‘Contact Information’ screen. You can also access this screen by clicking the ‘Original Submitter Information’ link within the navigation header.

The purpose of the ‘Original Submitter Information’ screen is to capture the information of the Authorized Official who submitted the original Risk Evaluation Request for which you are filing a Withdrawal Request.

- **Copy from CDX:** Click the ‘Copy from CDX’ link to copy CDX registration information.
- **First Name:** Enter the first name of the original submitter. This is a required field.
- **Last Name:** Enter the last name of the original submitter. This is a required field.
- **Position:** Enter the job title of the original submitter.
- **Company Name:** Enter the company name of the original submitter. This is a required field.
- **Phone Number:** Enter the phone number of the original submitter. This is a required field.
- **Phone Number Extension:** Enter the extension to the phone number, if applicable.
- **Email Address:** Enter the email address of the original submitter. This is a required field.
- **Mailing Address 1:** Enter the mailing address of the original submitter. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the original submitter, if applicable.
- **City:** Enter the city of the mailing address of the original submitter. This is a required field.
- **State:** Select the state of the mailing address of the original submitter. This is a required field if ‘United States’ is identified as the country.
- **Postal Code:** Enter the postal code of the mailing address of the original submitter. This is a required field.
- **Country:** Select the country of the mailing address of the original submitter from the drop-down menu. This is a required field.

Exhibit 5-4 shows a screen capture of the Withdrawal Request ‘Original Submitter Information’ screen (Scroll 1):

Exhibit 5-4 Withdrawal Request – Original Submitter Information Screen (Scroll 1)

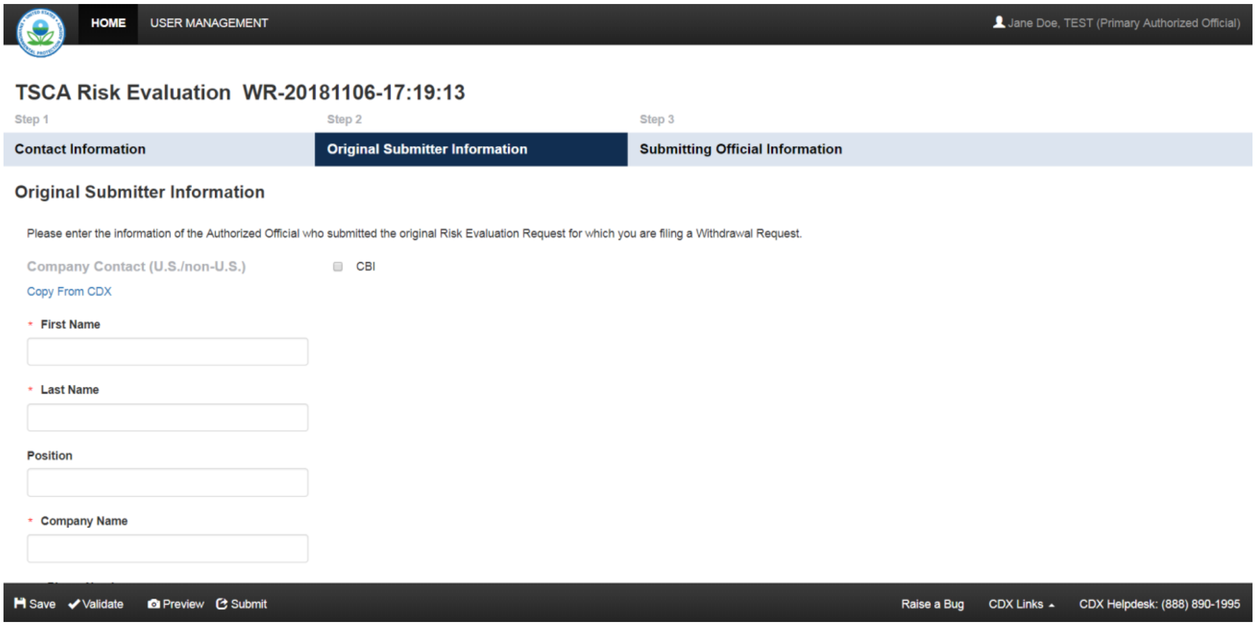


Exhibit 5-5 shows a screen capture of the Withdrawal Request ‘Original Submitter Information’ screen (Scroll 2):

Exhibit 5-5 Withdrawal Request – Original Submitter Information Screen (Scroll 2)

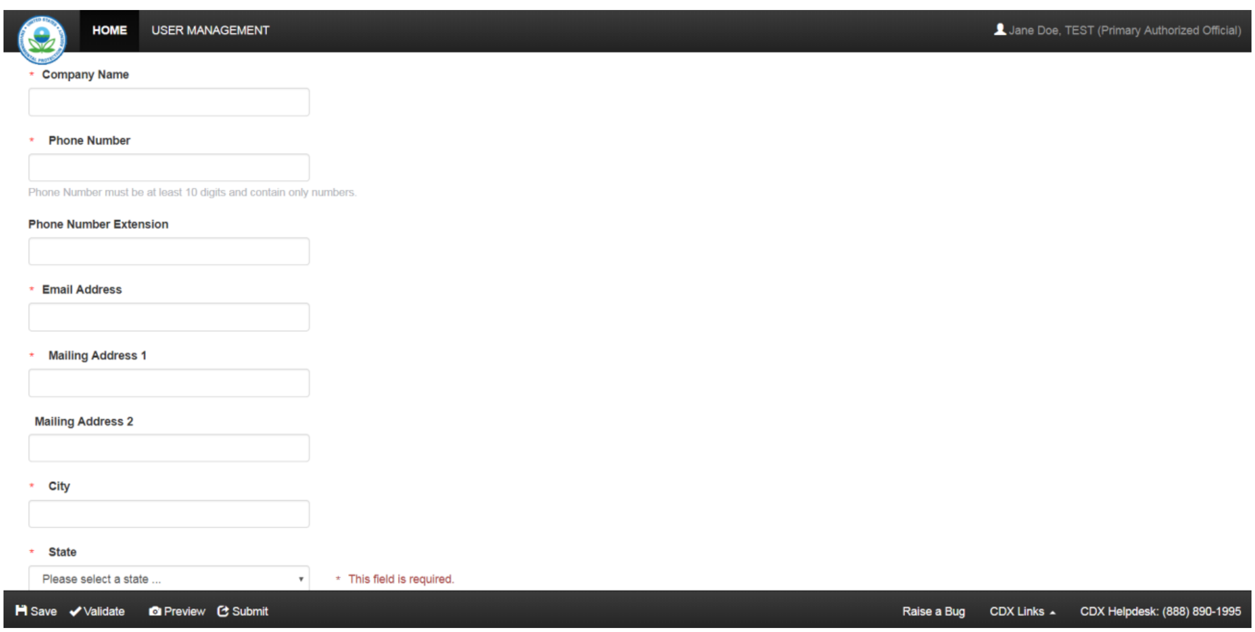
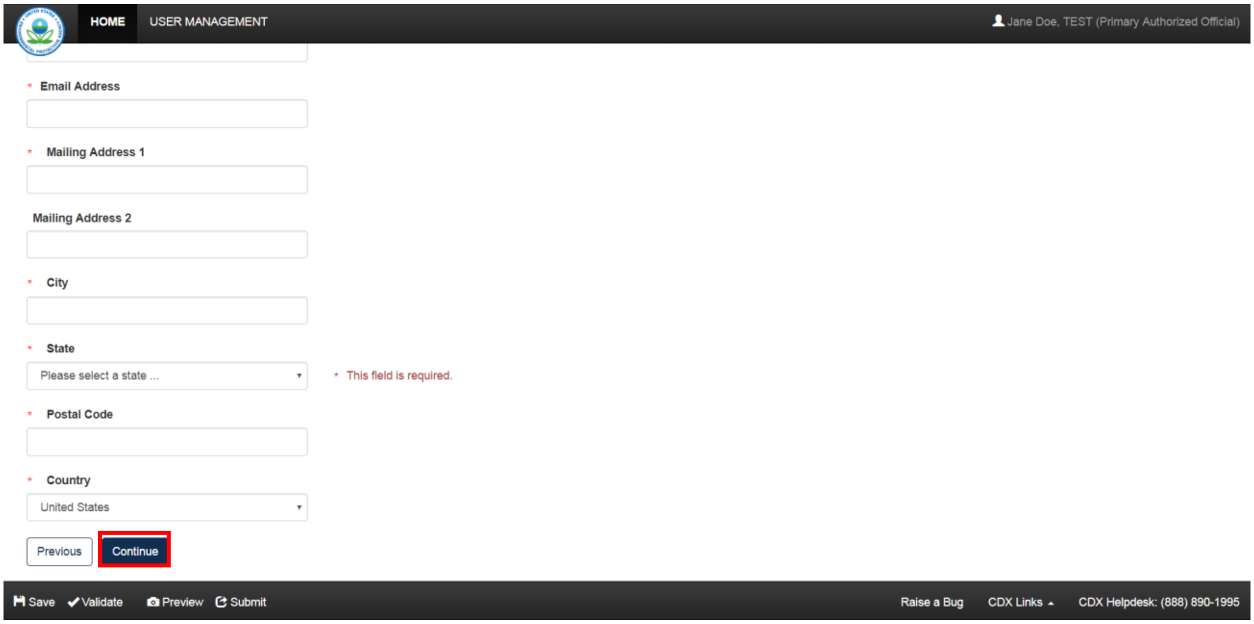


Exhibit 5-6 shows a screen capture of the Withdrawal Request 'Original Submitter Information' screen (Scroll 3):

Exhibit 5-6 Withdrawal Request – Original Submitter Information Screen (Scroll 3)



Navigation: Click the 'Continue' button to navigate to the 'Submitting Official Information' screen.

5.4 Submitting Official Information

You can access the 'Submitting Official Information' screen by clicking the 'Continue' button from the 'Original Submitter Information' screen. You can also access this screen by clicking the 'Submitting Official Information' link within the navigation header.

The information below has been pre-populated from CDX registration. If the information listed is incorrect, please make the appropriate edits to your user information in CDX registration.

- **Submitter is CBI:** Check the 'CBI' checkbox to claim the submitter information as confidential.
- **First Name:** Displays the first name of the submitter.
- **Middle Initial:** Displays the middle initial of the submitter.
- **Last Name:** Displays the last name of the submitter.
- **Company Name:** Displays the company name of the submitter.
- **Phone Number:** Displays the phone number of the submitter.
- **Email Address:** Displays the email address of the submitter.

- **Mailing Address 1:** Displays line 1 of the mailing address of the submitter.
- **City:** Displays the city of the mailing address of the submitter.
- **State:** Displays the state of the mailing address of the submitter.
- **Postal Code:** Displays the postal code of the mailing address of the submitter.
- **Country:** Displays the country of the mailing address of the submitter.
- **This confirmation is required to proceed with the submission process:** Check the legal verification checkbox to begin the submission process; this is required and gets reset when accessing the form.

Exhibit 5-7 shows a screen capture of the Withdrawal Request 'Submitting Official Information' screen (Scroll 1):

Exhibit 5-7 Withdrawal Request – Submitting Official Information Screen (Scroll 1)

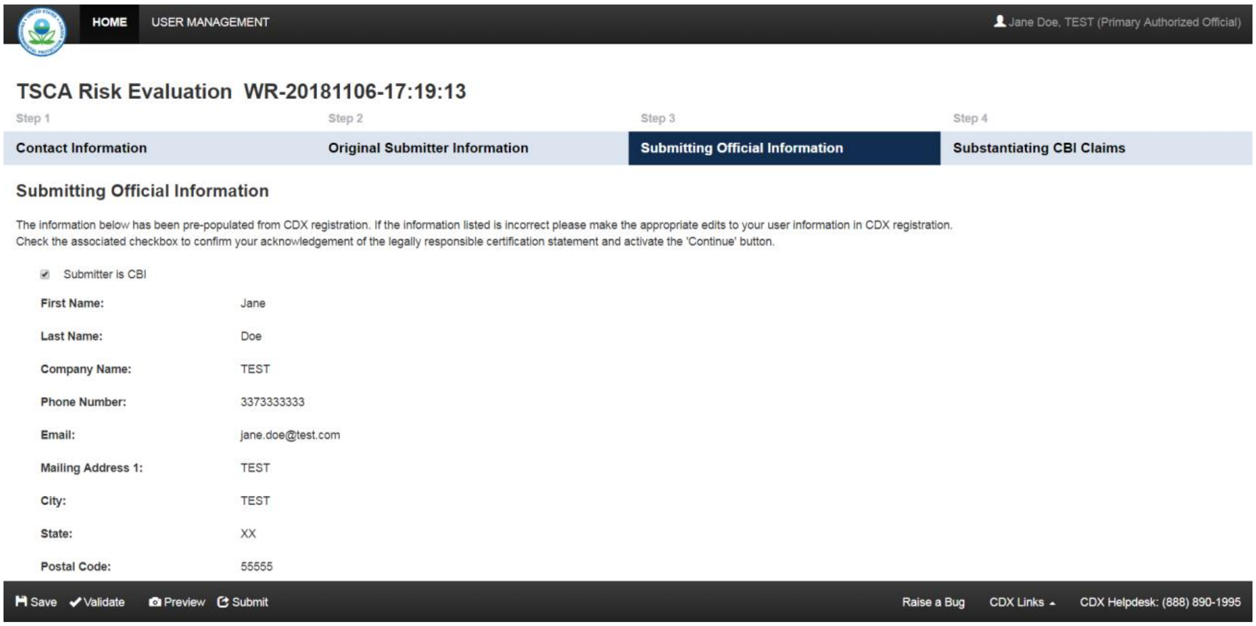
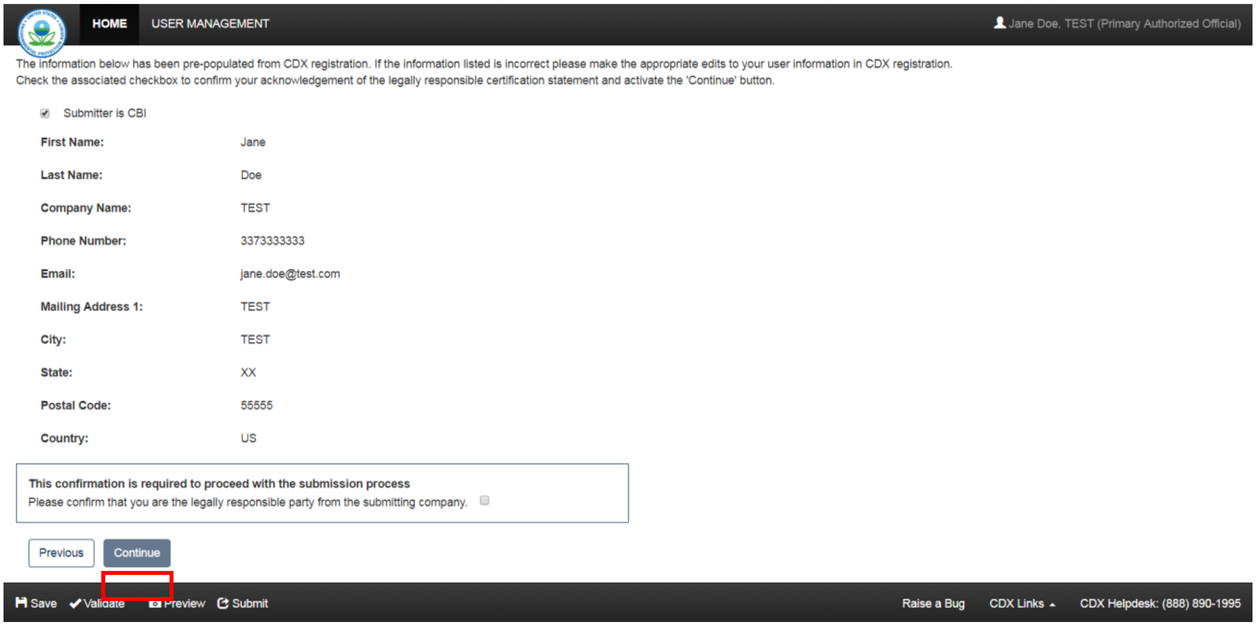


Exhibit 5-8 shows a screen capture of the Withdrawal Request ‘Submitting Official Information’ screen (Scroll 2):

Exhibit 5-8 Withdrawal Request – Submitting Official Information Screen (Scroll 2)



Navigation: If any CBI claims were made, check the legal verification checkbox and click the ‘Continue’ button to navigate to the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen. You can also access this screen by clicking the ‘Substantiating CBI Claims’ link within the navigation header. If no CBI claims were made, check the legal verification checkbox and click the ‘Start Submission Process’ button to begin the submission process.

5.5 Instructions for Substantiating Confidential Business Information (CBI) Claims

You can access the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen by claiming information as CBI within a Withdrawal Request and clicking the ‘Continue’ button from the ‘Submitting Official Information’ screen. You can also access this screen by clicking the ‘Substantiating CBI Claims’ link within the navigation header. This screen will not generate until a CBI claim is made within a form. Information claimed CBI must either be substantiated or claimed exempt pursuant to TSCA Section 14(c)(2) at the time of submission.

For more information regarding CBI substantiation, please refer to **Section 4.10.**

6 Initial Response

The purpose of the Initial Response is for a manufacturer or importer to respond to a preliminary list published by the EPA in the federal register. Consortium leaders who are not the manufacturer or importer do not need to submit this form.

6.1 Create an Initial Response

To create a new Initial Response, navigate to the Risk Evaluation 'Home' screen and select 'Initial Response' from the 'Form Type' drop-down menu. Refer to **Section 3.2** for additional details regarding the Risk Evaluation 'Home' screen.

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

6.2 Contact

You can navigate to the 'Contact' screen by clicking the 'Create' button and creating a new passphrase, or by accessing an Initial Response that is 'In Progress' and entering the passphrase associated with the selected request.

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

- **Submission Alias:** Enter the submission alias. Upon navigating to the screen, the application displays an auto-generated editable submission alias in the following format: <Form Type-YYYYMMDD-HH:MM:SS >. This is a required field.
- **CBI:** Check the 'CBI' checkbox to claim the contact information as confidential.
- **Copy from CDX:** Click the 'Copy from CDX' link to copy CDX registration information.
- **First Name:** Enter the first name of the contact. This is a required field.
- **Last Name:** Enter the last name of the contact. This is a required field.
- **Position:** Enter the job title of the contact.
- **Company Name:** Enter the company name of the contact. This is a required field.
- **Phone Number:** Enter the phone number of the contact. This is a required field.
- **Phone Number Extension:** Enter the extension to the phone number, if applicable.
- **Email Address:** Enter the email address of the contact.
- **Mailing Address 1:** Enter the mailing address of the contact. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the contact, if applicable.

- **City:** Enter the city of the mailing address of the contact. This is a required field.
- **State:** Select the state of the mailing address of the contact. This is a required field if 'United States' is identified as the country.
- **Postal Code:** Enter the postal code of the mailing address of the contact. This is a required field.
- **Country:** Select the country of the mailing address of the contact from the drop-down menu. Selecting a non-US country generates the 'United States Agent' screen. This is a required field.

Exhibit 6-1shows a screen capture of the Initial Response 'Contact' screen (Scroll 1):

Exhibit 6-1 Initial Response – Contact Screen (Scroll 1)

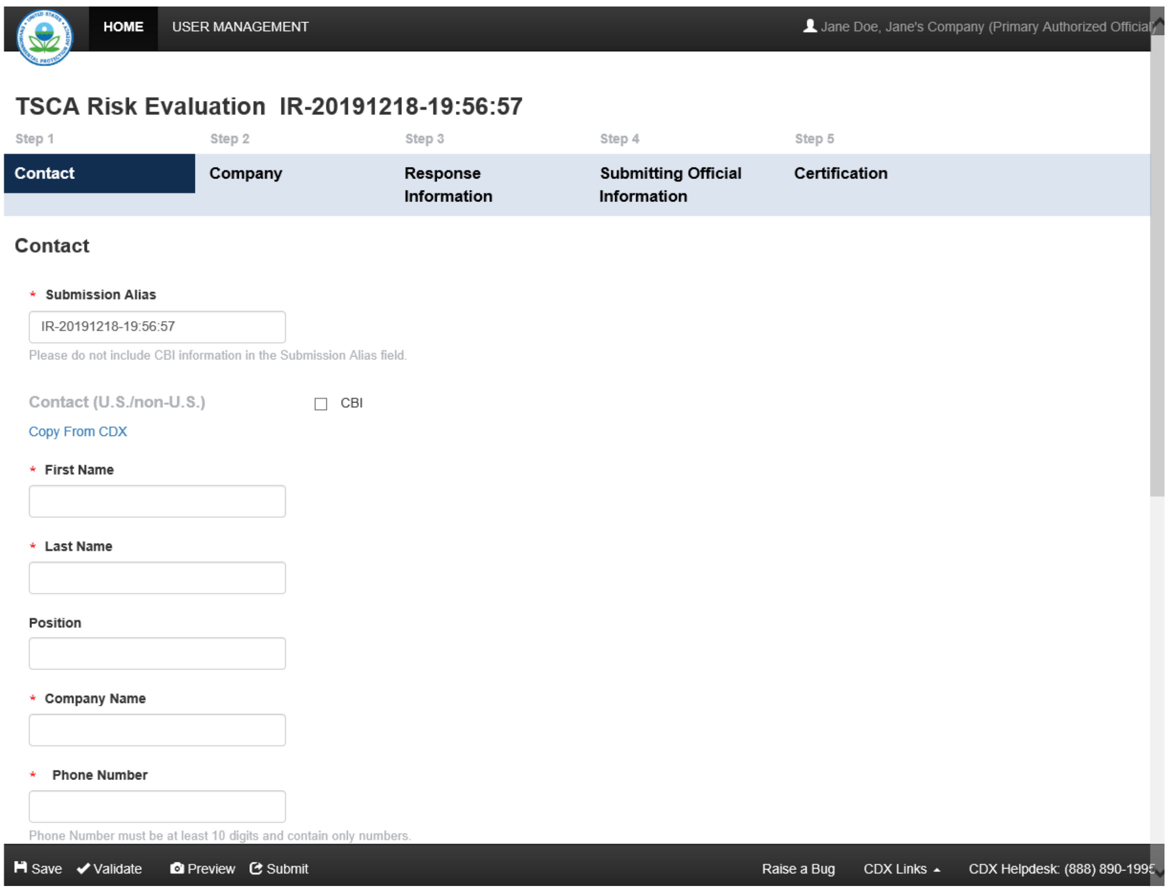
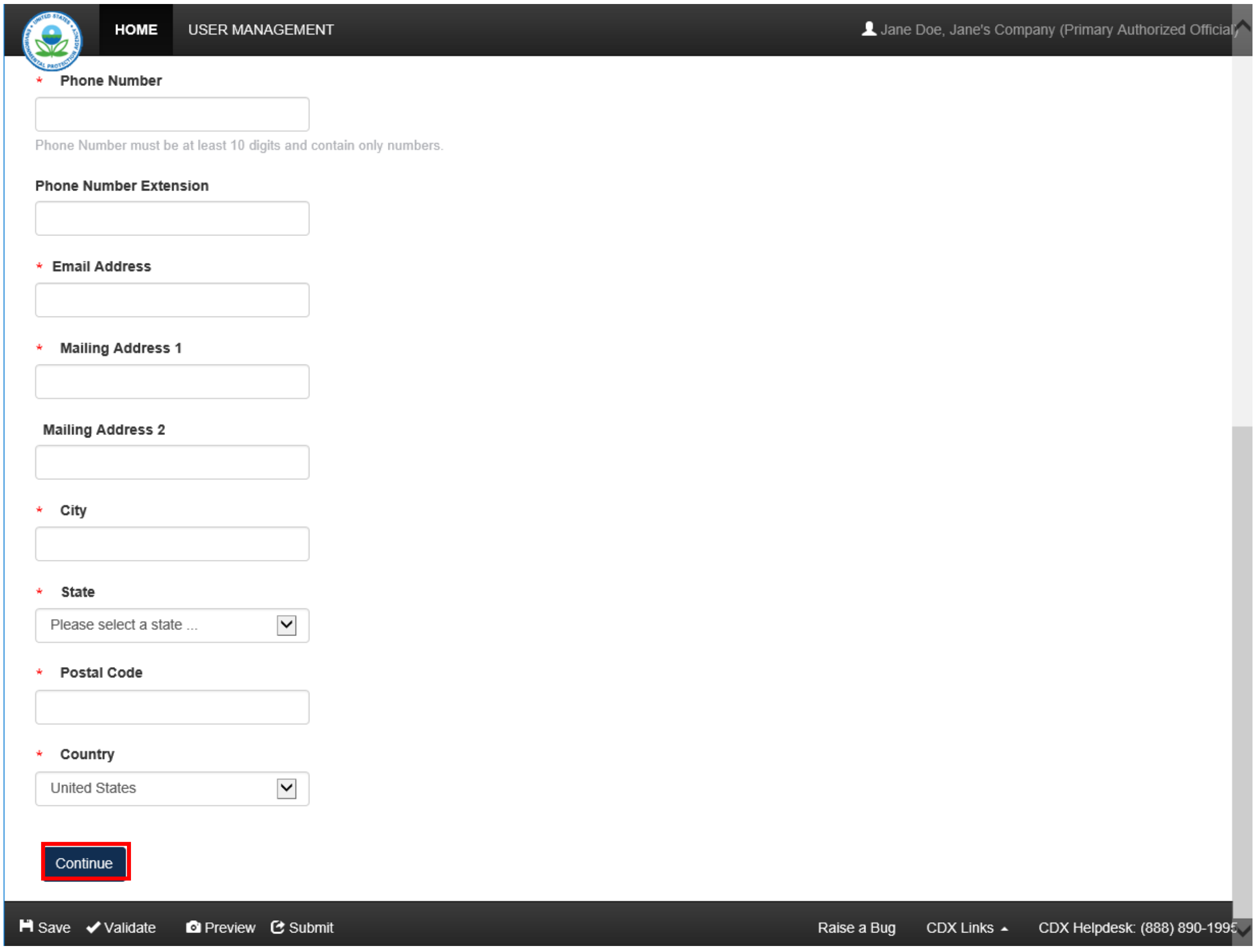


Exhibit 6-2 shows a screen capture of the Initial Response ‘Contact’ screen (Scroll 2):

Exhibit 6-2 Initial Response – Contact Screen (Scroll 2)



Navigation: Click the ‘Continue’ button to navigate to the ‘Chemical Substance or Category’ screen if a U.S. contact is identified and the request is submitted on behalf of the reporting organization. Click the ‘Continue’ button to navigate to the ‘Submitting on Behalf of Consortium’ screen if the request is submitted on behalf of a consortium. You can also access this screen by clicking the ‘Chemical Substance or Category’ or ‘Submitting on Behalf of Consortium’ link, respectively, within the navigation header. Click the ‘Continue’ button to navigate to the ‘United States Agent’ screen if a non-U.S. contact is identified. You can also access this screen by clicking the ‘U.S. Agent’ link within the navigation header.

6.3 United States Agent

You can navigate to the 'United States Agent' screen by identifying a non-U.S. contact and clicking the 'Continue' button on the 'Contact' screen.

The 'United States Agent' screen provides fields to input identifying information for a U.S. agent.

- **CBI:** Check the 'CBI' checkbox to claim the agent information as confidential.
- **First Name:** Enter the first name of the agent. This is a required field.
- **Last Name:** Enter the last name of the agent. This is a required field.
- **Position:** Enter the job title of the agent.
- **Company Name:** Enter the company name of the agent. This is a required field.
- **Phone Number:** Enter the phone number of the agent. This is a required field.
- **Phone Number Extension:** Enter the extension to the phone number, if applicable.
- **Email Address:** Enter the email address of the agent. This is a required field.
- **Mailing Address 1:** Enter the mailing address of the agent. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the agent, if applicable.
- **City:** Enter the city of the mailing address of the agent. This is a required field.
- **State:** Select the state of the mailing address of the agent. This is a required field.
- **Postal Code:** Enter the postal code of the mailing address of the agent. This is a required field.
- **Country:** Displays 'United States.'

Exhibit 6-3 shows a screen capture of the Initial Response ‘United States Agent’ screen (Scroll 1):

Exhibit 6-3: Initial Response – United States Agent Screen (Scroll 1)

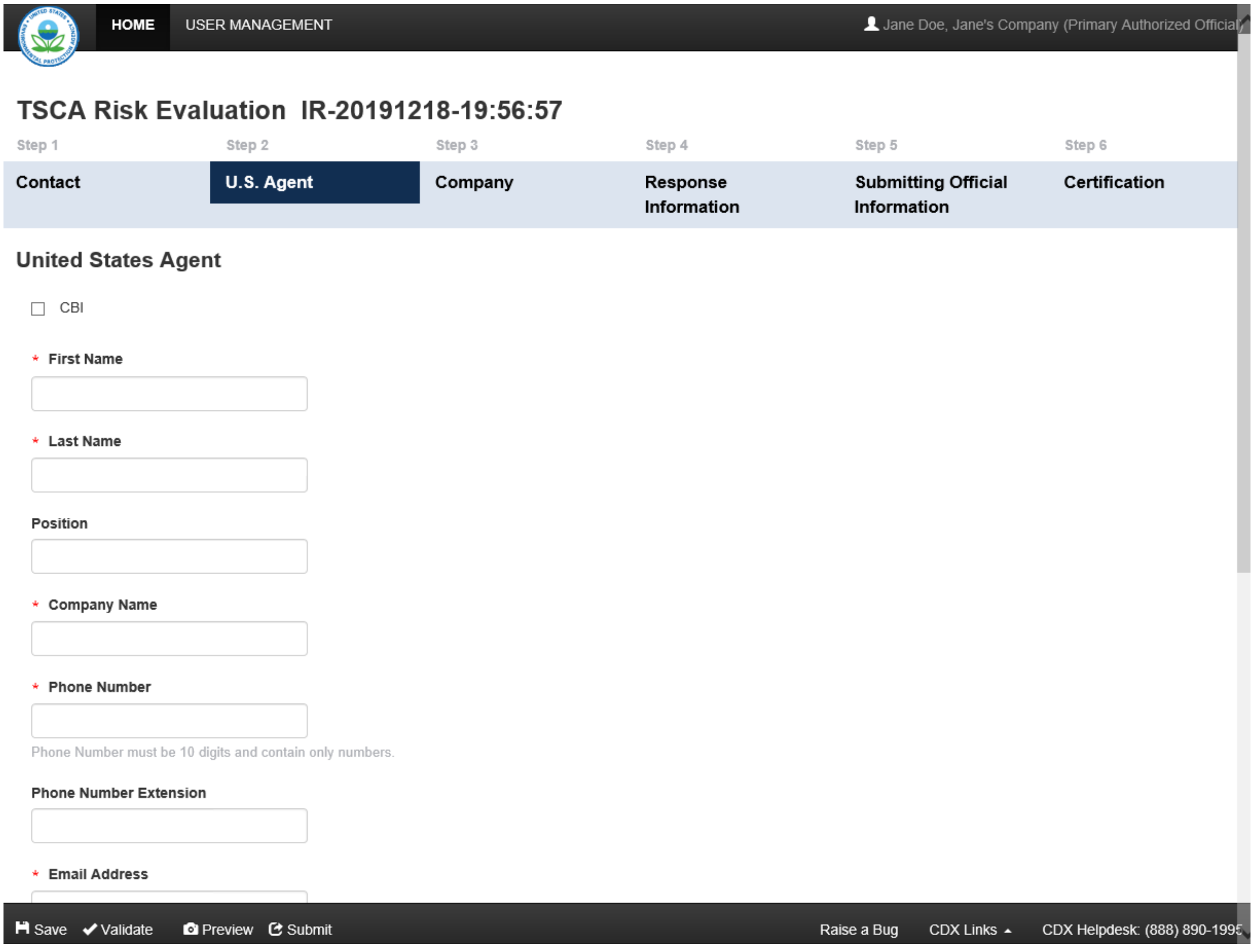
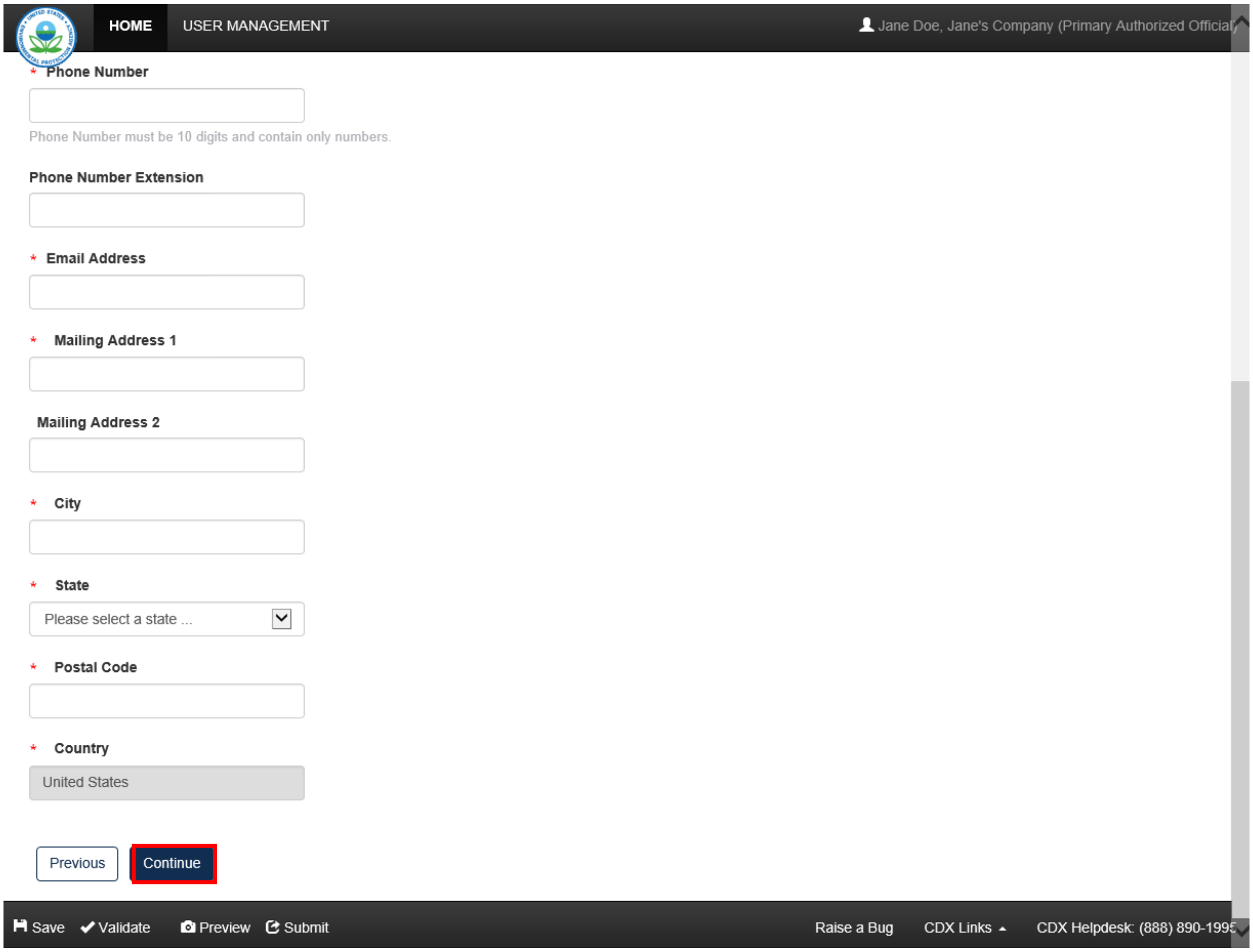


Exhibit 6-4shows a screen capture of the Initial Response ‘United States Agent’ screen (Scroll 2):

Exhibit 6-4 Initial Response – United States Agent Screen (Scroll 2)



Navigation: Click the ‘Continue’ button to navigate to the ‘Company’ screen. You can also access this screen by clicking the ‘Company’ link within the navigation header.

6.4 Company

You can access the ‘Company’ screen by clicking the ‘Continue’ button from the ‘Contact’ screen if identifying a U.S. contact. If identifying a non-U.S. contact within the ‘Contact’ screen, you can access this screen by clicking the ‘Continue’ button from the ‘United States Agent’ screen. You can also access this screen by clicking the ‘Company’ link within the navigation header.

The ‘Company’ screen displays the following fields and columns of information:

- **Company Name:** Enter the name of the company of the contact. This is a required field.
- **CBI:** Check the 'CBI' checkbox to claim the company information as confidential.
- **Mailing Address 1:** Enter the mailing address of the company. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the company, if applicable.
- **City:** Enter the city of the mailing address of the company. This is a required field.
- **State:** Select the state of the mailing address of the company. This is a required field if 'United States' is identified as the country.
- **Postal Code:** Enter the postal code of the mailing address of the company. This is a required field.
- **Country:** Displays 'United States.'
- **Company Size Certification:** Select a radio button option for the company size certification. See **Section 4.3** for the fee structure. See **Section 4.3.1**for Small Business Concern definition. This is required.
- **Will you be joining a consortium?:** Select a radio button option. This is required.

Exhibit 6-5shows a screen capture of the Initial Response ‘Company’ screen (Scroll 1):

Exhibit 6-5 Initial Response – Company Screen (Scroll 1)

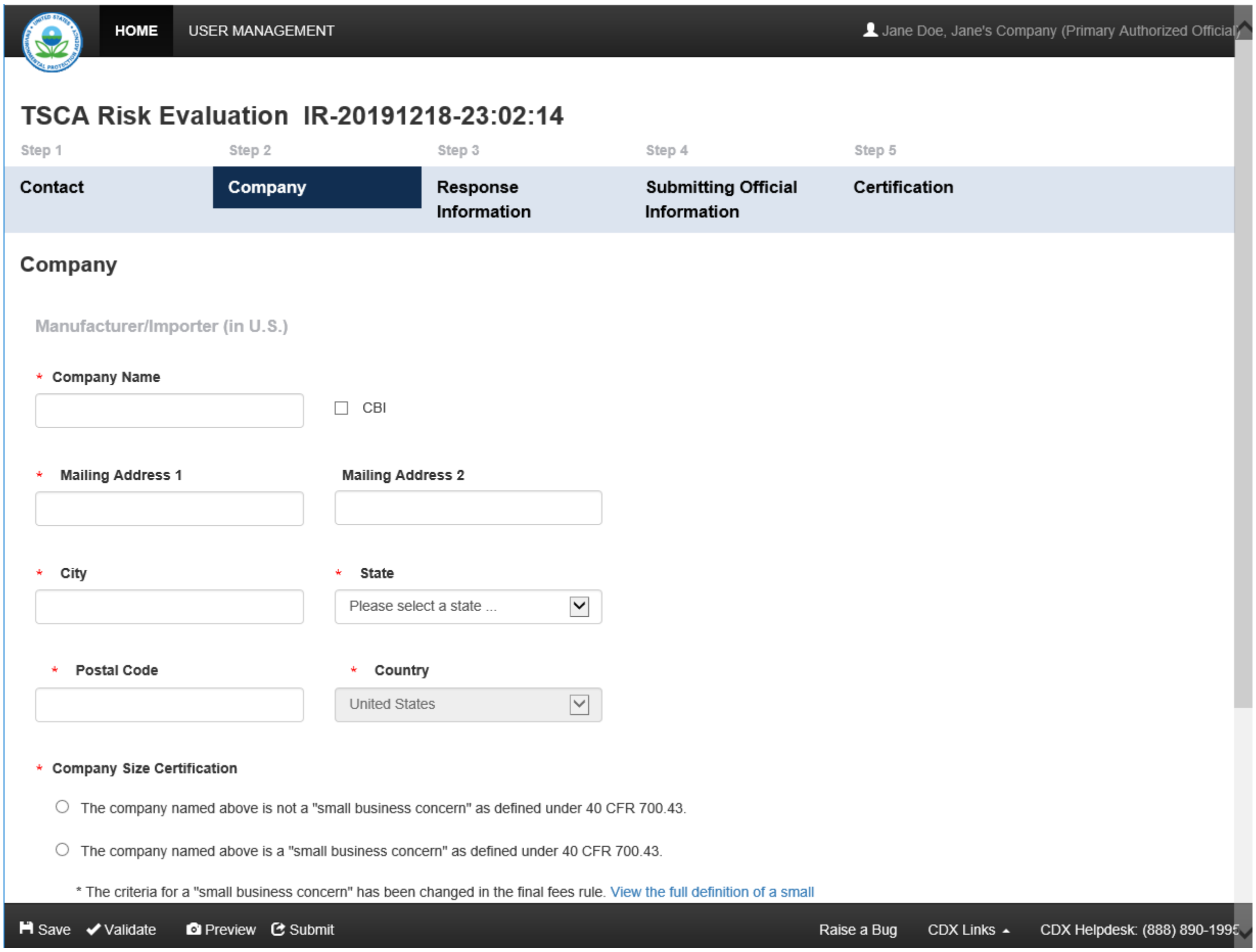
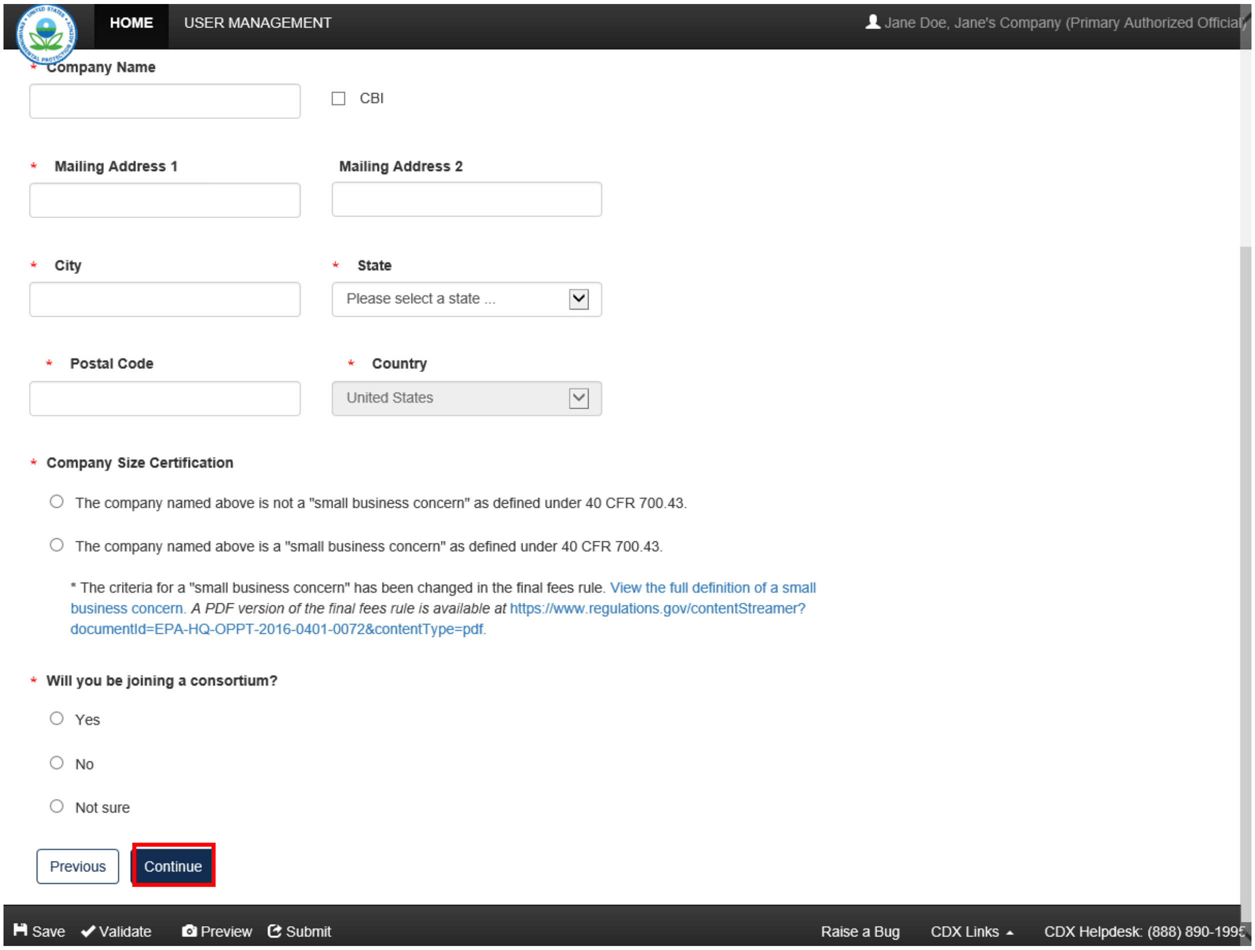


Exhibit 6-6 shows a screen capture of the Initial Response ‘Company’ screen (Scroll 2):

Exhibit 6-6 Initial Response – Company Screen (Scroll 2)



Navigation: Click the ‘Continue’ button to navigate to the ‘Response Information’ screen. You can also access this screen by clicking the ‘Response Information’ link within the navigation header.

6.5 Response Information

You can access the ‘Response Information’ screen by clicking the ‘Continue’ button from the ‘Company’ screen if identifying a U.S. contact. You can also access this screen by clicking the ‘Response Information’ link within the navigation header.

The ‘Response Information’ screen displays the following fields and columns of information:

- **Risk Evaluation Activity:** Select the Risk Evaluation Activity you are responding to in the drop-down. This is required.
- **Response Options:** Select one response option. Select 'Self-Identification' if you are representing a company that is a manufacturer or importer of the chemical substance subject to the Risk Evaluation Activity. Select 'Certification of No Manufacture' if you are representing a company that was included in error on EPA's Preliminary List of responsible fee payers for the Risk Evaluation Activity. Select 'Certification of Cessation' if you are representing a company that was manufacturer or importer of the chemical substance subject to this Risk Evaluation Activity. A selection is required.
- **Additional Information and Attachments (Only if Requested by Agency):** Use this section to submit additional information regarding your initial response.
- **File Name:** Displays the file name of the uploaded document.
- **File Description:** Displays the description of the uploaded document.
- **Page Count:** Displays the number of pages in the uploaded document.
- **Date:** Displays the date that the uploaded document was attached.
- **CBI:** Displays a 'Y' or an 'N' to indicate the confidentiality status of the uploaded document. **Action:** Click the 'Delete' icon (**)** to remove the uploaded document.
- **Attach Document:** Click the 'Attach Document' link to generate the 'Attach Document' window.

Exhibit 6-7 shows a screen capture of the 'Response Information' screen (Scroll 1):

Exhibit 6-7 Response Information – Screen (Scroll 1)

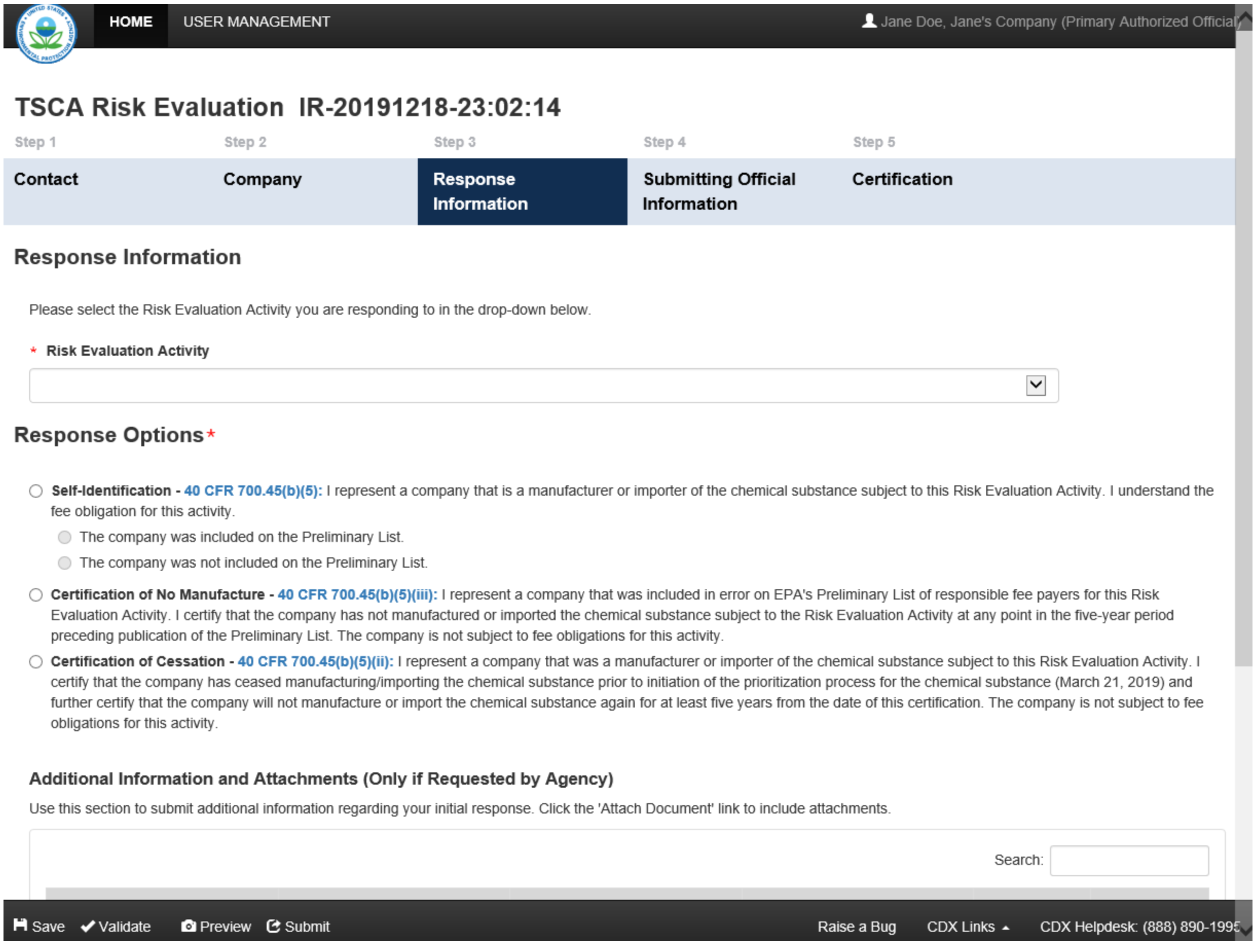
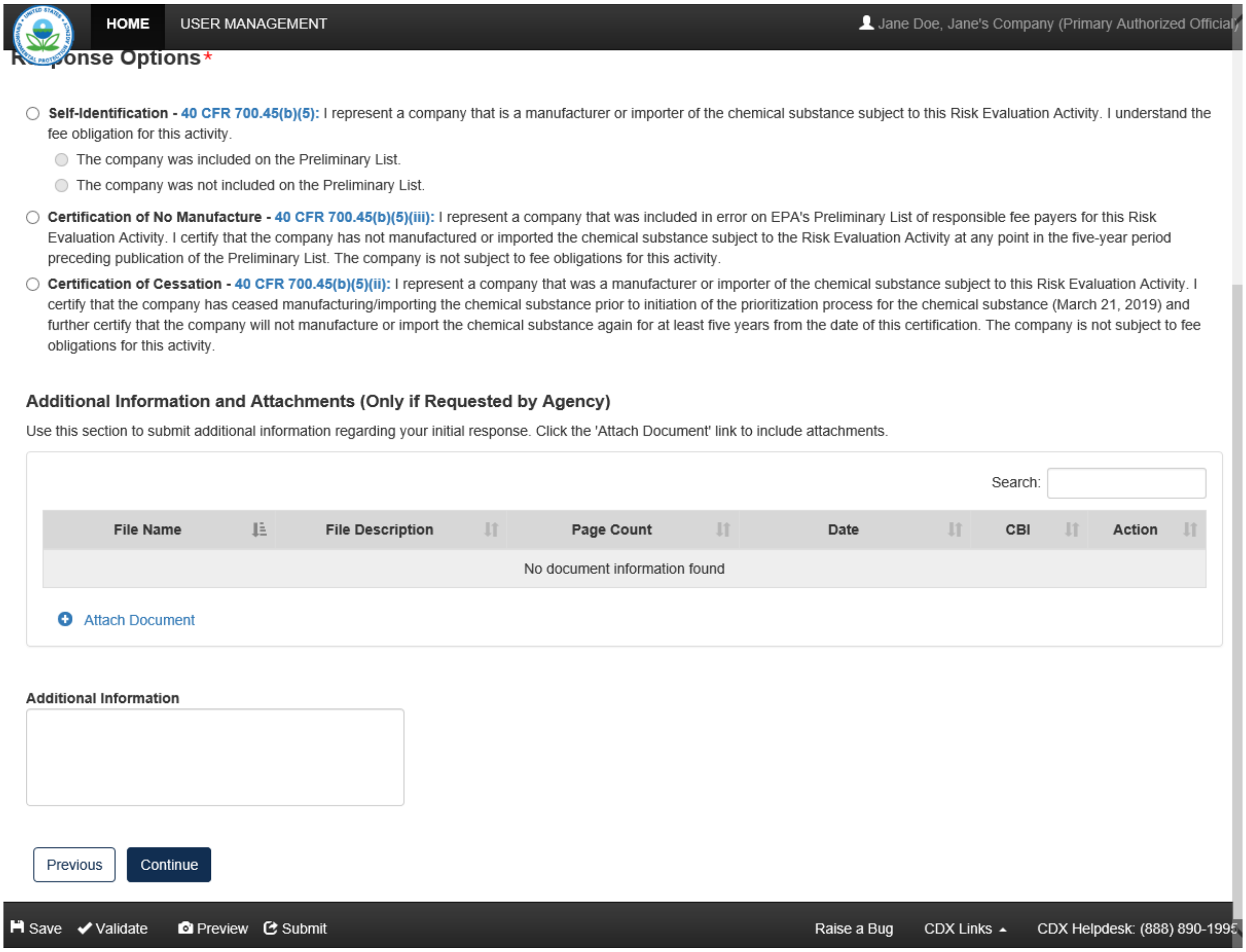


Exhibit 6-8 shows a screen capture of the ‘Response Information’ screen (Scroll 2):

Exhibit 6-8 Initial Response – Response Information Screen (Scroll 2)



6.6 Submitting Official Information

You can access the ‘Submitting Official Information’ screen by clicking the ‘Continue’ button from the ‘Response Information’ screen if the request is submitted on behalf of the reporting organization. You can also access this screen by clicking the ‘Submitting Official Information’ link within the navigation header.

The information below has been pre-populated from CDX registration. If the information listed is incorrect please make the appropriate edits to your user information in CDX registration.

- **Submitter is CBI:** Check the ‘CBI’ checkbox to claim the submitter information as confidential.
- **First Name:** Displays the first name of the submitter.

- **Middle Initial:** Displays the middle initial of the submitter.
- **Last Name:** Displays the last name of the submitter.
- **Company Name:** Displays the company name of the submitter.
- **Phone Number:** Displays the phone number of the submitter.
- **Email Address:** Displays the email address of the submitter.
- **Mailing Address 1:** Displays line 1 of the mailing address of the submitter.
- **City:** Displays the city of the mailing address of the submitter.
- **State:** Displays the state of the mailing address of the submitter.
- **Postal Code:** Displays the postal code of the mailing address of the submitter.
- **Country:** Displays the country of the mailing address of the submitter.
- **This confirmation is required to proceed with the submission process:** Check the legal verification checkbox to begin the submission process; this is required and gets reset when accessing the form.

Exhibit 6-9 shows a screen capture of the Initial Response ‘Submitting Official Information’ screen (Scroll 1):

Exhibit 6-9 Initial Response – Submitting Official Information Screen (Scroll 1)

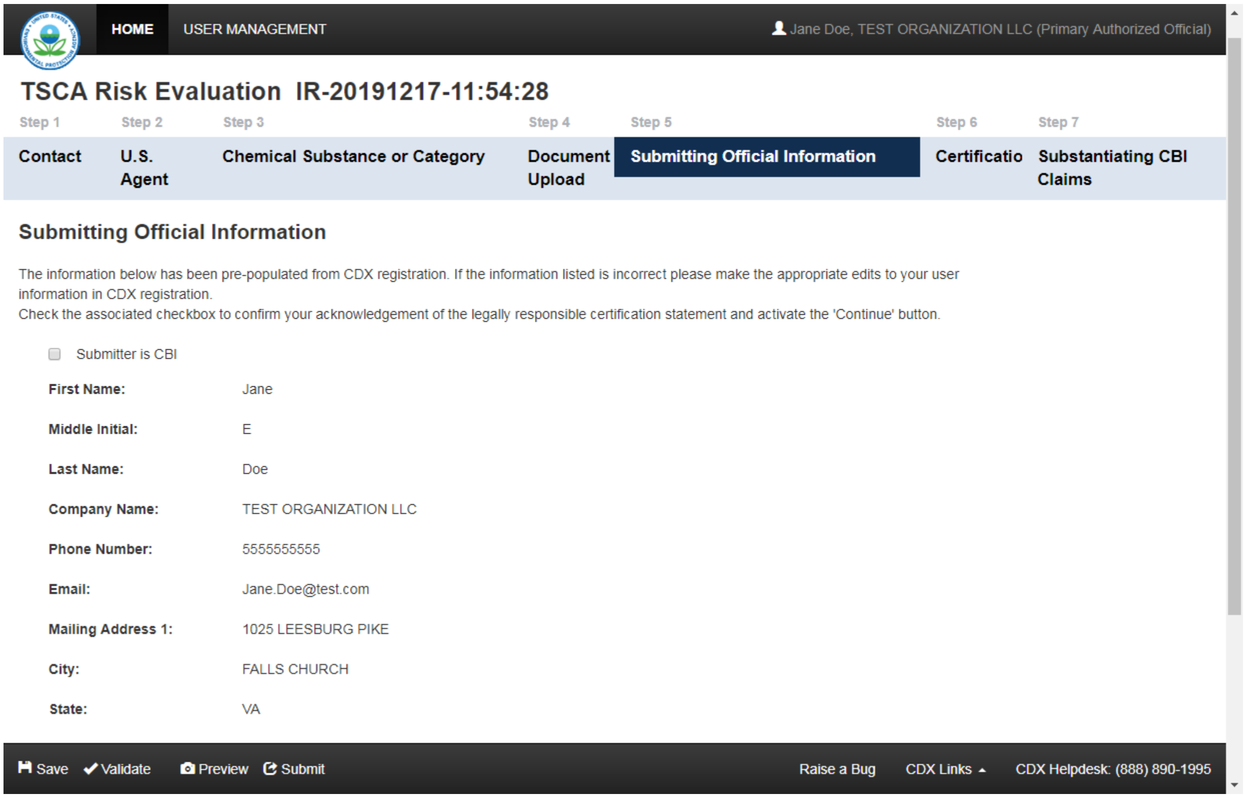
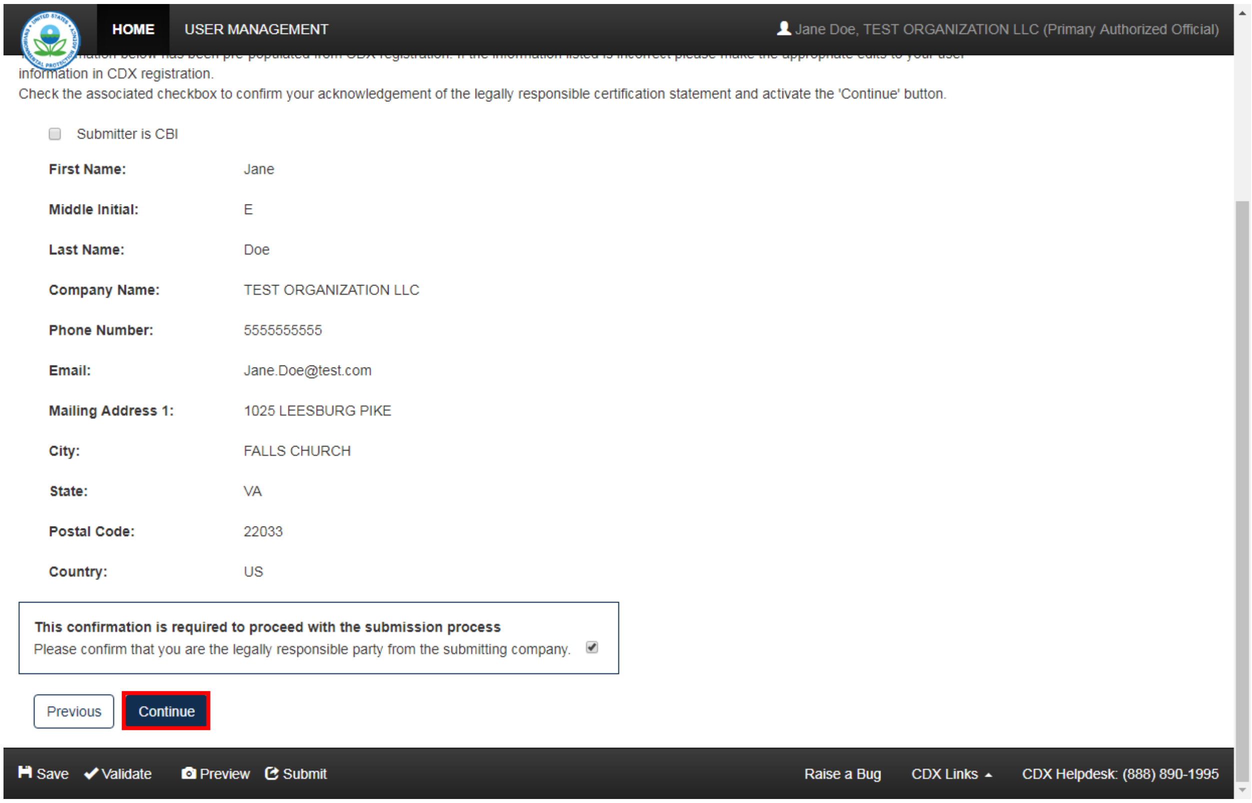


Exhibit 6-10 shows a screen capture of the Initial Response ‘Submitting Official Information’ screen (Scroll 2):

Exhibit 6-10 Initial Response – Submitting Official Information Screen (Scroll 2)



Navigation: Click the ‘Continue’ button to navigate to the ‘Submission of Referenced Information’ screen. You can also access this screen by clicking the ‘Certification’ link within the navigation header.

6.7 Submission of Referenced Information

You can access the ‘Submission of Referenced Information’ screen by clicking the ‘Continue’ button from the ‘Submitting Official Information’ screen. You can also access this screen by clicking the ‘Certification’ link within the navigation header.

The purpose of the ‘Submission of Referenced Information’ screen is for users to commit to providing EPA referenced information contained in this Risk Evaluation request.

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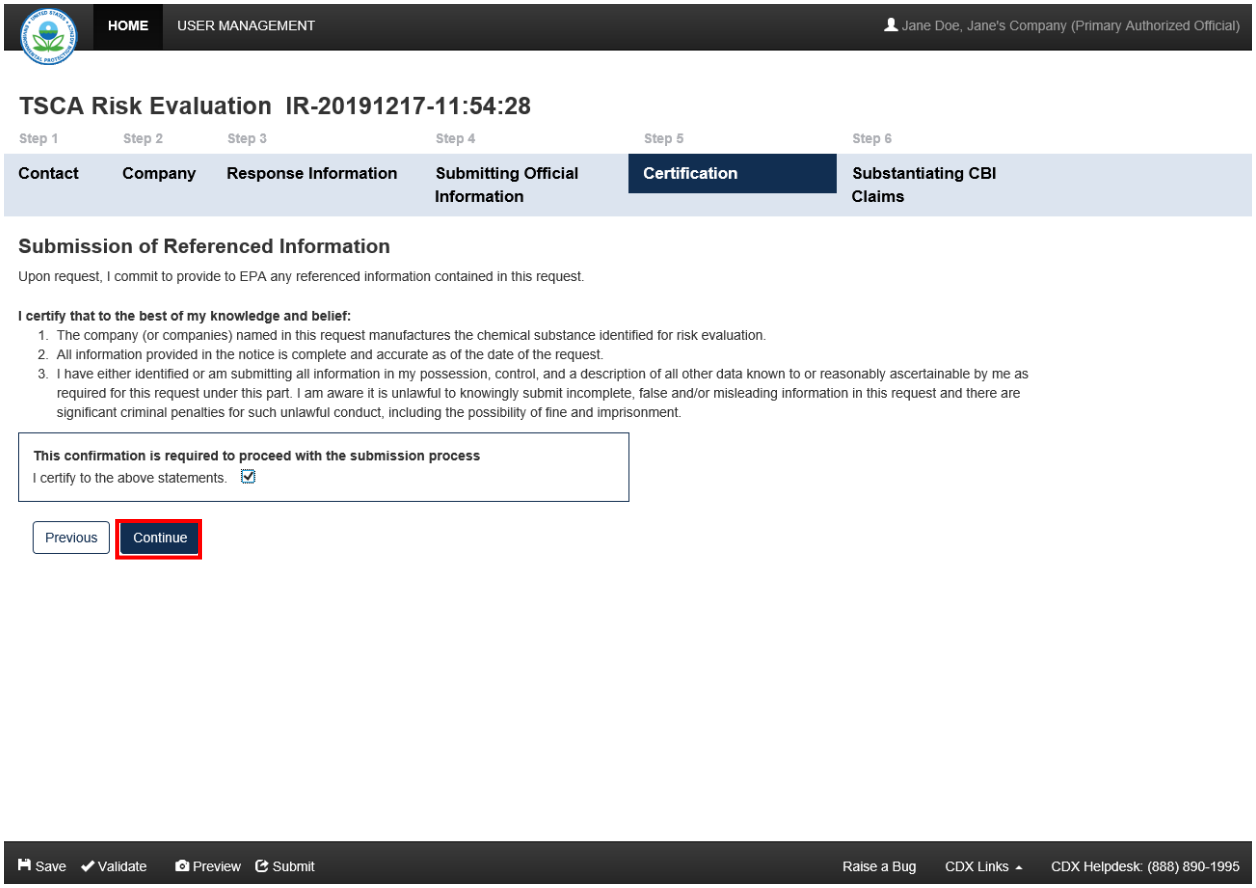
Exhibit 6-11 shows a screen capture of the Initial Response ‘Submission of Referenced Information’ screen:

Exhibit 6-11 Initial Response – Submission of Referenced Information Screen



Navigation: If any CBI claims were made, check the certification checkbox and click the 'Continue' button to navigate to the 'Instructions for Substantiating Confidential Business Information (CBI) Claims' screen. You can also access this screen by clicking the 'Substantiating CBI Claims' link within the navigation header. If no CBI claims were made, check the certification checkbox and click the 'Start Submission Process' button to initiate the submission process.

6.8 Instructions for Substantiating Confidential Business Information (CBI) Claims

EPA modified the electronic reporting applications for TSCA submissions to accept CBI substantiations for CBI claims made during the creation of electronic submissions. Other than information exempt from substantiation under TSCA Section 14(c)(2), users who wish to assert CBI claims for data within a submission must substantiate those claims at the time of submission as required by TSCA Section 14(c)(3).

You can access the 'Instructions for Substantiating Confidential Business Information (CBI) Claims' screen by claiming information as CBI within a form and clicking the 'Continue' button from the ‘Submission of Referenced Information’ screen. You can also access this screen by clicking the ‘Substantiating CBI Claims’ link within the navigation header. This screen will not generate until a CBI claim is made within a submission. Information claimed CBI must either be substantiated or claimed exempt pursuant to TSCA Section 14(c)(2) at the time of submission.

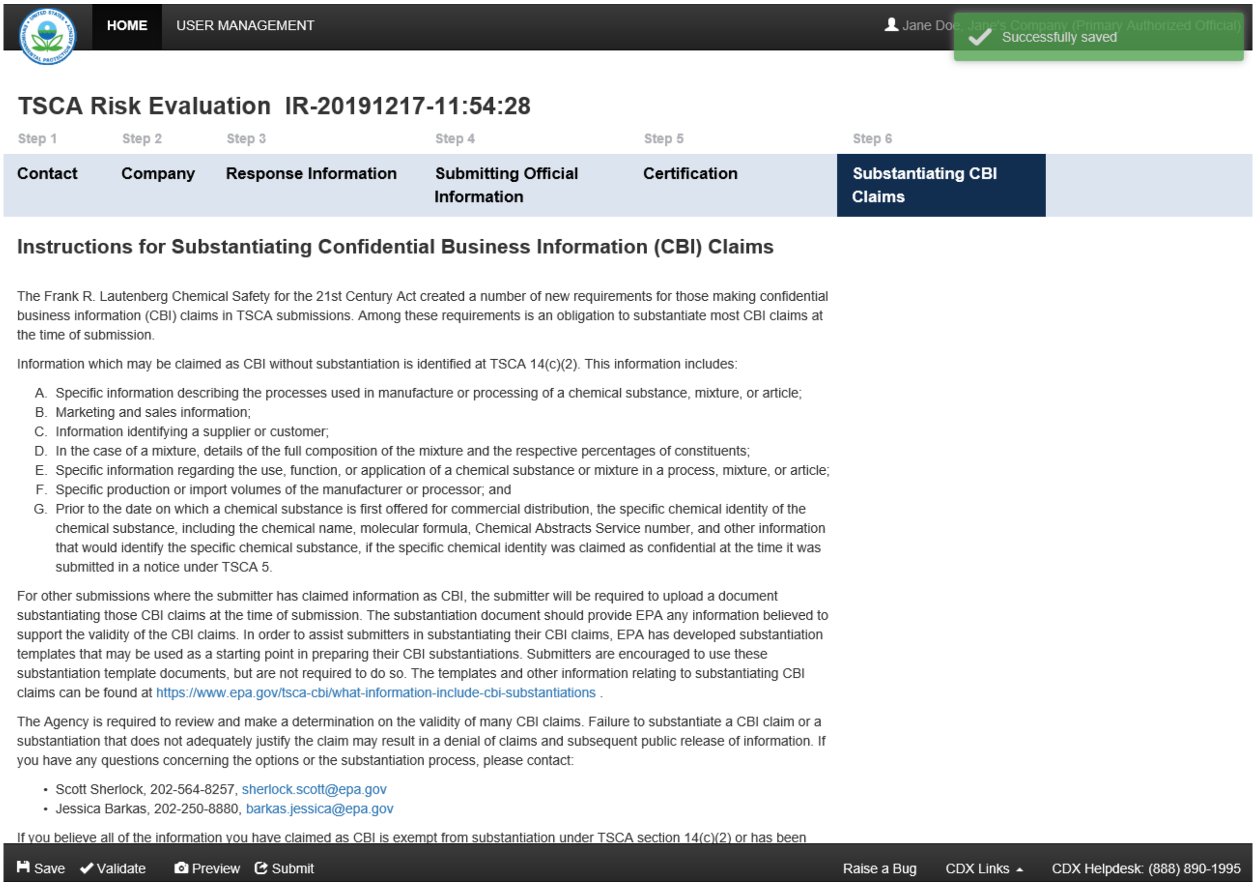
To substantiate a CBI claim, upload documentation asserting your claim(s) on the ‘Instructions for Substantiating CBI Claims’ screen within the form. You may also opt-out of substantiation on the ‘Instructions for Substantiating CBI Claims’ screen if, for example, you believe your CBI claim is exempt under TSCA Section 14(c)(2). Common exemption reasons can be found at https://www.epa.gov/tsca-cbi/what-information-include-cbi-substantiations. To opt-out of substantiation at the time of submission, all CBI claims within a submission must be exempt.

- **Substantiation Opt-Out:** Check this checkbox to opt out of providing CBI substantiation. You will be required to provide reasoning if you choose to opt out.
- **Substantiation Opt-Out Reason:** Enter reasoning for opting out of CBI substantiation. This is a required field.
- **Attach Document for CBI Substantiation:** Click the ‘Attach Document for CBI Substantiation’ link to generate the ‘Attach Documents for CBI Substantiation’ pop-up window.

If you are unfamiliar with substantiating CBI claims or require assistance preparing substantiation documents, EPA offers a link to templates and other information for substantiating CBI claims on the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen. It is suggested that you right-click the link and open in a new tab or new window so you do not leave your submission as this may affect your saved data.

Exhibit 6-12 shows a screen capture of the 'Instructions for Substantiating Confidential Business Information (CBI) Claims' screen (Scroll 1):

Exhibit 6-12 Initial Response – Instructions for Substantiating Confidential Business Information (CBI) Claims Screen (Scroll 1)



HOME USER MANAGEMENT Jane Doe, Jane's Company (Primary Authorized Official)

Successfully saved

TSCA Risk Evaluation IR-20191217-11:54:28

Step 1 Contact | Step 2 Company | Step 3 Response Information | Step 4 Submitting Official Information | Step 5 Certification | Step 6 Substantiating CBI Claims

Instructions for Substantiating Confidential Business Information (CBI) Claims

The Frank R. Lautenberg Chemical Safety for the 21st Century Act created a number of new requirements for those making confidential business information (CBI) claims in TSCA submissions. Among these requirements is an obligation to substantiate most CBI claims at the time of submission.

Information which may be claimed as CBI without substantiation is identified at TSCA 14(c)(2). This information includes:

A. Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article;
B. Marketing and sales information;
C. Information identifying a supplier or customer;
D. In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents;
E. Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article;
F. Specific production or import volumes of the manufacturer or processor; and
G. Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under TSCA 5.

For other submissions where the submitter has claimed information as CBI, the submitter will be required to upload a document substantiating those CBI claims at the time of submission. The substantiation document should provide EPA any information believed to support the validity of the CBI claims. In order to assist submitters in substantiating their CBI claims, EPA has developed substantiation templates that may be used as a starting point in preparing their CBI substantiations. Submitters are encouraged to use these substantiation template documents, but are not required to do so. The templates and other information relating to substantiating CBI claims can be found at https://www.epa.gov/tsca-cbi/what-information-include-cbi-substantiations .

The Agency is required to review and make a determination on the validity of many CBI claims. Failure to substantiate a CBI claim or a substantiation that does not adequately justify the claim may result in a denial of claims and subsequent public release of information. If you have any questions concerning the options or the substantiation process, please contact:

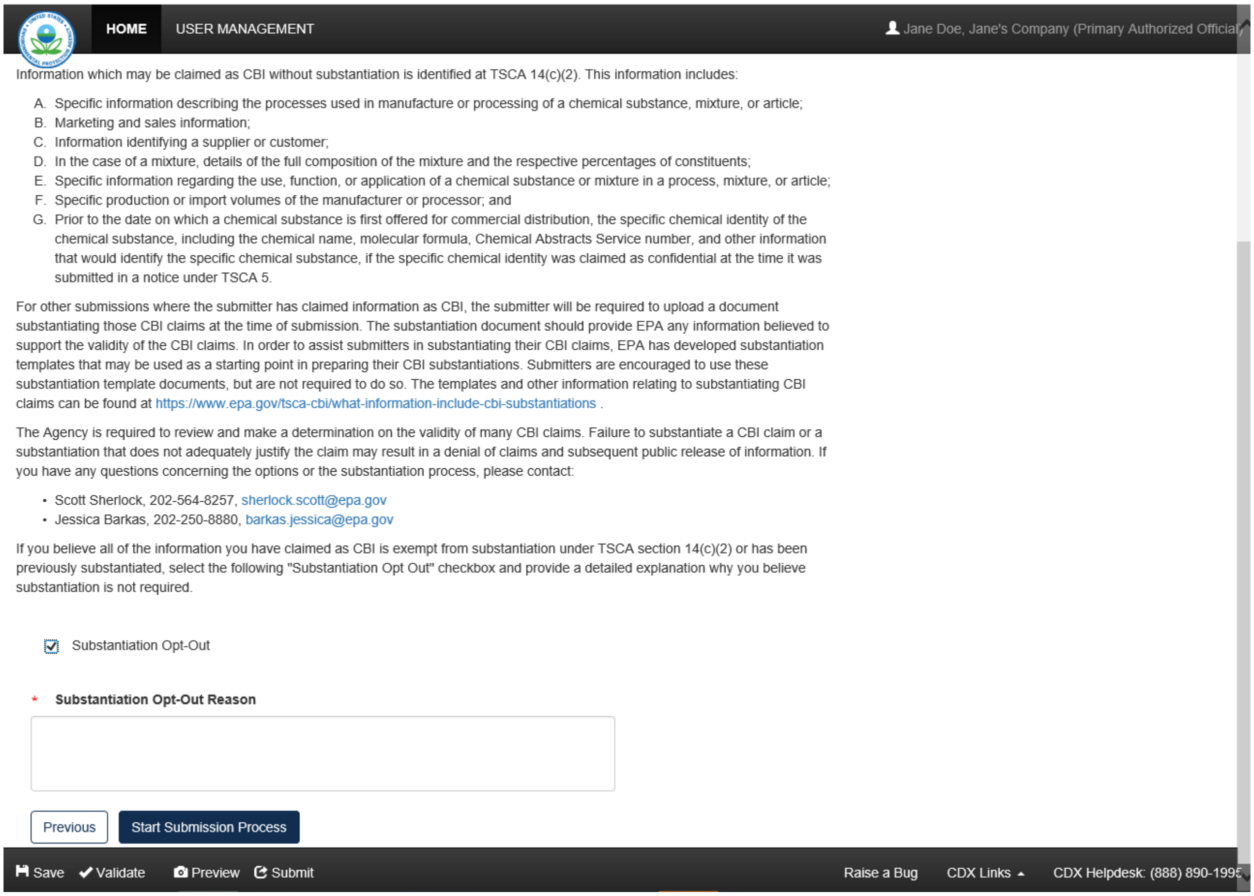
- Scott Sherlock, 202-564-8257, sherlock.scott@epa.gov
- Jessica Barkas, 202-250-8880, barkas.jessica@epa.gov

If you believe all of the information you have claimed as CBI is exempt from substantiation under TSCA section 14(c)(2) or has been

Save Validate Preview Submit Raise a Bug CDX Links CDX Helpdesk: (888) 890-1995

Exhibit 6-13 shows a screen capture of the 'Instructions for Substantiating Confidential Business Information (CBI) Claims' screen (Scroll 2).

Exhibit 6-13 Initial Response – Instructions for Substantiating Confidential Business Information (CBI) Claims Screen (Scroll 2)


HOME USER MANAGEMENT Jane Doe, Jane's Company (Primary Authorized Official)

Information which may be claimed as CBI without substantiation is identified at TSCA 14(c)(2). This information includes:

A. Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article;
B. Marketing and sales information;
C. Information identifying a supplier or customer;
D. In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents;
E. Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article;
F. Specific production or import volumes of the manufacturer or processor; and
G. Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under TSCA 5.

For other submissions where the submitter has claimed information as CBI, the submitter will be required to upload a document substantiating those CBI claims at the time of submission. The substantiation document should provide EPA any information believed to support the validity of the CBI claims. In order to assist submitters in substantiating their CBI claims, EPA has developed substantiation templates that may be used as a starting point in preparing their CBI substantiations. Submitters are encouraged to use these substantiation template documents, but are not required to do so. The templates and other information relating to substantiating CBI claims can be found at https://www.epa.gov/tsca-cbi/what-information-include-cbi-substantiations .

The Agency is required to review and make a determination on the validity of many CBI claims. Failure to substantiate a CBI claim or a substantiation that does not adequately justify the claim may result in a denial of claims and subsequent public release of information. If you have any questions concerning the options or the substantiation process, please contact:

- Scott Sherlock, 202-564-8257, sherlock.scott@epa.gov
- Jessica Barkas, 202-250-8880, barkas.jessica@epa.gov

If you believe all of the information you have claimed as CBI is exempt from substantiation under TSCA section 14(c)(2) or has been previously substantiated, select the following "Substantiation Opt Out" checkbox and provide a detailed explanation why you believe substantiation is not required.

Substantiation Opt-Out

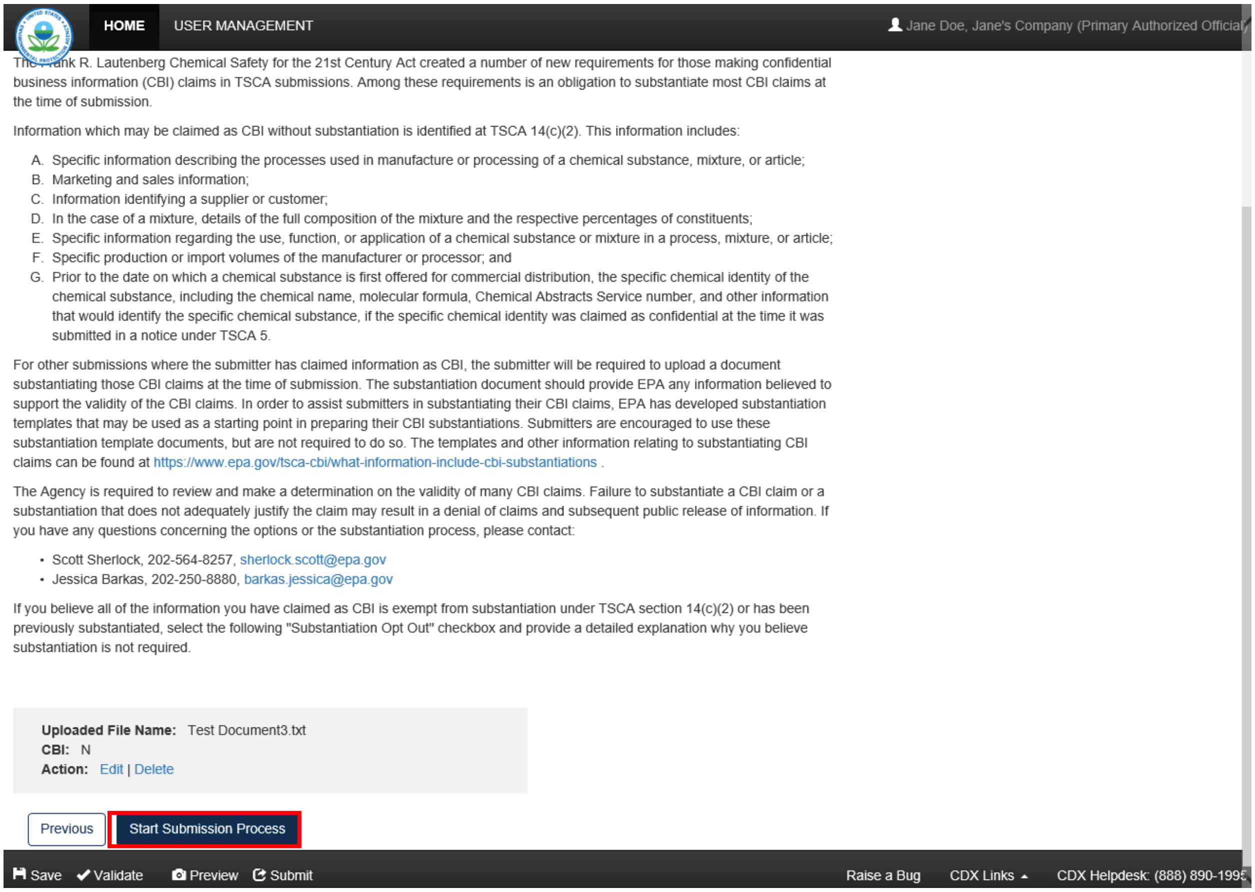
* Substantiation Opt-Out Reason

Previous Start Submission Process

Save Validate Preview Submit Raise a Bug CDX Links CDX Helpdesk: (888) 890-1995

Exhibit 6-14 shows a screen capture of the 'Instructions for Substantiating Confidential Business Information (CBI) Claims' screen (Scroll 3):

Exhibit 6-14 Initial Response – Instructions for Substantiating Confidential Business Information (CBI) Claims Screen (Scroll 3)



Navigation: Click the 'Start Submission Process' button to begin the submission process.

6.9 Attach Documents for CBI Substantiation

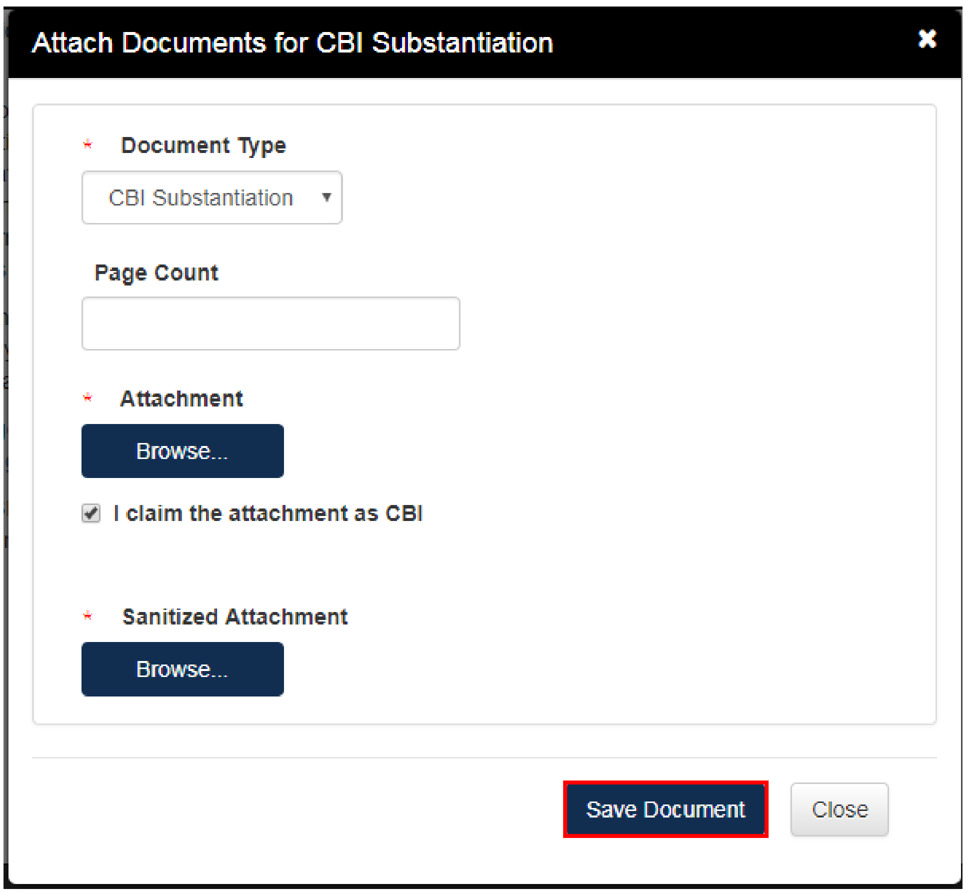
You can access the 'Attach Documents for CBI Substantiation' window by clicking the 'Attach Document for CBI Substantiation' link within the 'Instructions for Substantiating Confidential Business Information (CBI) Claims' screen.

- **Document Type:** 'CBI Substantiation' is stored in the 'Document Type' drop-down menu.
- **Page Count:** Enter the number of pages in the attached document.
- **Attachment:** Click the 'Browse' button to search for and select a document to attach. This is a required field.

- **I claim the attachment as CBI:** Check the 'I claim the attachment as CBI' checkbox to claim the document as confidential.
- **Sanitized Attachment:** Click the 'Browse' button to search for and select a sanitized document to attach. This is a required field, if it displays.
- **Save Document:** Click the 'Save Document' button to save the uploaded CBI substantiation document(s).
- **Close:** Click the 'Close' button to close the 'Attach Documents for CBI Substantiation' window without saving any uploaded attachment information.

Exhibit 6-15 shows a screen capture of the 'Attach Documents for CBI Substantiation' window:

Exhibit 6-15 Attach Documents for CBI Substantiation Window



Navigation: Click the 'Save Document' button to upload the substantiation document and navigate back to the 'Instructions for Substantiating Confidential Business Information (CBI) Claims' screen.

7 EPA Initiated Risk Evaluation Request

The purpose of the EPA Initiated Risk Evaluation request is to determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. Select this form type if you are manufacturer/importer and/or consortium leader responding to the finalized Risk Evaluation Request published by EPA in the Federal Register.

7.1 Create a EPA Initiated Risk Evaluation

To create a new EPA Initiated Risk Evaluation, navigate to the Risk Evaluation 'Home' screen and select 'EPA Initiated Risk Evaluation' from the 'Form Type' drop-down menu. Refer to **Section 3.2** for additional details regarding the Risk Evaluation 'Home' screen.

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

7.2 Contact

You can navigate to the 'Contact' screen by clicking the 'Create' button and creating a new passphrase, or by accessing an EPA Initiated Risk Evaluation request that is 'In Progress' and entering the passphrase associated with the selected request.

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

- **Submission Alias:** Enter the submission alias. Upon navigating to the screen, the application displays an auto-generated editable submission alias in the following format: <Form Type-YYYYMMDD-HH:MM:SS >. This is a required field.
- **N/A:** Select the 'N/A' radio button to indicate that the form will be submitted on behalf of the reporting organization. Selecting this radio button generates the 'Fees Certification' page.
- **This is a submission on behalf of a consortium:** Select the 'This is a submission on behalf of a consortium to indicate that the request is submitted on behalf of a consortium. Selecting this radio button generates the 'Submitting on Behalf of Consortium' screen.
- **CBI:** Check the 'CBI' checkbox to claim the contact information as confidential.
- **Copy from CDX:** Click the 'Copy from CDX' link to copy CDX registration information.
- **First Name:** Enter the first name of the contact. This is a required field.
- **Last Name:** Enter the last name of the contact. This is a required field.
- **Position:** Enter the job title of the contact.
- **Company Name:** Enter the company name of the contact. This is a required field.

- **Additional Companies:** Enter an additional company in this field, if applicable.
- **Add:** Click the button to add the company entry into the 'Additional Companies' table.
- **Additional Company Name:** Displays the additional company name(s) associated with the contact.
- **Action:** Click the 'Delete' icon (✖) to remove an additional company name.
- **Phone Number:** Enter the phone number of the contact. This is a required field.
- **Phone Number Extension:** Enter the extension to the phone number, if applicable.
- **Email Address:** Enter the email address of the contact.
- **Mailing Address 1:** Enter the mailing address of the contact. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the contact, if applicable.
- **City:** Enter the city of the mailing address of the contact. This is a required field.
- **State:** Select the state of the mailing address of the contact. This is a required field if 'United States' is identified as the country.
- **Postal Code:** Enter the postal code of the mailing address of the contact. This is a required field.
- **Country:** Select the country of the mailing address of the contact from the drop-down menu. Selecting a non-US country generates the 'United States Agent' screen. This is a required field.

Exhibit 7-1 shows a screen capture of the ‘Contact’ screen (EPA Initiated Risk Evaluation) (Scroll 1):

Exhibit 7-1 EPA Initiated Risk Evaluation – Contact Screen (Scroll 1)

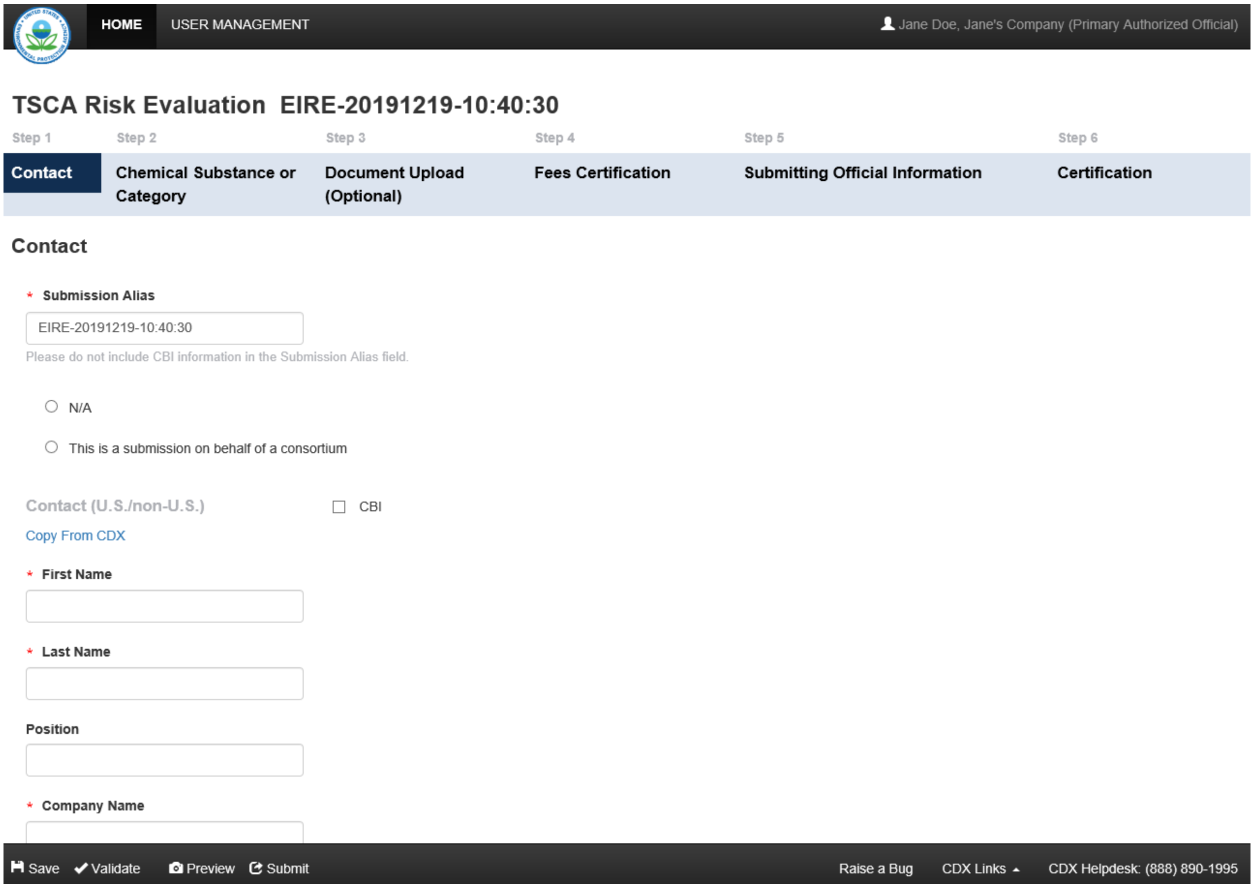


Exhibit 7-2 shows a screen capture of the ‘Contact’ screen (EPA Initiated Risk Evaluation) (Scroll 2):

Exhibit 7-2 EPA Initiated Risk Evaluation – Contact Screen (Scroll 2)

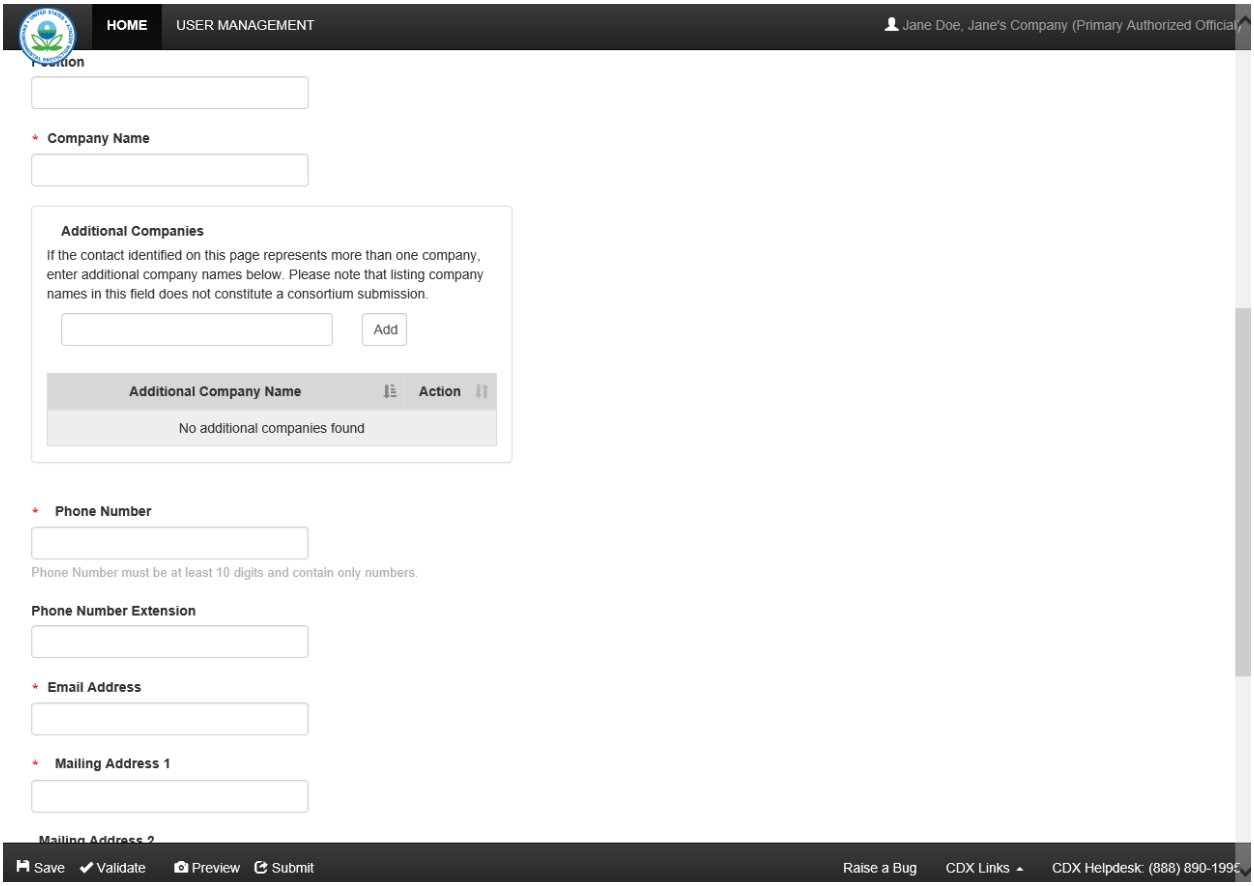
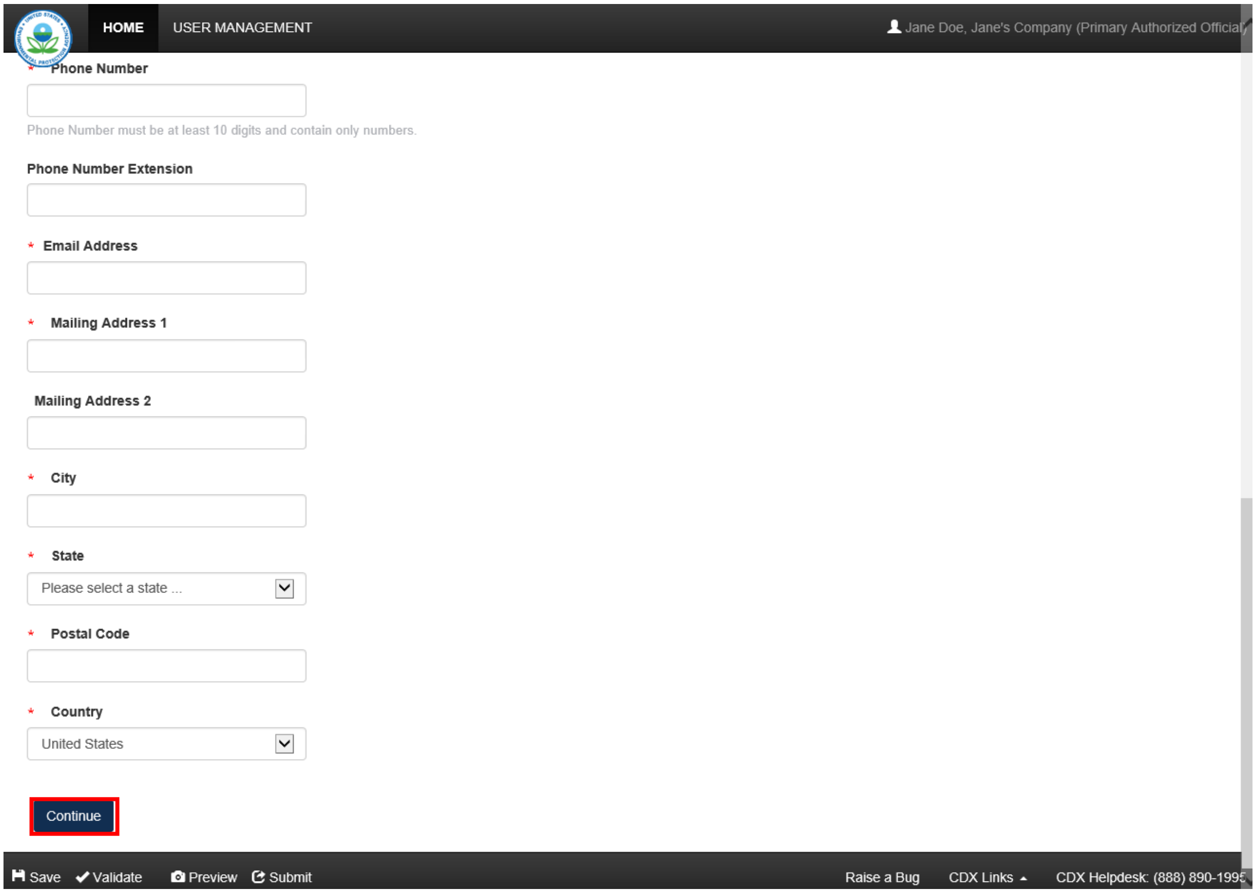

HOME
USER MANAGEMENT
Jane Doe, Jane's Company (Primary Authorized Official)
Company Name
Additional Companies
If the contact identified on this page represents more than one company, enter additional company names below. Please note that listing company names in this field does not constitute a consortium submission.
Add
Additional Company Name
Action
No additional companies found
Phone Number
Phone Number must be at least 10 digits and contain only numbers.
Phone Number Extension
Email Address
Mailing Address 1
Save
Validate
Preview
Submit
Raise a Bug
CDX Links
CDX Helpdesk: (888) 890-1995

Exhibit 7-3 shows a screen capture of the ‘Contact’ screen (Scroll 3):

Exhibit 7-3 EPA Initiated Risk Evaluation – Contact Screen (Scroll 3)



Navigation: Click the ‘Continue’ button to navigate to the ‘Chemical Substance or Category’ screen if a U.S. contact is identified and the request is submitted on behalf of the reporting organization. Click the ‘Continue’ button to navigate to the ‘Submitting on Behalf of Consortium’ screen if the request is submitted on behalf of a consortium. You can also access this screen by clicking the ‘Chemical Substance or Category’ or ‘Submitting on Behalf of Consortium’ link, respectively, within the navigation header. Click the ‘Continue’ button to navigate to the ‘United States Agent’ screen if a non-U.S. contact is identified. You can also access this screen by clicking the ‘U.S. Agent’ link within the navigation header.

7.3 Submitting on Behalf of Consortium

You can navigate to the ‘Submitting on Behalf of Consortium’ screen by selecting the ‘This is a submission on behalf of a consortium’ radio button and clicking the ‘Continue’ button on the ‘Contact’ screen.

The 'Submitting on Behalf of Consortium' screen provides fields to capture consortium information and individual consortium members. The user populating the form is identified as a consortium member by default upon navigating to the 'Submitting on Behalf of Consortium' page. A minimum of two consortium members is required.

- **Consortium Name:** Enter the name of the consortium. This is a required field.
- **Consortium CBI:** Check the 'CBI' checkbox to claim the consortium as confidential.
- **Add Consortium Member:** Click the 'Add Consortium Member' button to generate a pop up with an additional set of consortium input fields. At least two (2) consortium members are required to be identified.
- **Case Number:** Enter the case number of the Initial Response form. The case number must be in the format 'IR-YY-####.' Enter 'N/A' if the consortium member did not submit an Initial Response. This is a required field.
- **First Name:** Enter the first name of the consortium member. This is a required field.
- **Last Name:** Enter the last name of the consortium member. This is a required field.
- **Position:** Enter the job title of the consortium member
- **Company Name:** Enter the company name of the consortium member. This is a required field.
- **Phone Number:** Enter the phone number of the consortium member. This is a required field.
- **Phone Number Extension:** Enter the extension to the phone number, if applicable.
- **Email Address:** Enter the email address of the consortium member. This is a required field.
- **Mailing Address 1:** Enter the mailing address of the consortium member. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the consortium member, if applicable.
- **City:** Enter the city of the mailing address of the consortium member. This is a required field.
- **State:** Select the state of the mailing address of the consortium member. This is a required field.
- **Postal Code:** Enter the postal code of the mailing address of the consortium member. This is a required field.
- **Country:** Select the country of the mailing address of the consortium member. This is a required field.
- **My company is a "small business concern" as defined under 40 CFR 700.43:** Select the radio button to indicate that the consortium is a small business concern. A fee certification statement is required to be selected

- **My company is not a "small business concern" as defined under 40 CFR 700.43:** Select the radio button to indicate that the consortium member does not represent a small business concern. A fee certification statement is required to be selected.

Exhibit 4-114 shows a screen capture of the ‘Consortium Member’ pop-up window (Scroll 1):

Exhibit 7-4 EPA Initiated Risk Evaluation – Consortium Member Pop Up Window (Scroll 1)

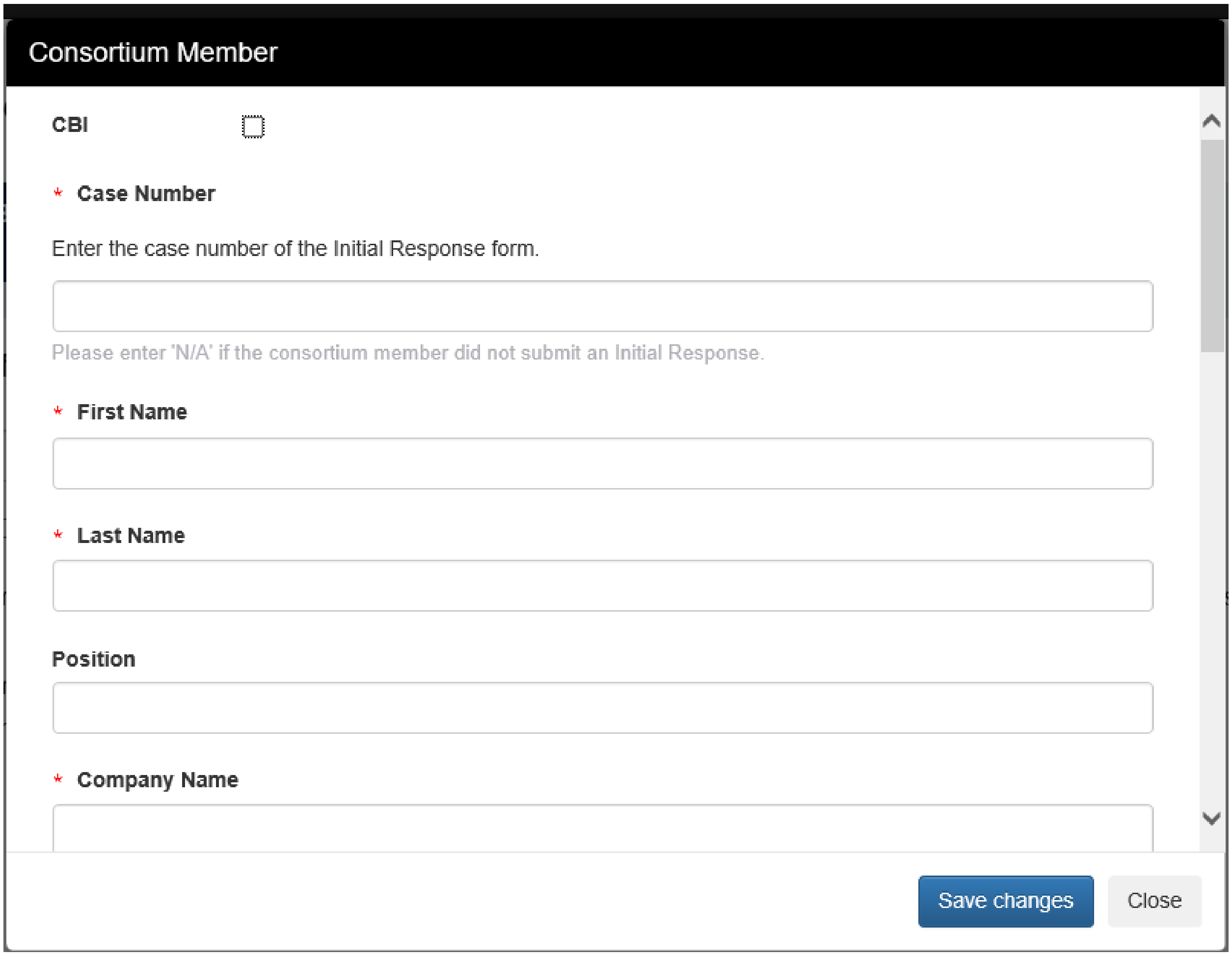


Exhibit 7-5 shows a screen capture of the 'Consortium Member' pop-up window (Scroll 2):

Exhibit 7-5 EPA Initiated Risk Evaluation – Consortium Member Pop Up Window (Scroll 2)

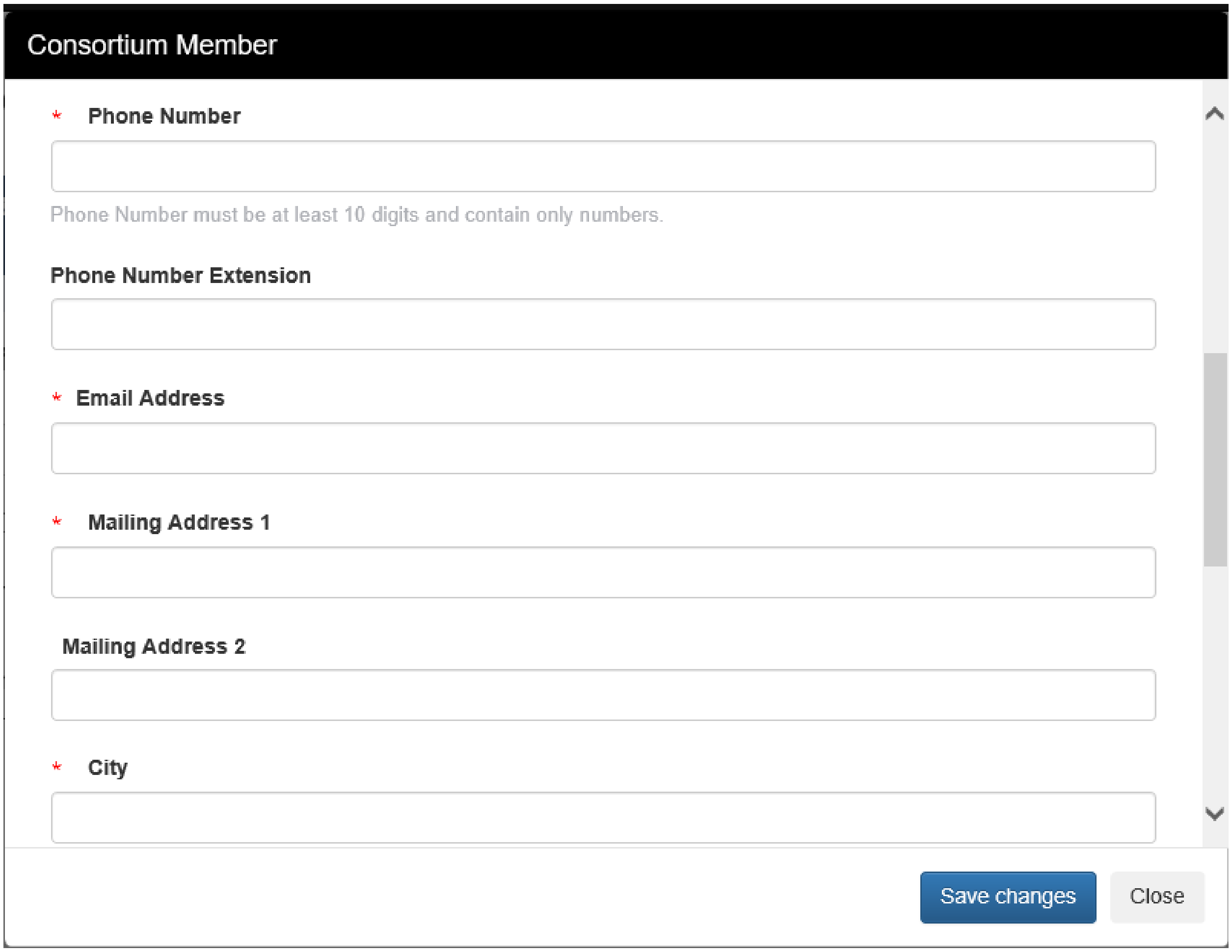
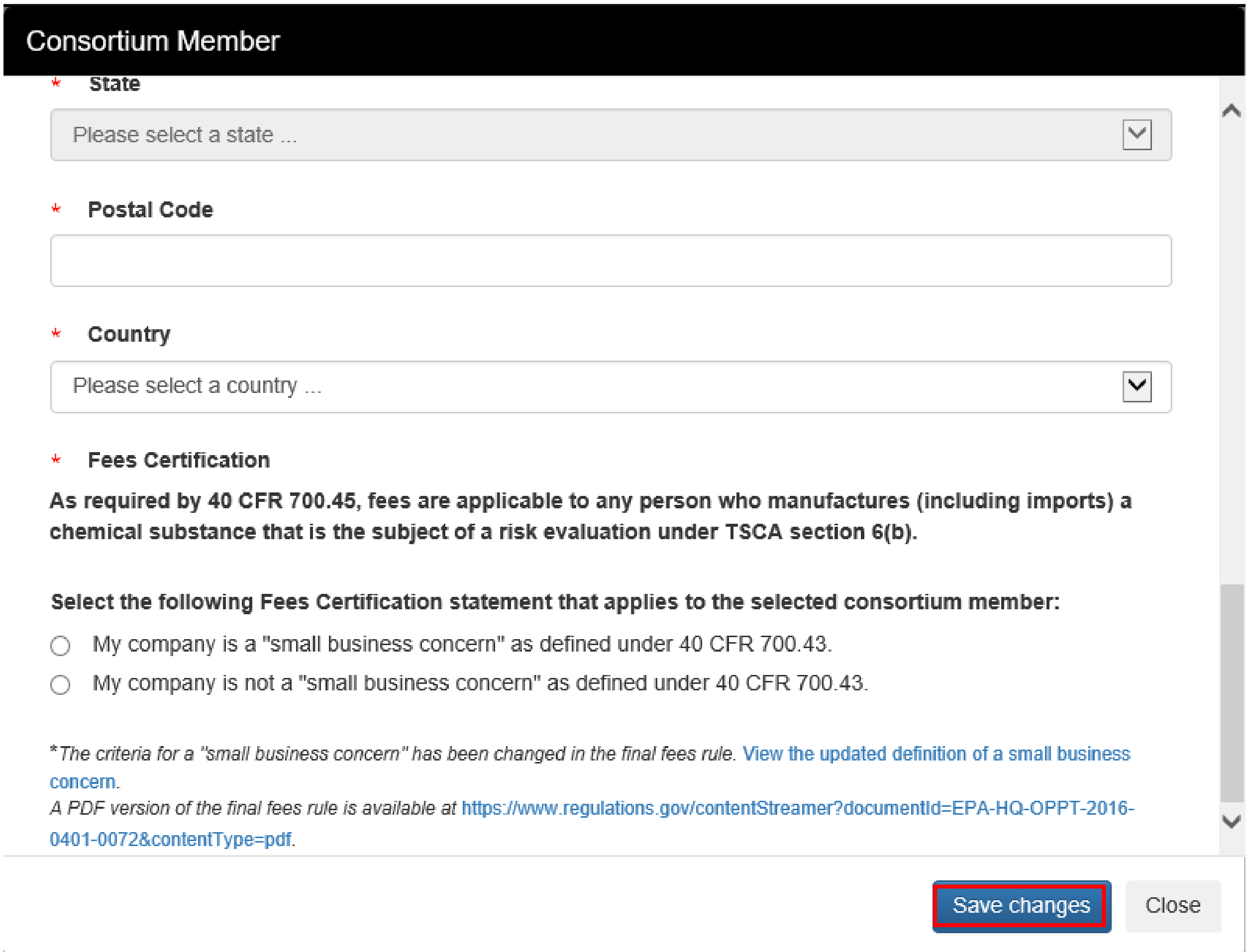


Exhibit 4-6 shows a screen capture of the ‘Consortium Member’ screen (Scroll 3):

Exhibit 7-6 EPA Initiated Risk Evaluation – Consortium Member Screen (Scroll 3)



Navigation: Click the ‘Save Changes’ button to save the consortium member information. Click the ‘Continue’ button to navigate to the ‘Chemical Substance or Category’ screen if the request is submitted on behalf of the reporting organization. You can also access this screen by clicking the ‘Chemical Substance or Category’ link within the navigation header. Click the ‘Continue’ button to navigate to the ‘U.S. Agent’ screen if a non-U.S. contact is identified. You can also access this screen by clicking the ‘U.S. Agent’ link within the navigation header.

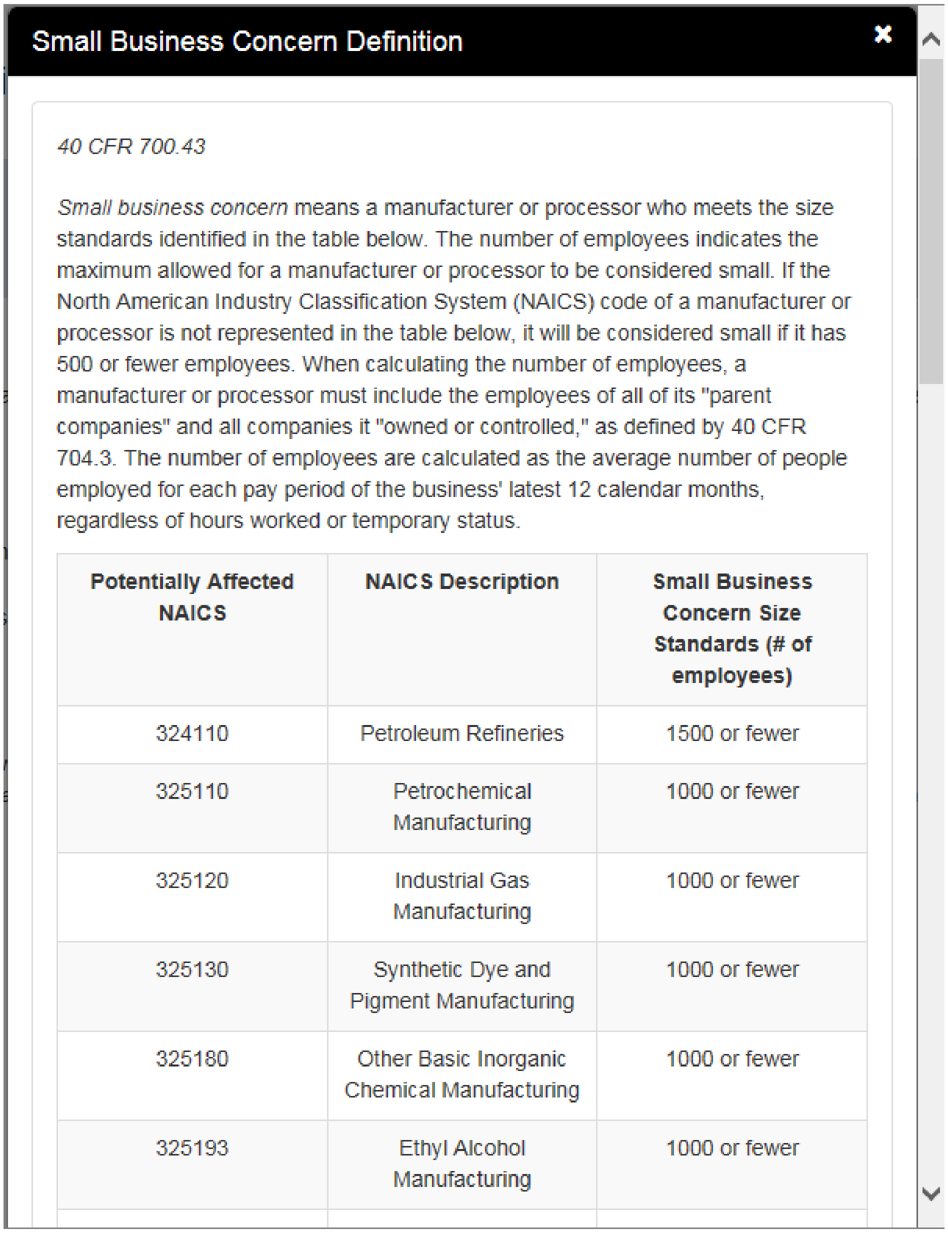
7.3.1 Small Business Concern Definition

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

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

Exhibit 7-7 shows a screen capture of the ‘Small Business Concern Definition’ window (Scroll 1):

Exhibit 7-7 EPA Initiated Risk Evaluation – Small Business Concern Definition Window (Scroll 1)



Small Business Concern Definition

40 CFR 700.43

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

Potentially Affected NAICS	NAICS Description	Small Business Concern Size Standards (# of employees)
324110	Petroleum Refineries	1500 or fewer
325110	Petrochemical Manufacturing	1000 or fewer
325120	Industrial Gas Manufacturing	1000 or fewer
325130	Synthetic Dye and Pigment Manufacturing	1000 or fewer
325180	Other Basic Inorganic Chemical Manufacturing	1000 or fewer
325193	Ethyl Alcohol Manufacturing	1000 or fewer

Exhibit 7-8 shows a screen capture of the ‘Small Business Concern Definition’ window (Scroll 2):

Exhibit 7-8 EPA Initiated Risk Evaluation – Small Business Concern Definition Window (Scroll 2)

325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	1250 or fewer
325199	All Other Basic Organic Chemical Manufacturing	1250 or fewer
325211	Plastics Material and Resin Manufacturing	1250 or fewer
325212	Synthetic Rubber Manufacturing	1000 or fewer
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	1000 or fewer
325311	Nitrogenous Fertilizer Manufacturing	1000 or fewer
325312	Phosphatic Fertilizer Manufacturing	750 or fewer
325314	Fertilizer (Mixing Only) Manufacturing	500 or fewer
325320	Pesticide and Other Agricultural Chemical Manufacturing	1000 or fewer
325411	Medicinal and Botanical Manufacturing	1000 or fewer
325412	Pharmaceutical Preparation Manufacturing	1250 or fewer
325413	InVitro Diagnostic Substance	1250 or fewer

Exhibit 7-9 shows a screen capture of the 'Small Business Concern Definition' window (Scroll 3):

Exhibit 7-9 EPA Initiated Risk Evaluation – Small Business Concern Definition Window (Scroll 3)

325414	Biological Product (except Diagnostic) Manufacturing	1250 or fewer
325510	Paint and Coating Manufacturing	1000 or fewer
325520	Adhesive Manufacturing	500 or fewer
325611	Soap and Other Detergent Manufacturing	1000 or fewer
325612	Polish and Other Sanitation Good Manufacturing	750 or fewer
325613	Surface Active Agent Manufacturing	750 or fewer
325620	Toilet Preparation Manufacturing	1250 or fewer
325910	Printing Ink Manufacturing	500 or fewer
325920	Explosives Manufacturing	750 or fewer
325991	Custom Compounding of Purchased Resins	500 or fewer
325992	Photographic Film, Paper, Plate and Chemical Manufacturing	1500 or fewer
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	500 or fewer

Exhibit 7-10 shows a screen capture of the 'Small Business Concern Definition' window (Scroll 4):

Exhibit 7-10 EPA Initiated Risk Evaluation – Small Business Concern Definition Window (Scroll 4)

325613	Surface Active Agent Manufacturing	750 or fewer
325620	Toilet Preparation Manufacturing	1250 or fewer
325910	Printing Ink Manufacturing	500 or fewer
325920	Explosives Manufacturing	750 or fewer
325991	Custom Compounding of Purchased Resins	500 or fewer
325992	Photographic Film, Paper, Plate and Chemical Manufacturing	1500 or fewer
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	500 or fewer
424690	Other Chemical and Allied Products Merchant Wholesalers	150 or fewer
424710	Petroleum Bulk Stations and Terminals	200 or fewer
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	200 or fewer

Navigation: Click the 'X' icon in the upper right-hand corner to close the 'Small Business Concern Definition' window.

7.3 United States Agent

You can navigate to the 'United States Agent' screen by identifying a non-U.S. contact and clicking the 'Continue' button on the 'Contact' screen.

The 'United States Agent' screen provides fields to input identifying information for a U.S. agent.

- **CBI:** Check the 'CBI' checkbox to claim the agent information as confidential.
- **First Name:** Enter the first name of the agent. This is a required field.
- **Last Name:** Enter the last name of the agent. This is a required field.
- **Position:** Enter the job title of the agent.
- **Company Name:** Enter the company name of the agent. This is a required field.
- **Phone Number:** Enter the phone number of the agent. This is a required field.
- **Phone Number Extension:** Enter the extension to the phone number, if applicable.
- **Email Address:** Enter the email address of the agent. This is a required field.
- **Mailing Address 1:** Enter the mailing address of the agent. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the agent, if applicable.
- **City:** Enter the city of the mailing address of the agent. This is a required field.
- **State:** Select the state of the mailing address of the agent. This is a required field.
- **Postal Code:** Enter the postal code of the mailing address of the agent. This is a required field.
- **Country:** Displays 'United States.'

Exhibit 7-11 shows a screen capture of the ‘United States Agent’ screen (Scroll 1):

Exhibit 7-11 EPA Initiated Risk Evaluation – United States Agent Screen (Scroll 1)

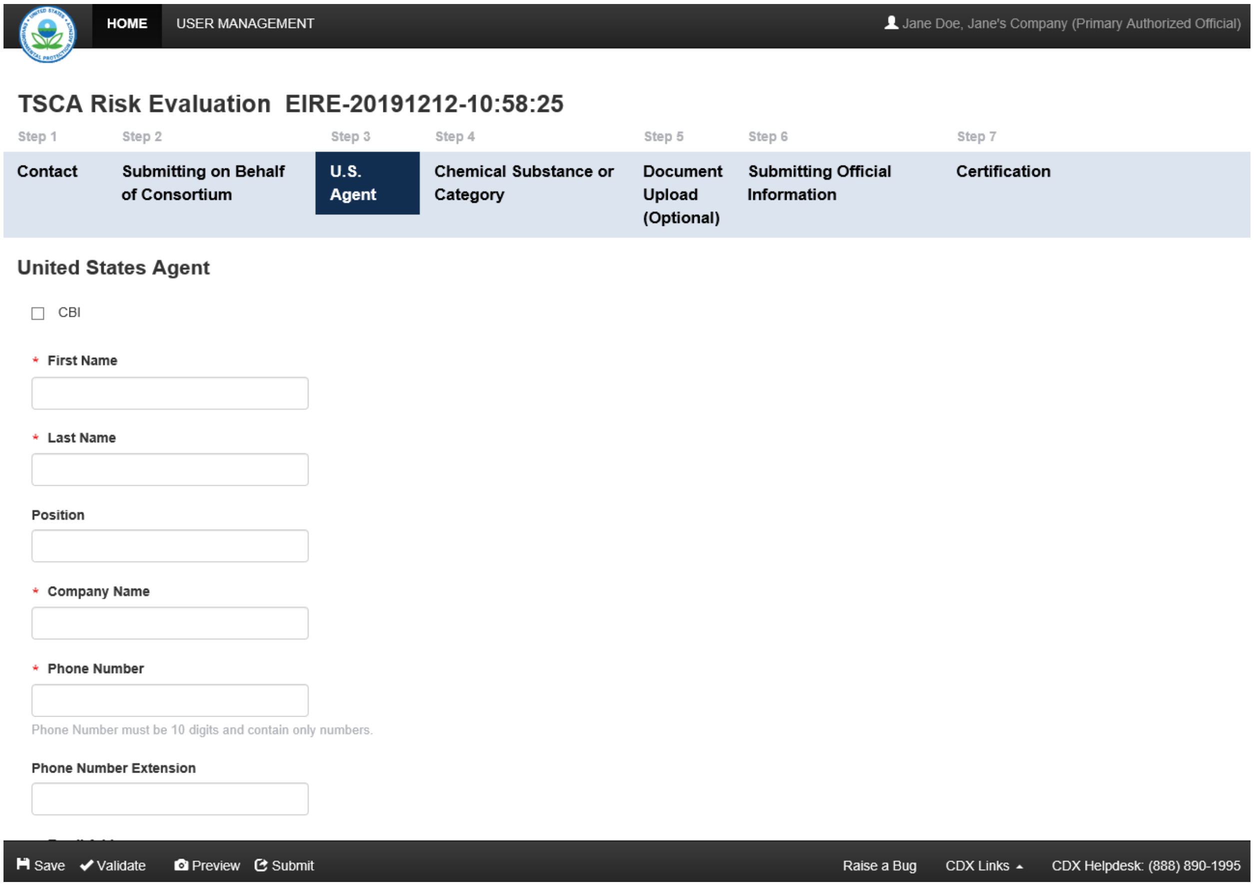
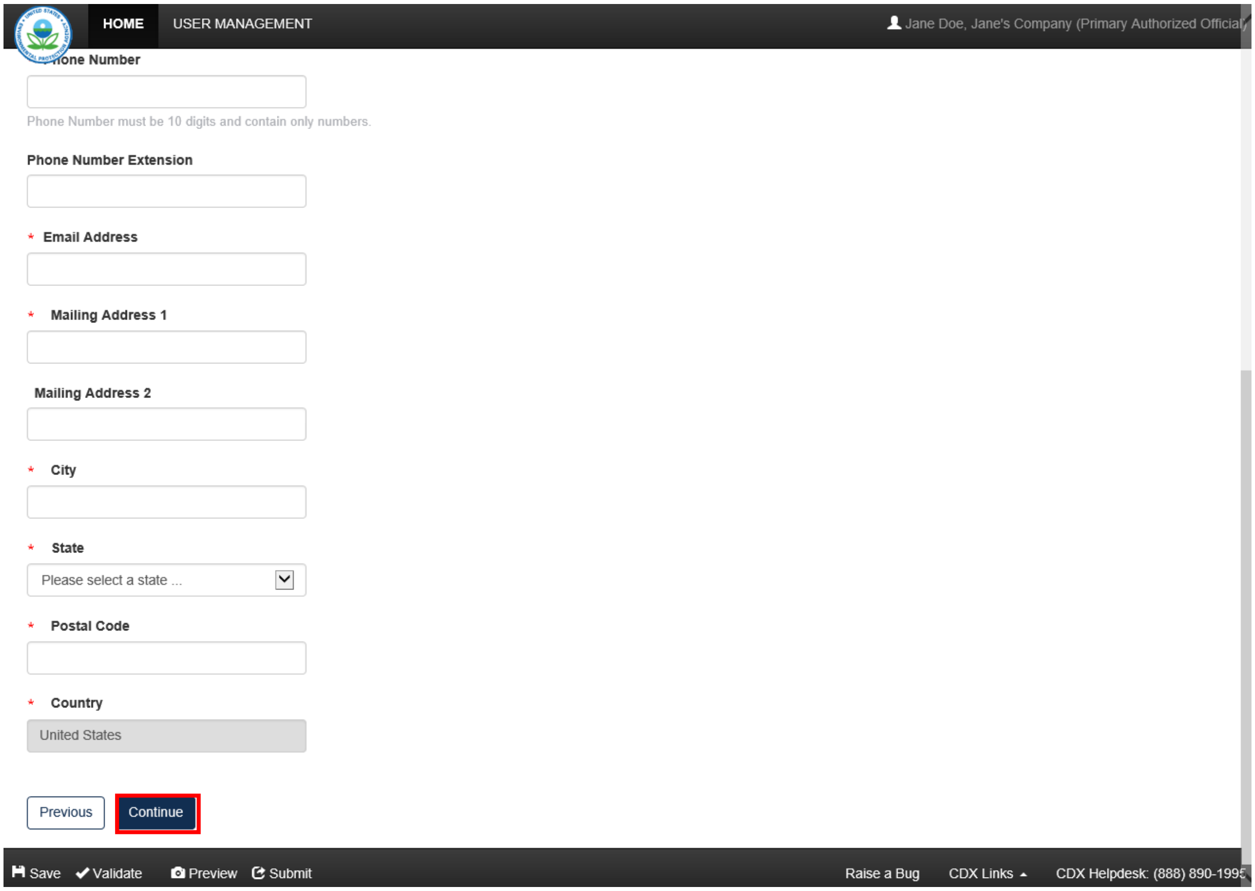


Exhibit 7-12 shows a screen capture of the ‘United States Agent’ screen (Scroll 2):

Exhibit 7-12 EPA Initiated Risk Evaluation – United States Agent Screen (Scroll 2)



Navigation: Click the 'Continue' button to navigate to the 'Chemical Substance or Category' screen if the request is submitted on behalf of the reporting organization. You can also access this screen by clicking the 'Chemical Substance or Category' link within the navigation header.

7.4 Chemical Substance or Category

You can access the 'Chemical Substance or Category' screen by clicking the 'Continue' button from the 'Contact' screen if identifying a U.S. contact. If identifying a non-U.S. contact within the 'Contact' screen, you can access this screen by clicking the 'Continue' button from the 'United States Agent' screen. You can also access this screen by clicking the 'Chemical Substance or Category' link within the navigation header.

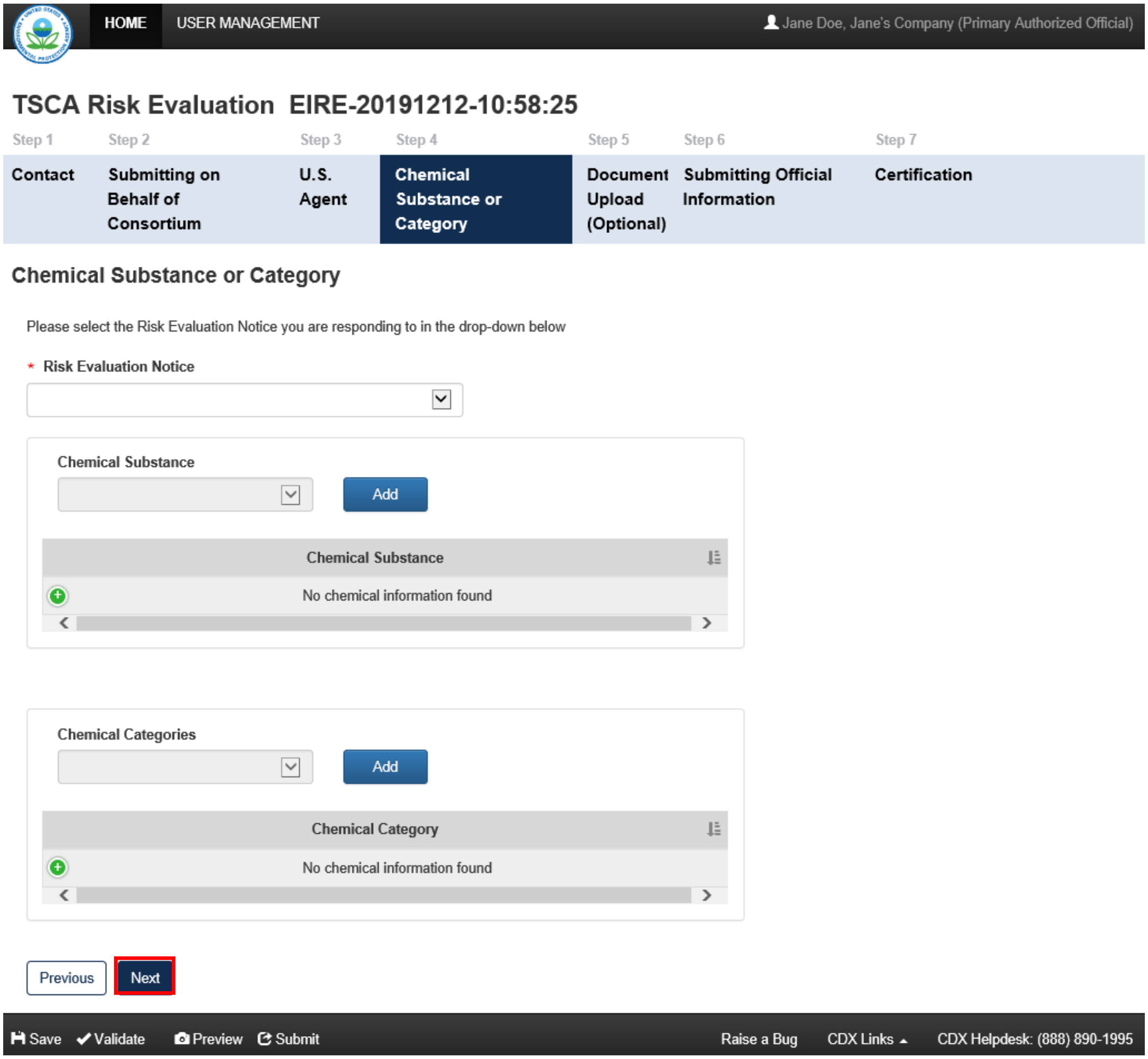
The 'Chemical Substance or Category' screen displays the following fields and columns of information:

- **Risk Evaluation Notice:** Select the Risk Evaluation Notice to which you are responding. This is a required field.

- **Chemical Substance Type:** Select the chemical substance type from the drop-down menu. This drop-down is disabled until a Risk Evaluation Notice is selected. Once selection is made from the drop-down, click 'Add' to add the chemical substance type to the table. At least one chemical substance or chemical category is required.
- **Chemical Categories:** Select the chemical categories from the drop-down menu. This is disabled until a Risk Evaluation Notice is selected. Once a selection is made from the drop-down, click 'Add' to add the chemical substance type to the table. At least one chemical substance or chemical category is required.

Exhibit 7-13 shows a screen capture of the ‘Chemical Substance or Category’ screen (Scroll 1):

Exhibit 7-13 EPA Initiated Risk Evaluation – Chemical Substance or Category Screen (Scroll 1)



Navigation: Click the ‘Next’ button to navigate to the ‘Document Upload’ screen. You can also access this screen by clicking the ‘Document Upload’ link within the navigation header.

7.5 Document Upload (Optional)

You can access the 'Document Upload' screen by clicking the 'Next' button from the 'Chemical Substance or Category' screen. You can also access this screen by clicking the 'Document Upload' link within the navigation header.

A condition of use rationale document is required to be uploaded within a Risk Evaluation request.

- **Condition of Use:** Enter text including a rationale for the conditions of use. The term 'condition of use' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, or distributed in commerce, used or disposed of.
- **CBI:** Check the box to indicate the confidentiality status of the Condition of Use.
- **Hazard Studies / Information:** Enter text of all existing information that is relevant to whether the chemical substance, under the conditions of use identified by the manufacturer, presents an unreasonable risk of injury to health or the environment. At minimum this must include:
  - hazard and exposure potential,
  - persistence and bioaccumulation,
  - potentially exposed or susceptible subpopulations the requester believes to be relevant,
  - whether there is any storage of the chemical substance near significant sources of drinking water (including storage facilities),
  - production volume or significant changes to the production volume, and
  - any other information relevant to the potential risks of the chemical substance.
- **CBI:** Check the box to indicate the confidentiality status of the Hazard Studies/ Information.
- **Additional Information:** Enter text for any additional information.
- **CBI:** Check the box to indicate the confidentiality status of the Additional Information.
- **Search:** Enter criteria to filter the uploaded document(s).
- **Document Type:** Displays the document type of the uploaded document.
- **Document Subtype:** Displays the document subtype of the uploaded document.
- **File Name:** Displays the file name of the uploaded document.
- **File Description:** Displays the description of the uploaded document.
- **Page Count:** Displays the number of pages in the uploaded document.
- **Date:** Displays the date that the uploaded document was attached.

- **CBI:** Displays a ‘Y’ or an ‘N’ to indicate the confidentiality status of the uploaded document.
- **Action:** Click the ‘Delete’ icon (❌) to remove the uploaded document.
- **Attach Document:** Click the ‘Attach Document’ link to generate the ‘Attach Document’ window. Refer to **Section 4.5.1** for further details on the ‘Attach Document’ window.
- **Information Submitted:** Enter text regarding the type of information that has been included in the risk evaluation form.
- **CBI:** Check the box to indicate the confidentiality status of the information submitted.

Exhibit 7-14 shows a screen capture of the ‘Document Upload’ screen (Scroll 1):

Exhibit 7-14 EPA Initiated Risk Evaluation – Document Upload Screen (Scroll 1)

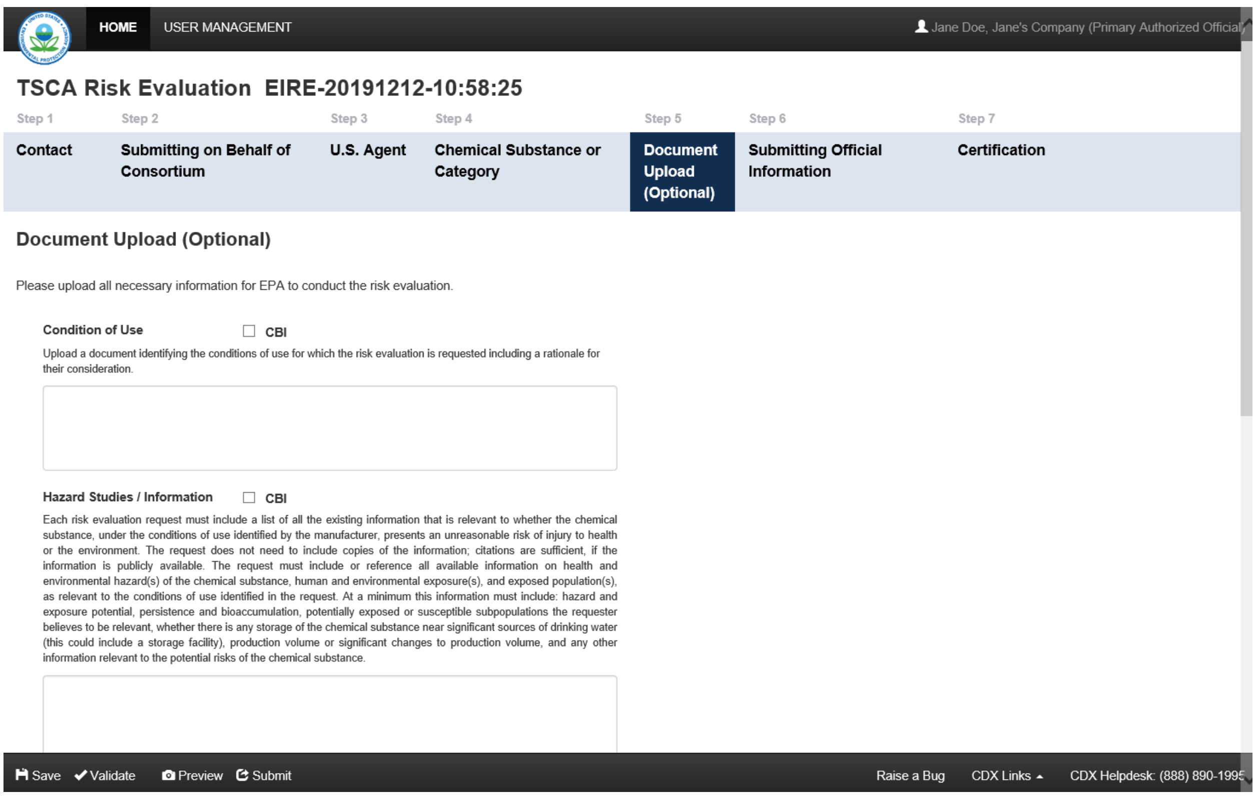
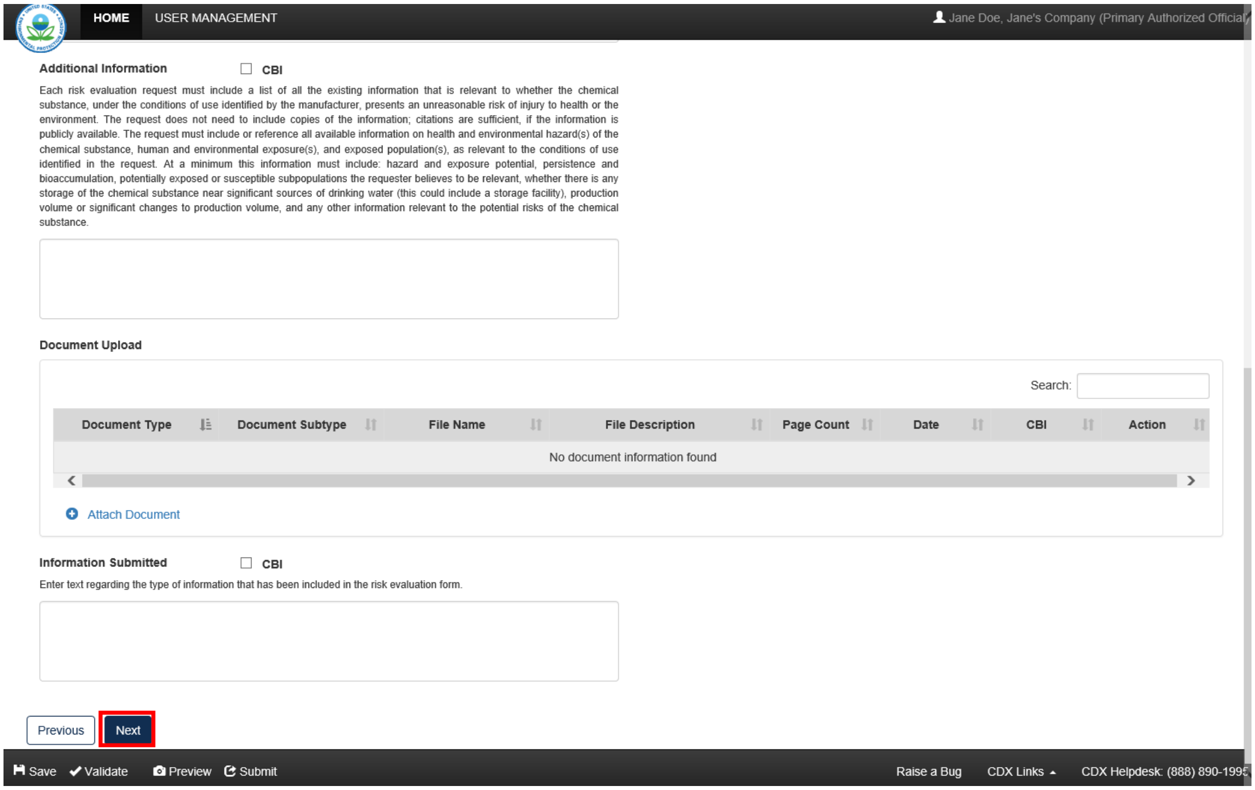


Exhibit 7-15 shows a screen capture of the ‘Document Upload’ screen (Scroll 2):

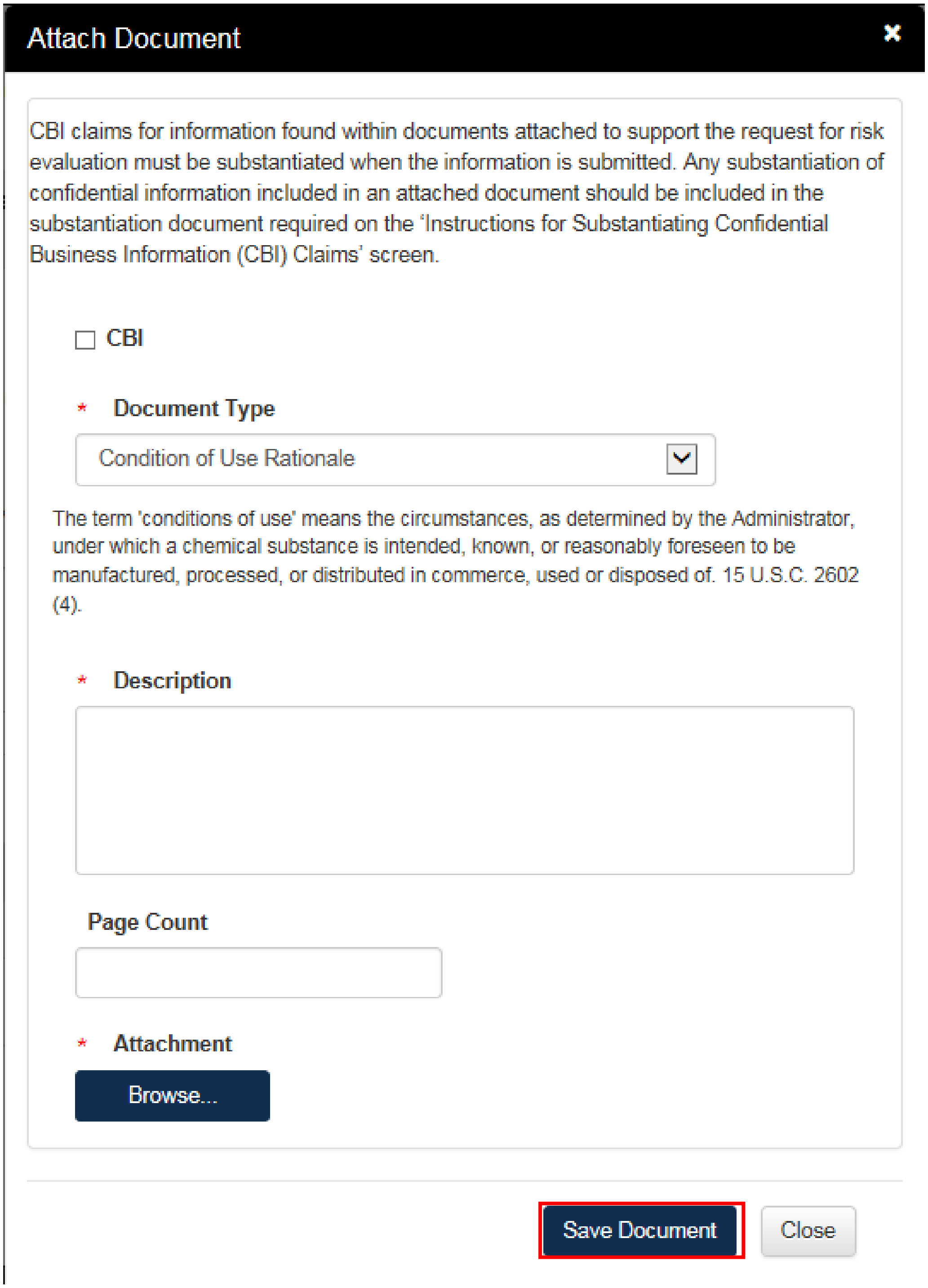
Exhibit 7-15 EPA Initiated Risk Evaluation – Document Upload Screen (Scroll 2)



Navigation: Click the ‘Next’ button to navigate to the ‘Submitting Official Information’ screen if this form is submitted on behalf of a consortium. You can also access this screen by clicking the ‘Submitting Official Information’ link within the navigation header. Click the ‘Next’ button to navigate to the ‘Fees Certification’ screen if this form is submitted on behalf of the reporting organization. You can also access this screen by clicking the ‘Fees Certification’ link within the navigation header.

Exhibit 7-16 shows a screen capture of the ‘Attach Document’ window:

Exhibit 7-16 EPA Initiated Risk Evaluation – Attach Document Window


Attach Document

CBI claims for information found within documents attached to support the request for risk evaluation must be substantiated when the information is submitted. Any substantiation of confidential information included in an attached document should be included in the substantiation document required on the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen.

CBI

* Document Type

Condition of Use Rationale

The term 'conditions of use' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, or distributed in commerce, used or disposed of. 15 U.S.C. 2602 (4).

* Description

Page Count

* Attachment

Browse...

Save Document

Close

Navigation: Click the 'Save Document' button to upload the selected attachment to the 'Documents' table.

7.6 Fees Certification

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

You can access the 'Fees Certification' screen by selecting the 'N/A' radio button within the 'Contact' screen and clicking the 'Continue' button from the 'Chemical Substance or Category' screen.

The purpose of the 'Fees Certification' screen is to inform EPA of the fee amount that a primary submitter pays on behalf of the reporting organization based on the business size. The certification statement selected on the 'Fees Certification' screen is non-editable when amending a Risk Evaluation Request. See **Section 4.3.1** for additional information regarding the definition of a small business concern.

Exhibit 7-17 shows the fee structure implemented for Risk Evaluation Requests:

Exhibit 7-17 EPA Initiated Risk Evaluation – Risk Evaluation Request Fee Structure

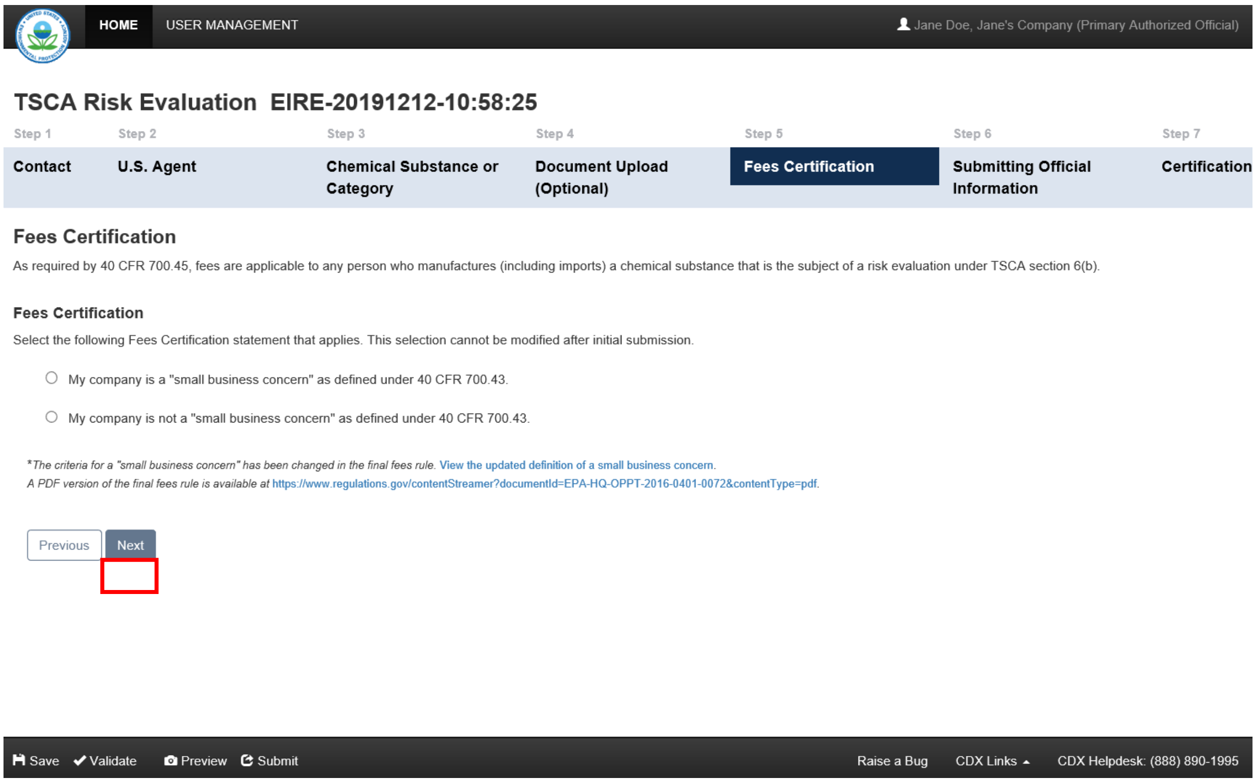
Business Concern	Fee Category	Fee Amount
Not a small business concern	EPA-initiated Risk Evaluation	• $1,350,000
	Manufacturer-requested risk evaluation on a chemical in the TSCA Work Plan	• Initial $1,250,000 payment + final invoice to recover 50% of Actual Costs
	Manufacturer-requested risk evaluation on a chemical not in the TSCA Work Plan	• Initial $2,500,000 payment+ final invoice to total 100% of Actual Costs
Small business	EPA-initiated Risk Evaluation	• $270,000
	Manufacturer-requested risk evaluation on a chemical in the TSCA Work Plan	• Initial $1,250,000 payment + final invoice to recover 50% of Actual Costs
	Manufacturer-requested risk evaluation on a chemical not in the TSCA Work Plan	• Initial $2,500,000 payment+ final invoice to total 100% of Actual Costs

The following certification statements display:

- **My company is a "small business concern" as defined under 40 CFR 700.43:** Select this radio button to indicate that the reporting organization is a small business concern.
- **My company is not a "small business concern" as defined under 40 CFR 700.43:** Select this radio button to indicate that the reporting organization is not a small business concern.

Exhibit 7-18 shows a screen capture of the 'Fees Certification' screen:

Exhibit 7-18 EPA Initiated Risk Evaluation – Fees Certification Screen



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

7.7 Submitting Official Information

You can access the 'Submitting Official Information' screen by clicking the 'Next' button from the 'Fees Certification' screen if the request is submitted on behalf of the reporting organization. You can also access this screen by clicking the 'Submitting Official Information' link within the navigation header.

The information below has been pre-populated from CDX registration. If the information listed is incorrect please make the appropriate edits to your user information in CDX registration.

- **Submitter is CBI:** Check the 'CBI' checkbox to claim the submitter information as confidential.
- **First Name:** Displays the first name of the submitter.
- **Middle Initial:** Displays the middle initial of the submitter.
- **Last Name:** Displays the last name of the submitter.
- **Company Name:** Displays the company name of the submitter.
- **Phone Number:** Displays the phone number of the submitter.
- **Email Address:** Displays the email address of the submitter.
- **Mailing Address 1:** Displays line 1 of the mailing address of the submitter.
- **City:** Displays the city of the mailing address of the submitter.
- **State:** Displays the state of the mailing address of the submitter.
- **Postal Code:** Displays the postal code of the mailing address of the submitter.
- **Country:** Displays the country of the mailing address of the submitter.
- **This confirmation is required to proceed with the submission process:** Check the legal verification checkbox to begin the submission process; this is required and gets reset when accessing the form.

Exhibit 7-19 shows a screen capture of the ‘Submitting Official Information’ screen (Scroll 1):

Exhibit 7-19 EPA Initiated Risk Evaluation – Submitting Official Information Screen (Scroll 1)

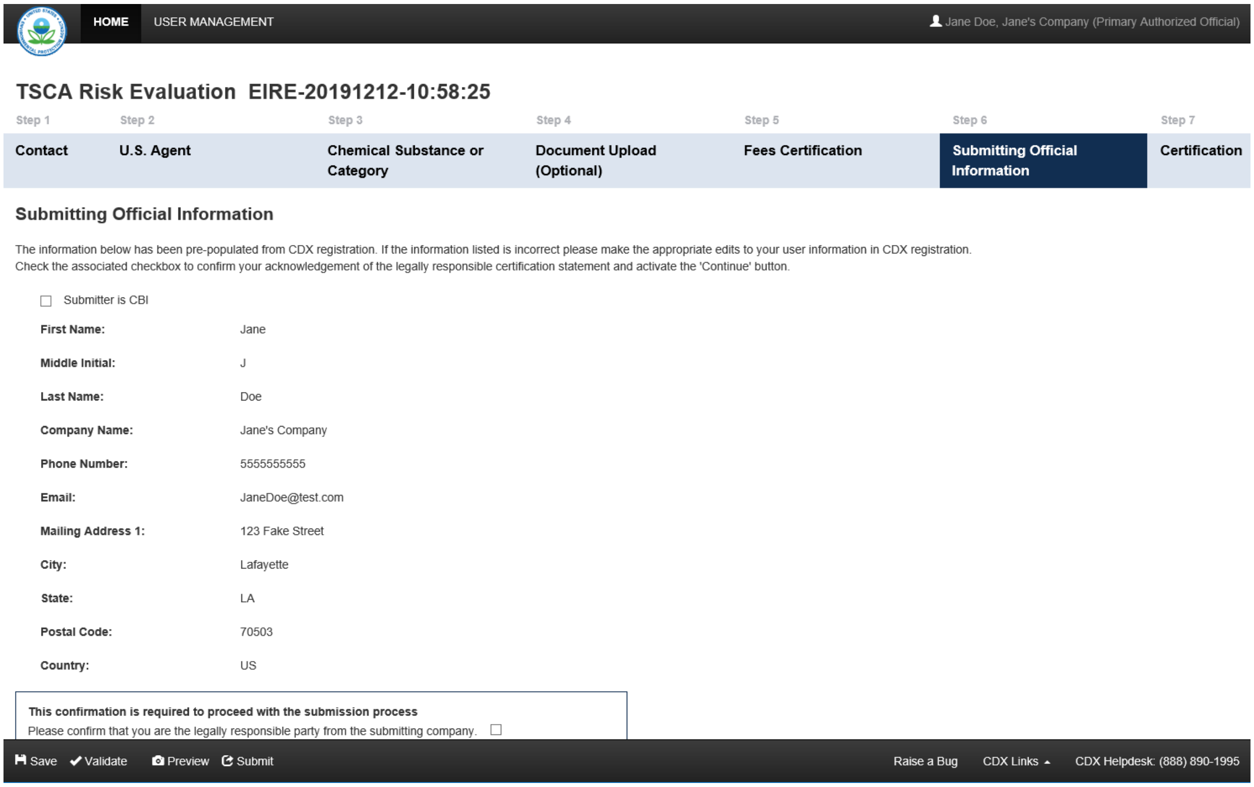
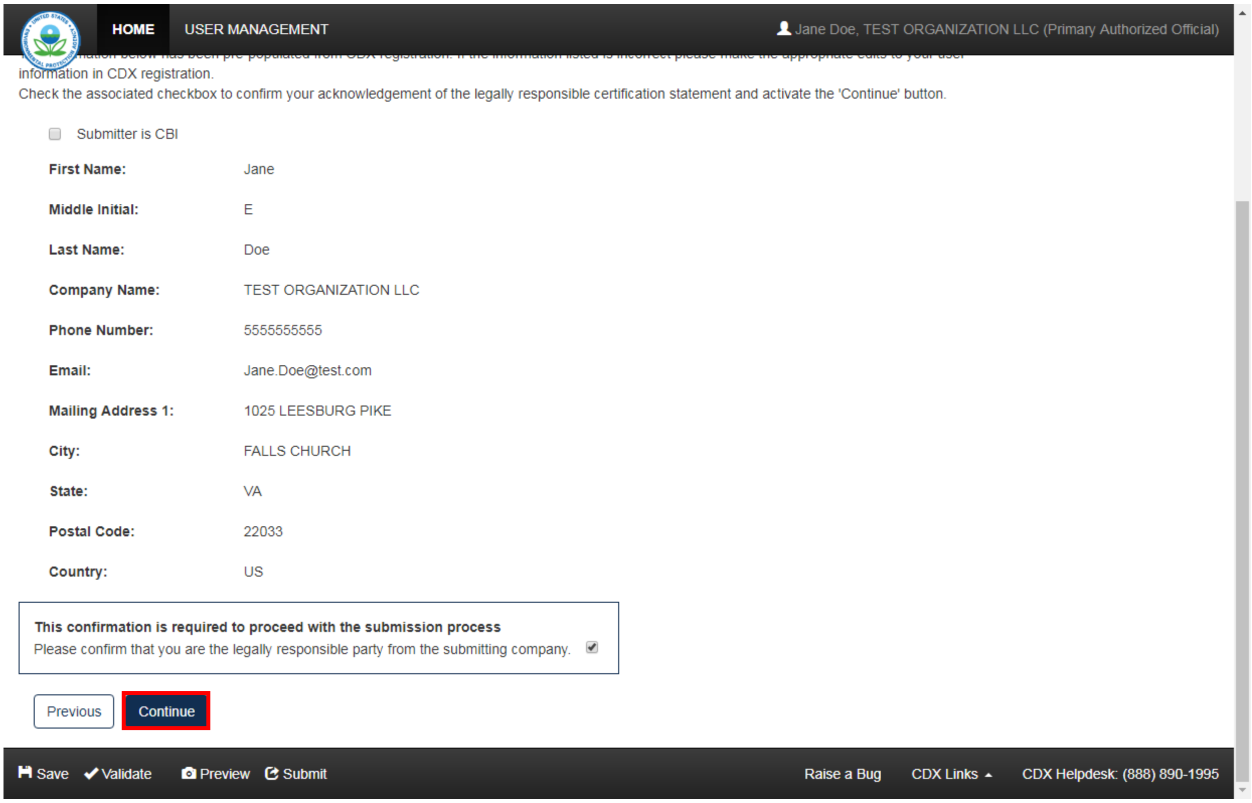


Exhibit 7-20 shows a screen capture of the 'Submitting Official Information' screen (Scroll 2):

Exhibit 7-20 EPA Initiated Risk Evaluation – Submitting Official Information Screen (Scroll 2)



Navigation: Click the 'Continue' button to navigate to the 'Submission of Referenced Information' screen. You can also access this screen by clicking the 'Certification' link within the navigation header.

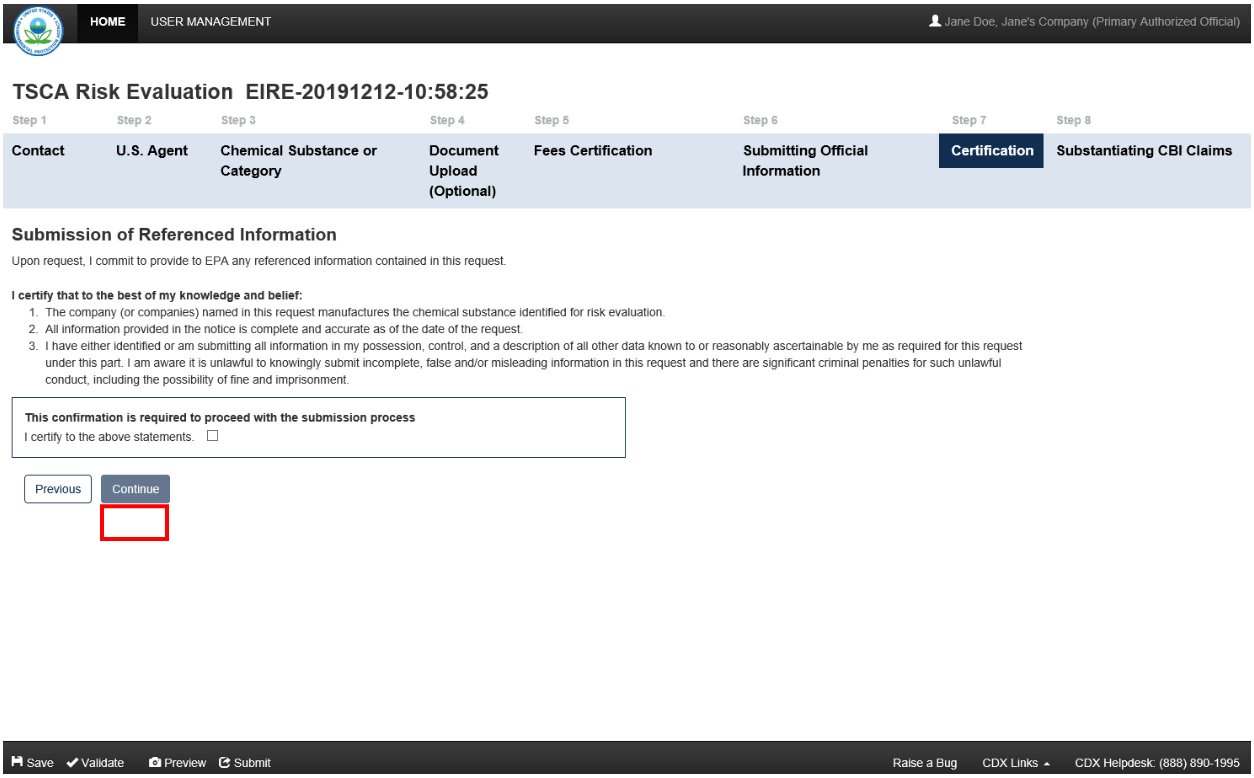
7.8 Submission of Referenced Information

You can access the 'Submission of Referenced Information' screen by clicking the 'Continue' button from the 'Submitting Official Information' screen. You can also access this screen by clicking the 'Certification' link within the navigation header.

The purpose of the 'Submission of Referenced Information' screen is for users to commit to providing EPA referenced information contained in this Risk Evaluation request.

Exhibit 7-21 shows a screen capture of the ‘Submission of Referenced Information’ screen:

Exhibit 7-21 EPA Initiated Risk Evaluation – Submission of Referenced Information Screen



Navigation: If any CBI claims were made, check the certification checkbox and click the ‘Continue’ button to navigate to the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen. You can also access this screen by clicking the ‘Substantiating CBI Claims’ link within the navigation header. If no CBI claims were made, check the certification checkbox and click the ‘Start Submission Process’ button to initiate the submission process.

7.9 Instructions for Substantiating Confidential Business Information (CBI) Claims

EPA modified the electronic reporting applications for TSCA submissions to accept CBI substantiations for CBI claims made during the creation of electronic submissions. Other than information exempt from substantiation under TSCA Section 14(c)(2), users who wish to assert CBI claims for data within a submission must substantiate those claims at the time of submission as required by TSCA Section 14(c)(3).

You can access the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen by claiming information as CBI within a form and clicking the ‘Continue’ button from the ‘Submission of Referenced Information’ screen. You can also access this screen by clicking the 'Substantiating CBI Claims' link within the navigation header. This screen will not generate until a CBI claim is made within a submission. Information claimed CBI must either be substantiated or claimed exempt pursuant to TSCA Section 14(c)(2) at the time of submission.

To substantiate a CBI claim, upload documentation asserting your claim(s) on the 'Instructions for Substantiating CBI Claims' screen within the form. You may also opt-out of substantiation on the 'Instructions for Substantiating CBI Claims' screen if, for example, you believe your CBI claim is exempt under TSCA Section 14(c)(2). Common exemption reasons can be found at https://www.epa.gov/tsca-cbi/what-information-include-cbi-substantiations. To opt-out of substantiation at the time of submission, all CBI claims within a submission must be exempt.

- **Substantiation Opt-Out:** Check this checkbox to opt out of providing CBI substantiation. You will be required to provide reasoning if you choose to opt out.
- **Substantiation Opt-Out Reason:** Enter reasoning for opting out of CBI substantiation. This is a required field.
- **Attach Document for CBI Substantiation:** Click the 'Attach Document for CBI Substantiation' link to generate the 'Attach Documents for CBI Substantiation' pop-up window.

If you are unfamiliar with substantiating CBI claims or require assistance preparing substantiation documents, EPA offers a link to templates and other information for substantiating CBI claims on the 'Instructions for Substantiating Confidential Business Information (CBI) Claims' screen. It is suggested that you right-click the link and open in a new tab or new window so you do not leave your submission as this may affect your saved data.

Exhibit 7-22 shows a screen capture of the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen (Scroll 1):

Exhibit 7-22 EPA Initiated Risk Evaluation – Instructions for Substantiating Confidential Business Information (CBI) Claims Screen (Scroll 1)

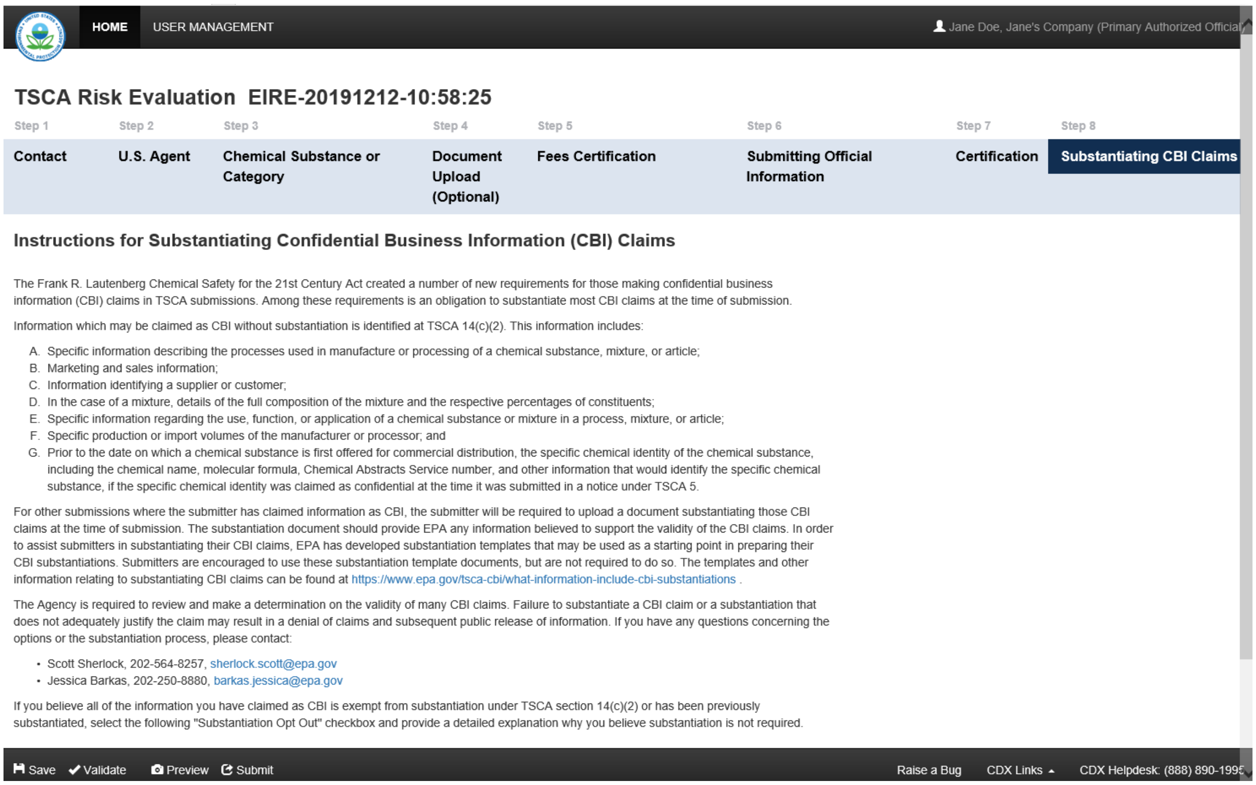
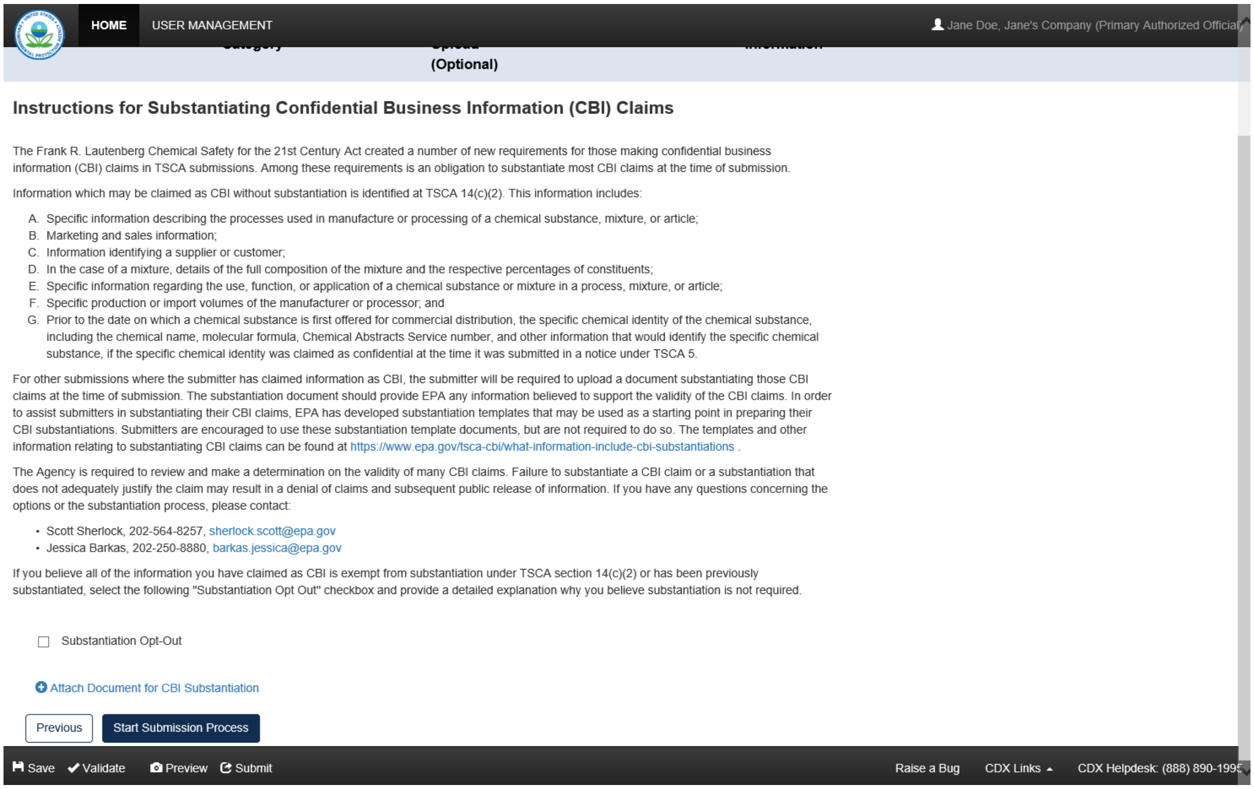


Exhibit 7-23 shows a screen capture of the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen (Scroll 2).

Exhibit 7-23 EPA Initiated Risk Evaluation – Instructions for Substantiating Confidential Business Information (CBI) Claims Screen (Scroll 2)


HOME USER MANAGEMENT Jane Doe, Jane's Company (Primary Authorized Official)

(Optional)

Instructions for Substantiating Confidential Business Information (CBI) Claims

The Frank R. Lautenberg Chemical Safety for the 21st Century Act created a number of new requirements for those making confidential business information (CBI) claims in TSCA submissions. Among these requirements is an obligation to substantiate most CBI claims at the time of submission.

Information which may be claimed as CBI without substantiation is identified at TSCA 14(c)(2). This information includes:

A. Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article;
B. Marketing and sales information;
C. Information identifying a supplier or customer;
D. In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents;
E. Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article;
F. Specific production or import volumes of the manufacturer or processor; and
G. Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under TSCA 5.

For other submissions where the submitter has claimed information as CBI, the submitter will be required to upload a document substantiating those CBI claims at the time of submission. The substantiation document should provide EPA any information believed to support the validity of the CBI claims. In order to assist submitters in substantiating their CBI claims, EPA has developed substantiation templates that may be used as a starting point in preparing their CBI substantiations. Submitters are encouraged to use these substantiation template documents, but are not required to do so. The templates and other information relating to substantiating CBI claims can be found at https://www.epa.gov/tsca-cbi/what-information-include-cbi-substantiations .

The Agency is required to review and make a determination on the validity of many CBI claims. Failure to substantiate a CBI claim or a substantiation that does not adequately justify the claim may result in a denial of claims and subsequent public release of information. If you have any questions concerning the options or the substantiation process, please contact:

- Scott Sherlock, 202-564-8257, sherlock.scott@epa.gov
- Jessica Barkas, 202-250-8880, barkas.jessica@epa.gov

If you believe all of the information you have claimed as CBI is exempt from substantiation under TSCA section 14(c)(2) or has been previously substantiated, select the following "Substantiation Opt Out" checkbox and provide a detailed explanation why you believe substantiation is not required.

☐ Substantiation Opt-Out

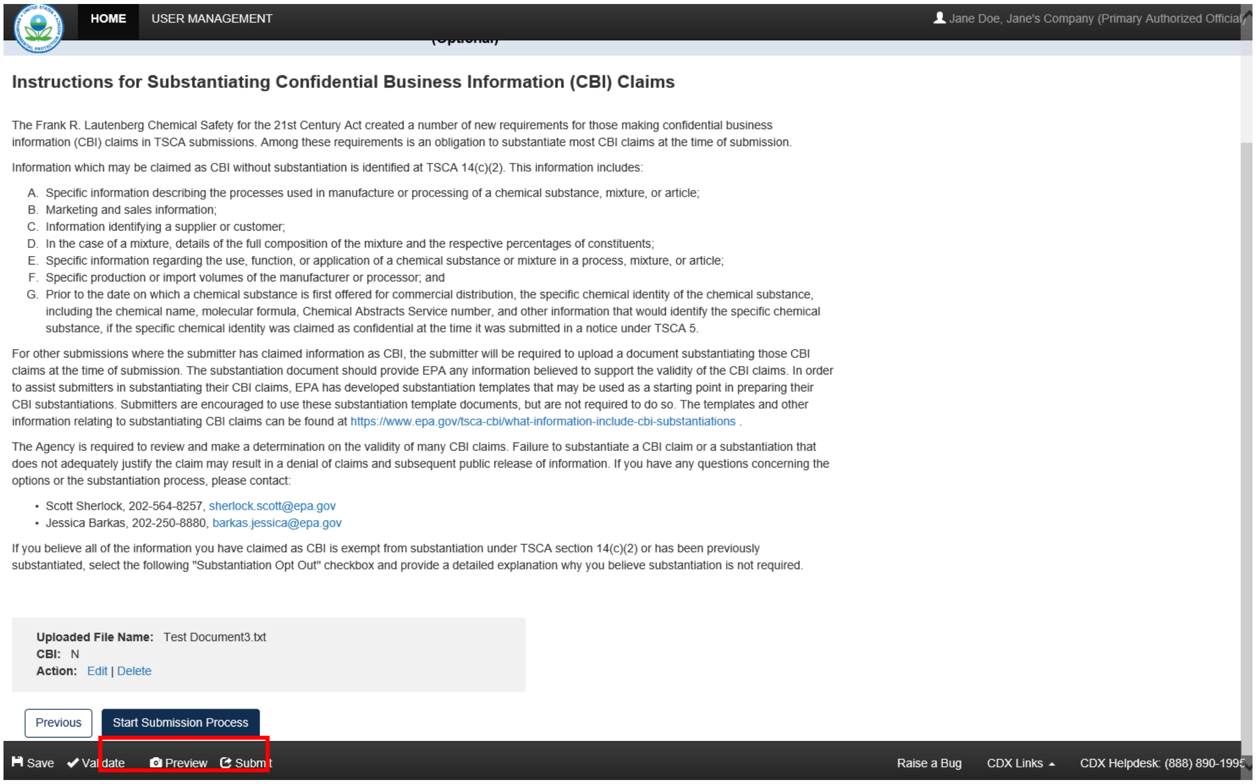
Attach Document for CBI Substantiation

Previous Start Submission Process

Save Validate Preview Submit Raise a Bug CDX Links CDX Helpdesk: (888) 890-1995

Exhibit 7-24 shows a screen capture of the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen (Scroll 3):

Exhibit 7-24 EPA Initiated Risk Evaluation – Instructions for Substantiating Confidential Business Information (CBI) Claims Screen (Scroll 3)



Navigation: Click the ‘Start Submission Process’ button to begin the submission process.

7.10 Attach Documents for CBI Substantiation

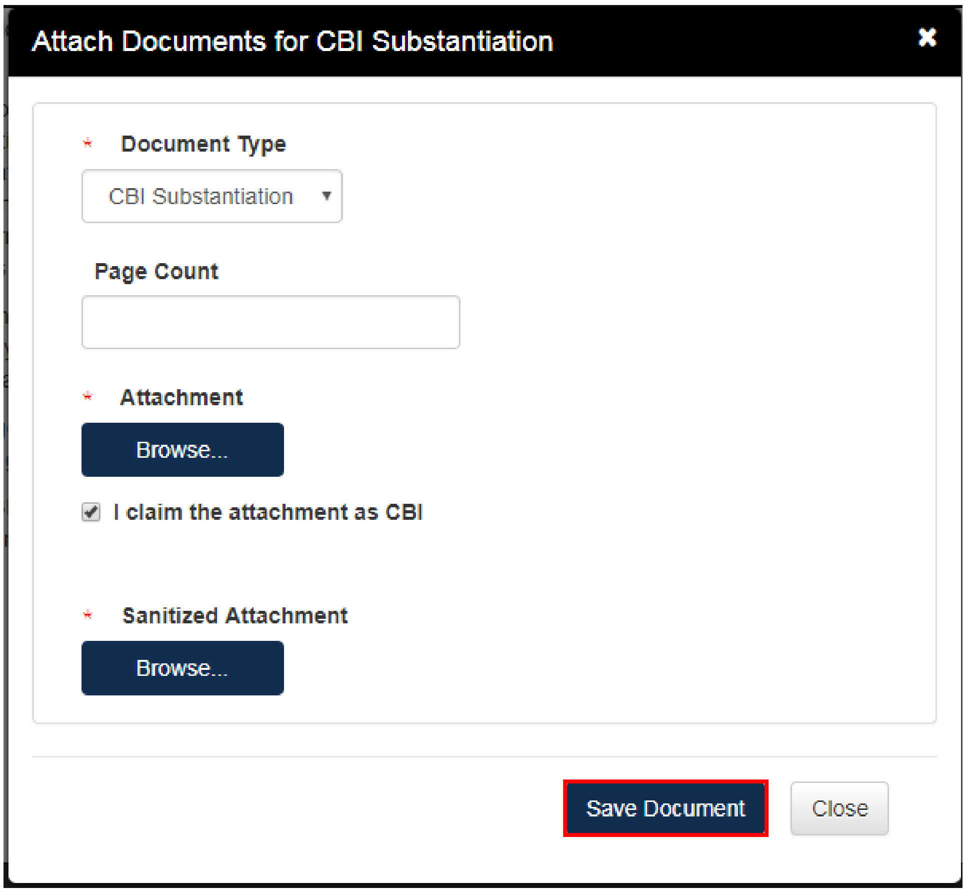
You can access the ‘Attach Documents for CBI Substantiation’ window by clicking the ‘Attach Document for CBI Substantiation’ link within the ‘Instructions for Substantiating Confidential Business Information (CBI) Claims’ screen.

- **Document Type:** ‘CBI Substantiation’ is stored in the ‘Document Type’ drop-down menu.
- **Page Count:** Enter the number of pages in the attached document.
- **Attachment:** Click the ‘Browse’ button to search for and select a document to attach. This is a required field.
- **I claim the attachment as CBI:** Check the ‘I claim the attachment as CBI’ checkbox to claim the document as confidential.

- **Sanitized Attachment:** Click the 'Browse' button to search for and select a sanitized document to attach. This is a required field, if it displays.
- **Save Document:** Click the 'Save Document' button to save the uploaded CBI substantiation document(s).
- **Close:** Click the 'Close' button to close the 'Attach Documents for CBI Substantiation' window without saving any uploaded attachment information.

Exhibit 7-25 shows a screen capture of the 'Attach Documents for CBI Substantiation' window:

Exhibit 7-25 EPA Initiated Risk Evaluation – Attach Documents for CBI Substantiation Window



Navigation: Click the 'Save Document' button to upload the substantiation document and navigate back to the 'Instructions for Substantiating Confidential Business Information (CBI) Claims' screen.

8 Preview

The system provides the option to preview a form during the submission process. Click the ‘Preview’ link, located within the bottom action bar, to preview a PDF file of the regular or sanitized version of the form. After you choose either the ‘Regular’ or ‘Sanitized’ PDF, the application generates a watermarked PDF draft of the form.

The watermark reads ‘Not For Submission’ and displays across each page in the background. The form preview displays the entire form in a printable format. The preview functionality provides the flexibility to track the status of the form and see the entire form in a single viewpoint.

Exhibit 8-1 shows a screen capture for the ‘Preview Risk Evaluation’ PDF:

Exhibit 8-1 Preview Risk Evaluation PDF

NON-CBI SUBMISSION

RISK EVALUATION	Submission Date:	
	Revised Date:	

Part I - Submitter Information

Submitter Information	Name of Authorized Official	Mailing Address	CBI
	Company Name	City, State, Zip	
		,	
	Position		
Contact	Contact	Address	CBI
	Company Name	City, State, Zip, Country	
		, , United States	
	Telephone Number	Email Address	
	Position		
United States Agent	Contact	Address	CBI
	Company Name	City, State, Zip	
	Telephone Number	Email Address	
	Position		

9 Validate

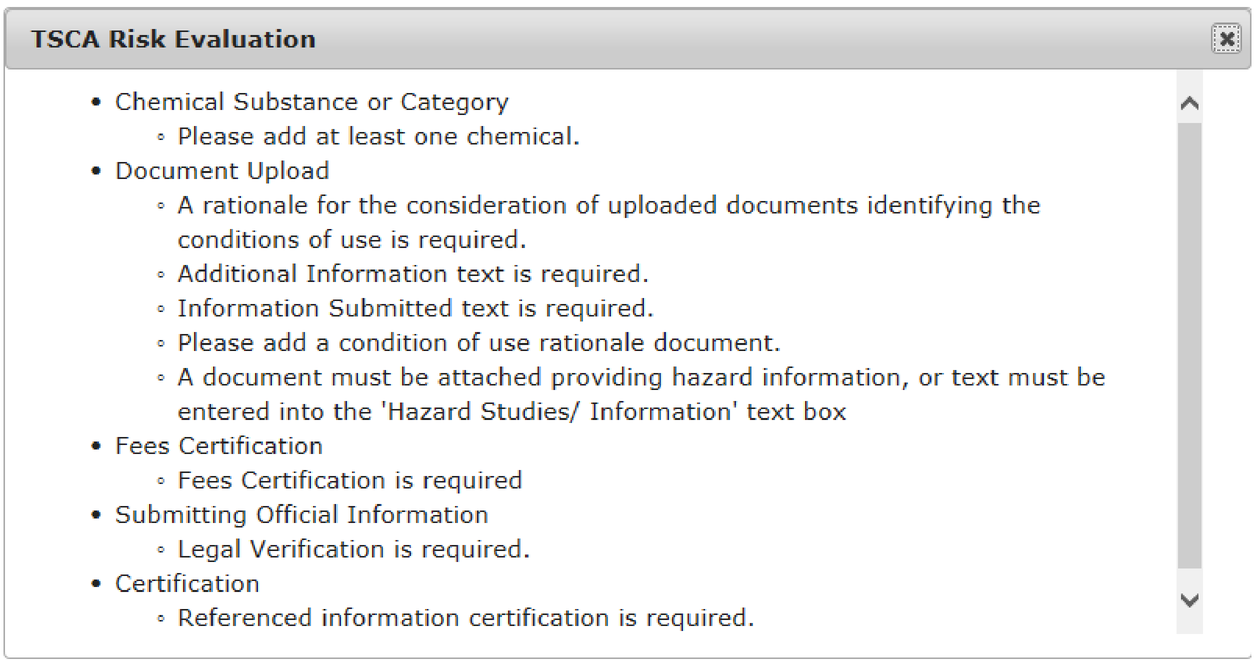
You can click the 'Validate' link located within the bottom action bar at any stage of completing a Risk Evaluation request. The 'TSCA Risk Evaluation' window displays when you click the 'Validate' link. Disable the pop-up blocker within your internet browser so that the 'TSCA Risk Evaluation' window displays correctly. The 'TSCA Risk Evaluation' window displays a report of all validation errors. During the validation process, the application validates each screen of the Risk Evaluation request to find missing and invalid data.

Validation Errors: Errors can be fixed by clicking the error link. The links will display the *Screen Title Name* (e.g., Chemical Substance or Category) and the associated error. After you click a link, the main application screen will display the section where the error occurred so you can easily fix the error. Once you have fixed the error(s), click the 'Validate' link again to refresh the 'TSCA Risk Evaluation' window. If the information you fixed passes validation, the error will be removed from the 'TSCA Risk Evaluation' window. You must fix all validation errors to submit the form to CDX successfully.

Click the 'X' button, located at the upper right-hand corner of the window, to close the 'TSCA Risk Evaluation' window.

Exhibit 9-1 shows a screen capture for the 'TSCA Risk Evaluation Validation' window:

Exhibit 9-1 TSCA Risk Evaluation Validation Window



10 Submit to EPA via CDX

As a Primary AO, you have the ability to sign and submit a Risk Evaluation request to EPA via CDX. You can save your form at any point during the data entry process. Any assigned Supports for your form cannot submit the Risk Evaluation request. The save functionality will allow you to return to that same form at any point in the future.

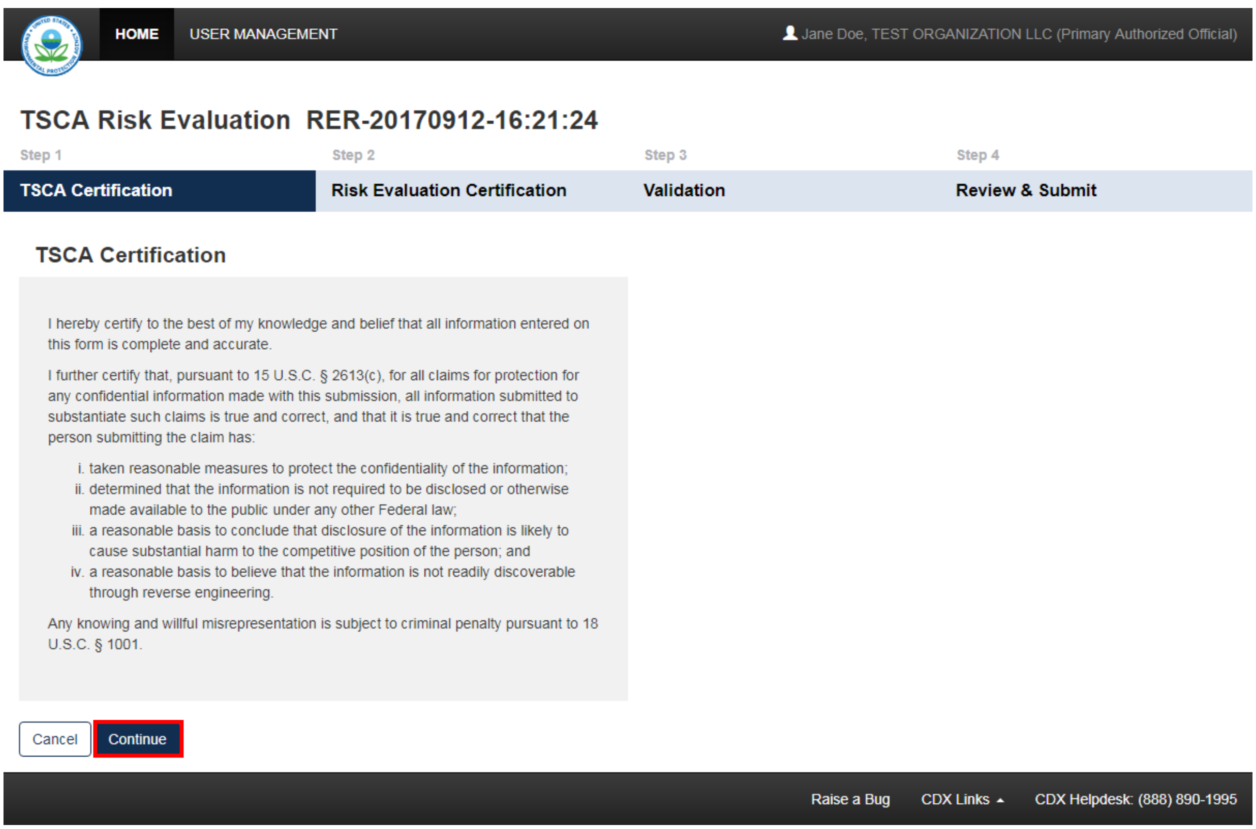
Once you complete all required information and correct all items failing validation, the system will allow the Risk Evaluation request to be successfully submitted.

10.1 TSCA Certification

Click the 'Start Submission Process' button from the 'Submission of Referenced Information' screen if there are no CBI claims, or the 'Instructions for Substantiating Confidential Business Information (CBI) Claims' screen if there are CBI claims, to access the 'TSCA Certification' screen.

Exhibit 10-1 shows a screen capture of the 'TSCA Certification' screen:

Exhibit 10-1 TSCA Certification Screen



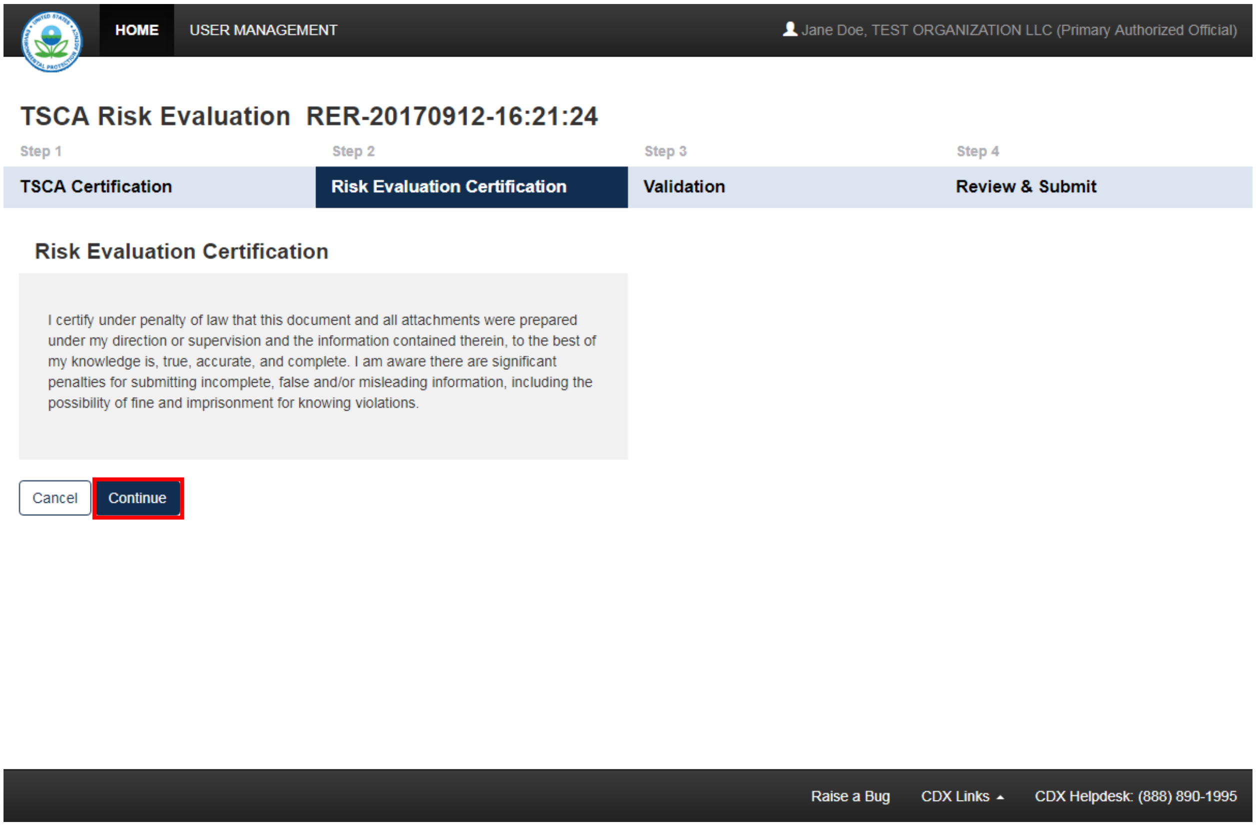
Navigation: Click the ‘Continue’ button to certify regarding the contents of the form and navigate to the ‘Risk Evaluation Certification’ screen.

10.2 Risk Evaluation Certification

Click the ‘Continue’ button from the ‘TSCA Certification’ screen to access the ‘Risk Evaluation Certification’ screen.

Exhibit 10-2 shows a screen capture of the ‘Risk Evaluation Certification’ screen:

Exhibit 10-2 Risk Evaluation Certification Screen



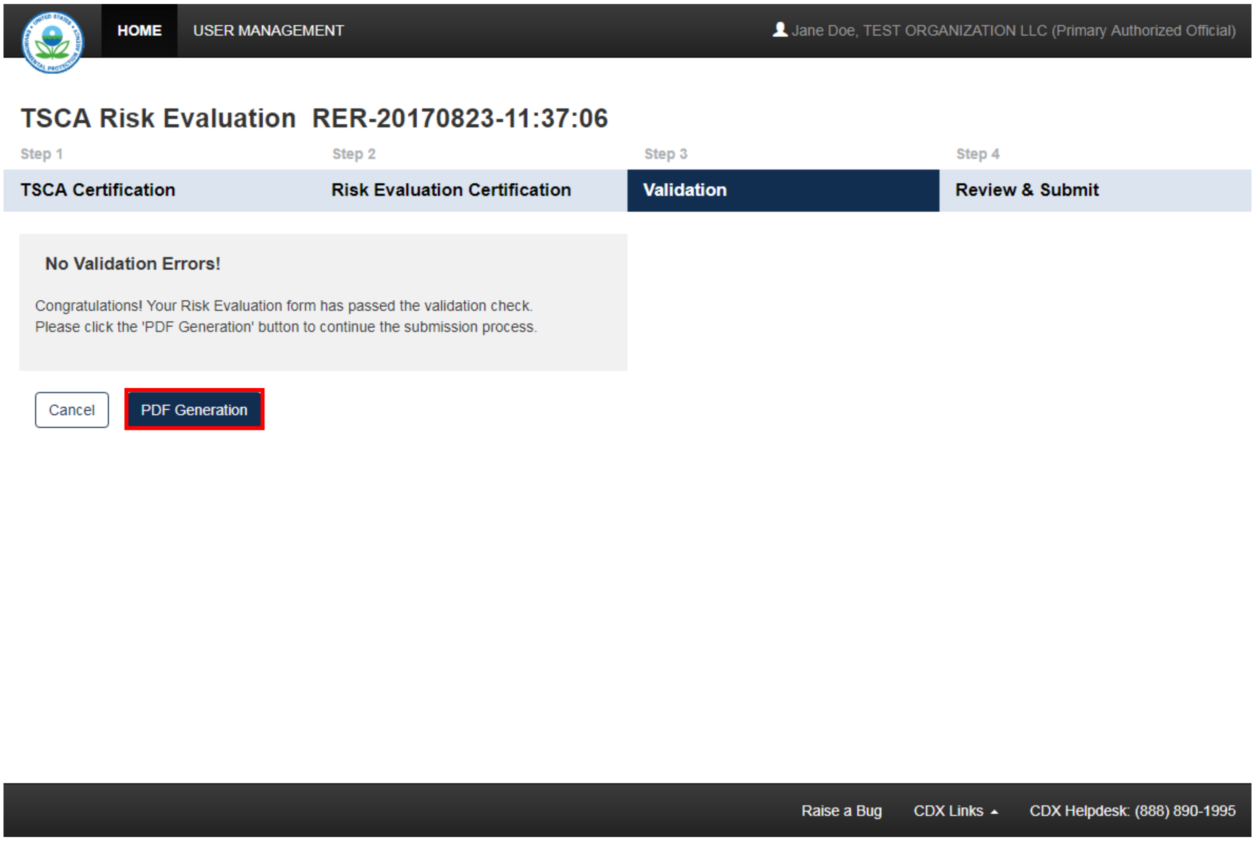
Navigation: Click the ‘Continue’ button to navigate to the ‘Validation’ screen.

10.3 Validation

Click the ‘Continue’ button from the ‘Risk Evaluation Certification’ screen to access the ‘Validation’ screen.

Exhibit 10-3 shows a screen capture of the ‘Validation’ screen:

Exhibit 10-3 Validation Screen



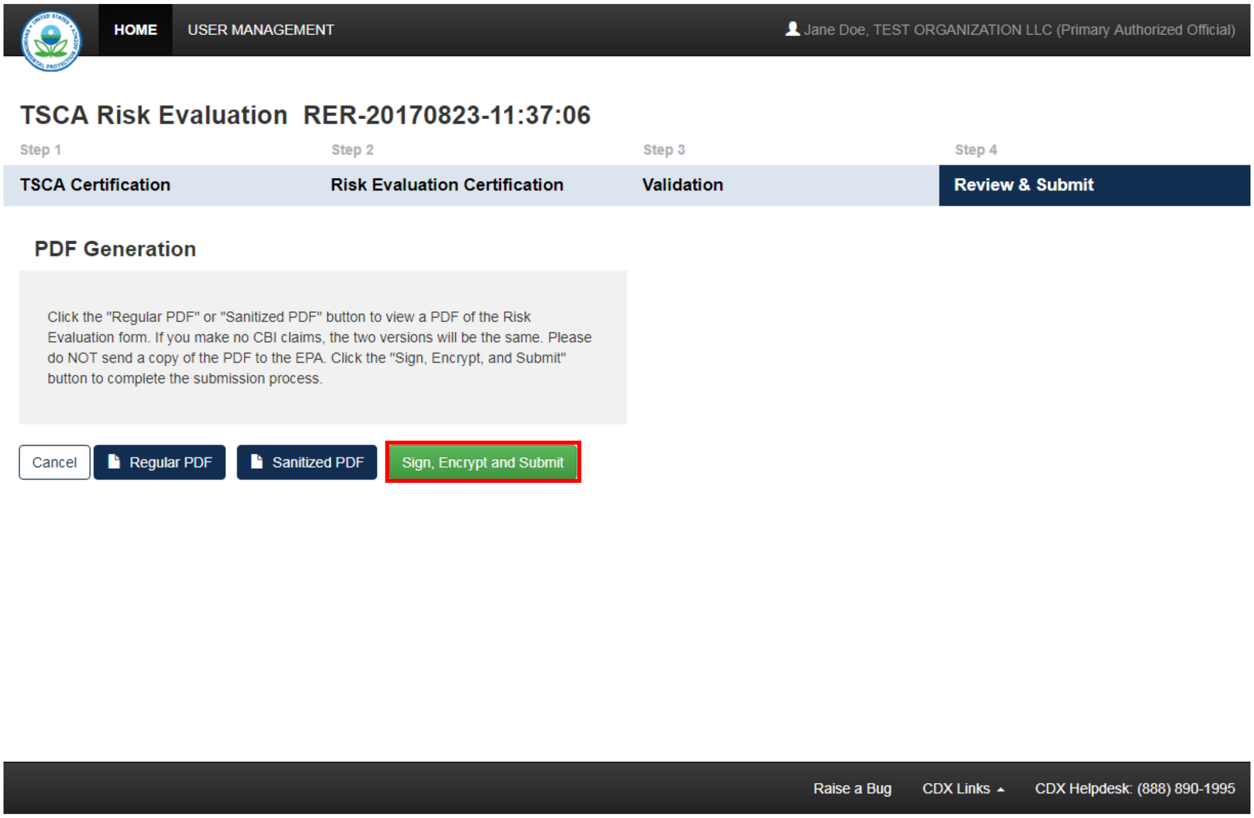
Navigation: Click the ‘PDF Generation’ button to navigate to the ‘PDF Generation’ screen.

10.4 Risk Evaluation PDF Generation

Click the ‘PDF Generation’ button from the ‘Validation’ screen to access the ‘PDF Generation’ screen.

Exhibit 10-4 shows a screen capture of the ‘PDF Generation’ screen:

Exhibit 10-4 PDF Generation Screen



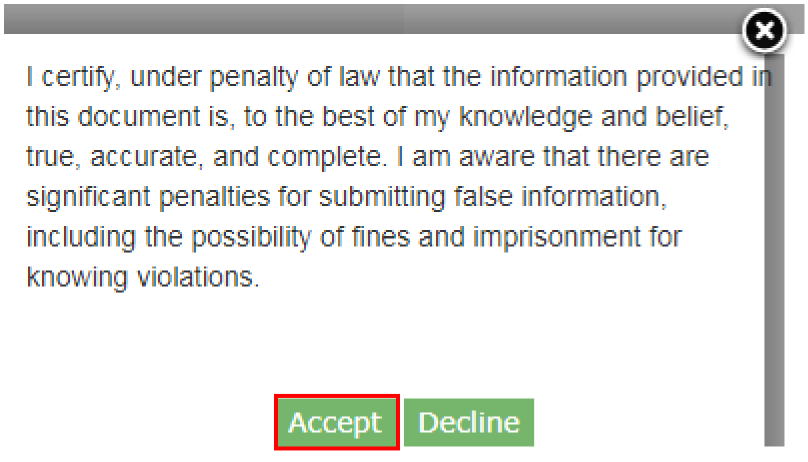
Navigation: Click the ‘Regular PDF’ button to generate a regular version of the Risk Evaluation PDF. Click the ‘Sanitized PDF’ button to generate a sanitized version of the Risk Evaluation PDF. Click the ‘Sign, Encrypt and Submit’ button to begin the CROMERR certification process.

10.5 CROMERR Certification

Click the ‘Sign, Encrypt and Submit’ button from the ‘PDF Generation’ screen to generate the ‘CROMERR Certification’ window.

Exhibit10-5 shows a screen capture of the ‘CROMERR Certification’ window:

Exhibit10-5 CROMERR Certification Window



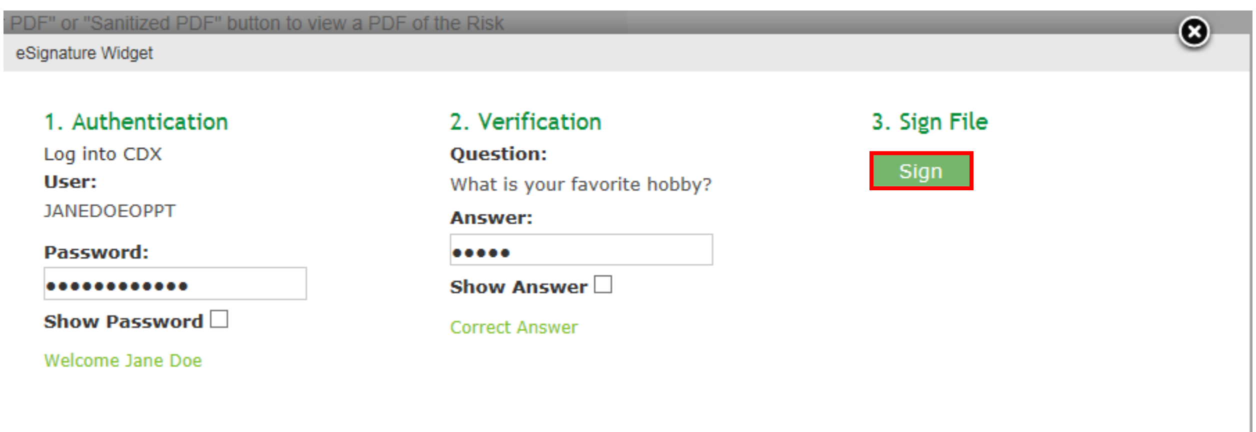
Navigation: Click the 'Accept' button to agree to the certification statement and generate the 'eSignature Widget.'

10.6 eSignature Widget

Click the 'Accept' button on the 'CROMERR Certification' window to accept the certification statement and generate the 'eSignature Widget.' The 'eSignature Widget' will prompt for the CDX login password and an answer to one of your security questions. Click the 'Sign' button on the 'eSignature Widget' to navigate to the 'Submission Finished' screen.

Exhibit 10-6 shows a screen capture of the 'eSignature Widget' window:

Exhibit 10-6 eSignature Widget Window



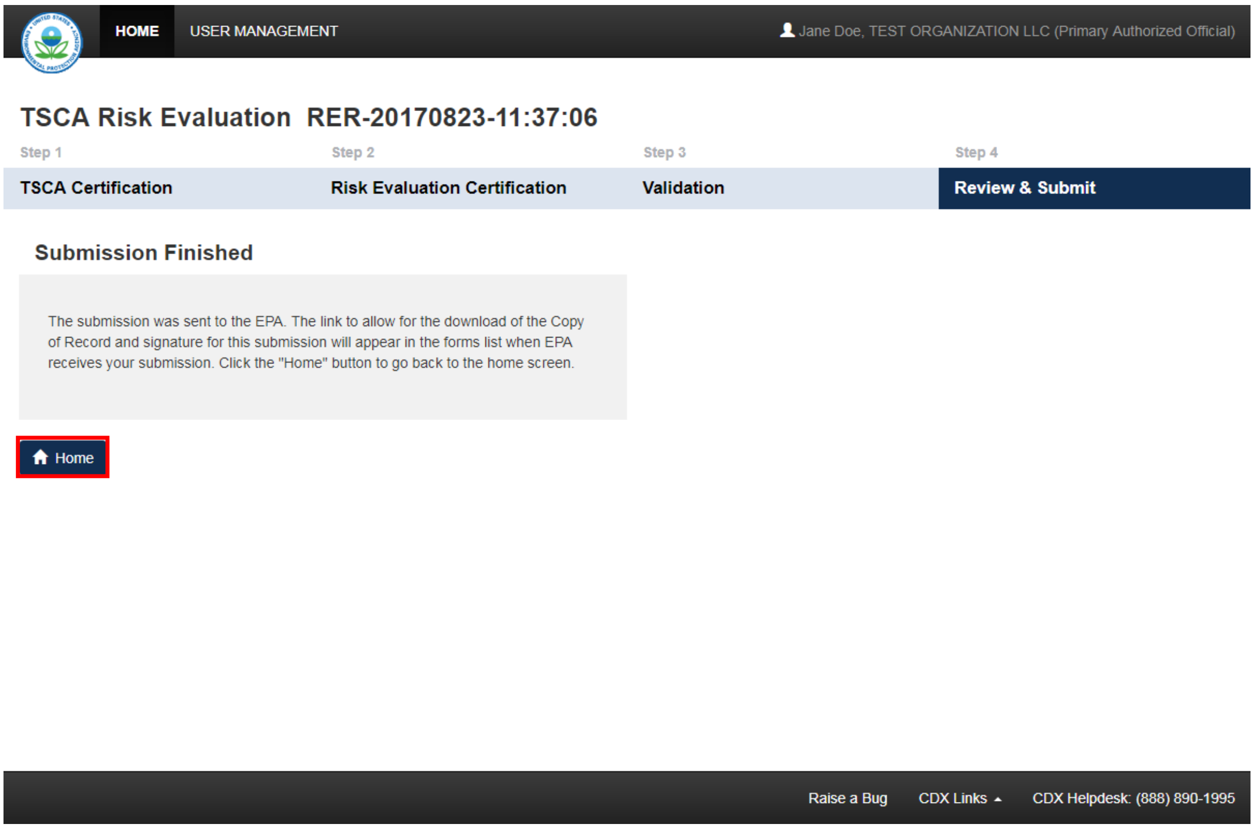
Navigation: Click the 'Sign' button on the 'eSignature Widget' to navigate to the 'Submission Finished' screen.

10.7 Submission Finished

Click the 'Sign' button on the 'eSignature Widget' to navigate to the 'Submission Finished' screen.

Exhibit 10-7 shows a screen capture of the 'Submission Finished' screen:

Exhibit 10-7 Submission Finished Screen



Navigation: Click the 'Home' button to navigate back to the TSCA Risk Evaluation 'Home' screen.

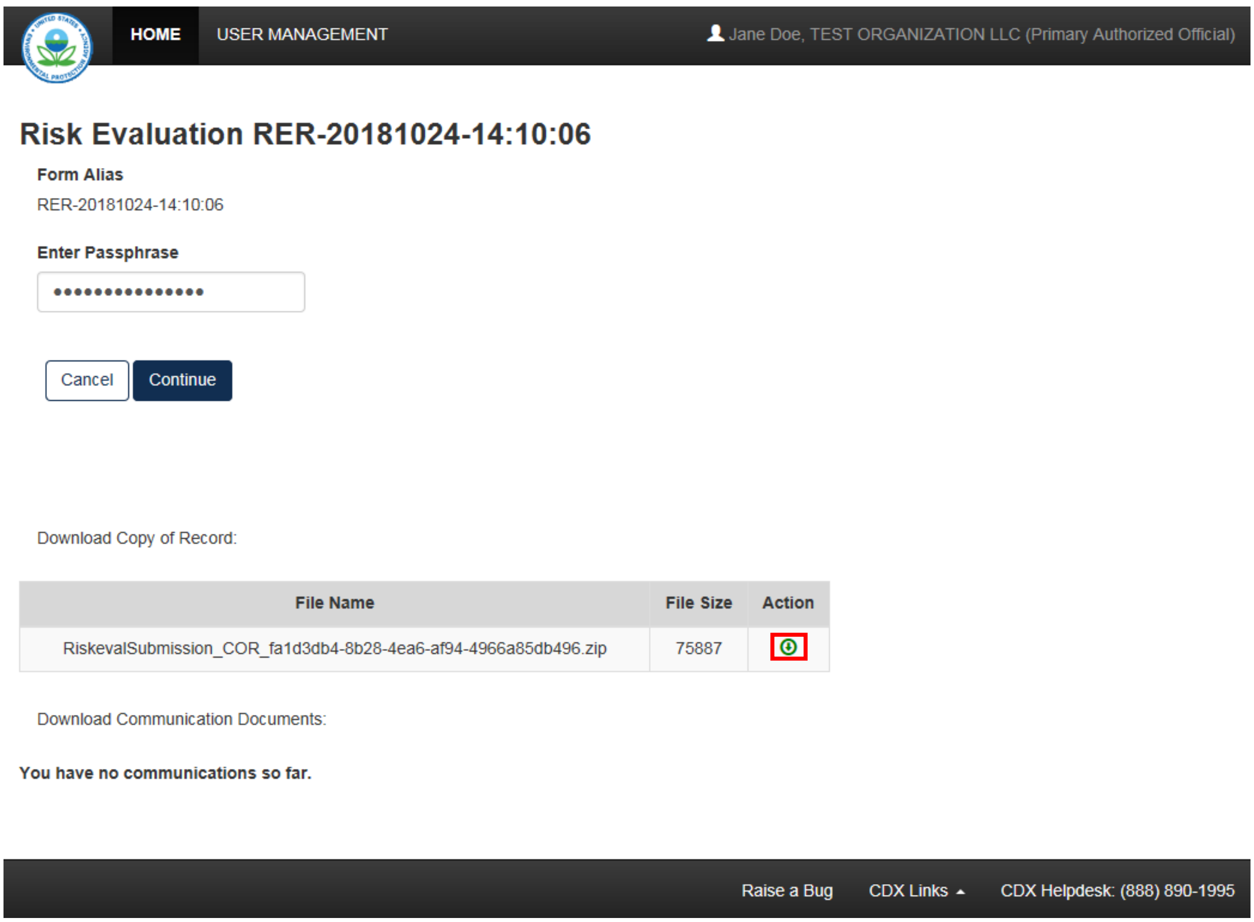
11 Download Copy of Record

To download a Copy of Record, navigate to the Risk Evaluation ‘Home’ screen and locate a form alias for which you have successfully completed a submission and which has a status of ‘Completed.’

Click the ‘Copy of Record’ icon ( ) from the ‘Submission History’ section of the Risk Evaluation ‘Home’ screen to navigate to the ‘Enter Passphrase’ screen to login into CDX. The ‘Enter Passphrase’ screen requires you to enter the passphrase originally associated with the form. If the passphrase is entered correctly, you will view the ‘CROMERR Certification’ message where you can acknowledge the certification. Once you accept the certification, the ‘eSignature Widget’ displays where you provide the correct CDX password, answer the 20-5-1 question, and click the ‘Sign’ button. The copy of record .zip file generates on the current page.

Exhibit 11-1 shows a screen capture of the ‘Download Copy of Record’ screen:

Exhibit 11-1 Download Copy of Record Screen



The screen displays the ‘File Name,’ ‘File Size,’ and ‘Action’ columns in a table format. The screen also displays a section for communication documents. Click the ‘Copy of Record’ icon ( ) to automatically download the .zip file containing the individual regular and sanitized PDFs.

12 EPA Communications

EPA may send electronic communications related to specific CDX submissions. In the event EPA sends an electronic communication, the original submitter will receive a notification to both their registered email address and inbox within CDX. The notification will inform the user that there is a new, submission-specific communication available from EPA. Example of EPA communications include a Notice of Deficiency or an Invoice.

Exhibit 12-1 shows a screen capture of a sample Notice of Deficiency (Email Notification) from CDX:

Exhibit 12-1 New EPA Communication Email Notification

Thu 10/25/2018 12:38 PM

noreply@epacdx.net

Notice of Deficiency for CBI Claims or a Generic Chemical Name in a TSCA Submission from U.S. EPA

To

Date: 10/25/2018 12:38:22

You have received a new Notice of Deficiency Concerning CBI Claims or a Generic Chemical Name in a TSCA Submission communication in your CDX account from the U.S. EPA related to CDX transactionId: _ccc0c206-d7ac-46bb-b0a8-ccded89f3b13.

If you can identify your TSCA submission using this CDX transaction ID, originally provided with the 'Copy of Record' XML file, you can use this identifier to quickly access the communication by following these steps:

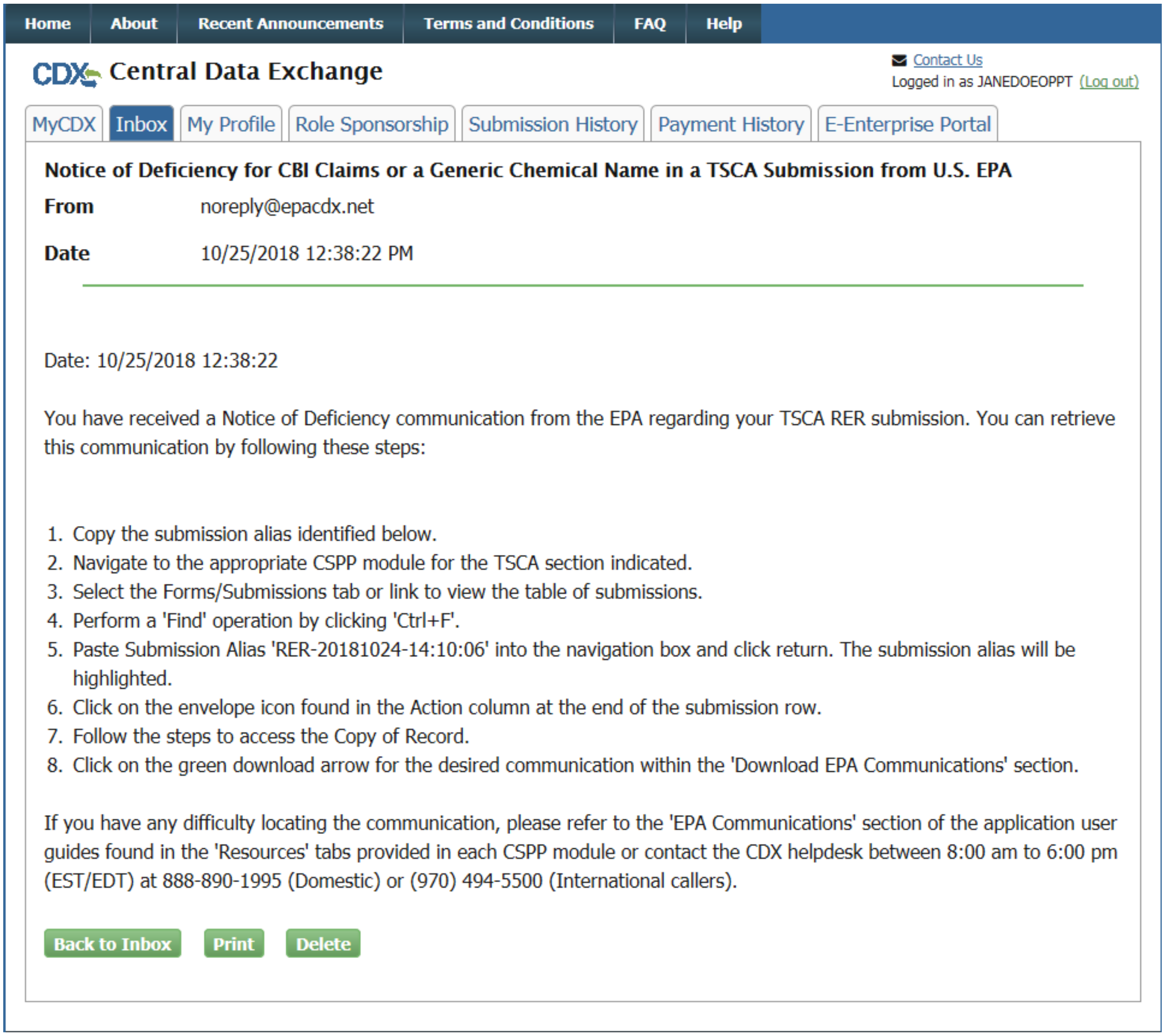
1. Log into CDX.
2. Navigate to the appropriate CSPP module for the submission related to CDX transactionId: _ccc0c206-d7ac-46bb-b0a8-ccded89f3b13. You will need to know the submission type related to previously referenced transactionID before selecting the CSPP module.
3. Select the Forms/Submissions tab or link to view the table of submissions.
4. Locate the submission related to CDX transactionId: _ccc0c206-d7ac-46bb-b0a8-ccded89f3b13. Performing a 'Find' operation by clicking 'Ctrl+F' and entering either the related case number or submission alias is an easy way to locate the submission if you have many in your table.
5. After you locate the related submission, click on the envelope icon found in the Action column at the end of the submission row.
6. Follow the steps to access the Copy of Record.
7. Click on the green download arrow for the desired communication within the 'Download EPA Communications' section.

If you cannot identify your submission using this CDX transaction ID, you can obtain more information about how to access this communication by following these steps:

1. Log into CDX.
2. Click on the 'Inbox' tab from your 'My CDX Screen' from your 'My CDX Screen'.
3. Search your CDX inbox for a message with the same subject line as this email. This message will provide additional instructions for accessing the Notice of Deficiency communication.

Exhibit 12-2 shows a screen capture of a sample CDX Inbox Notification:

Exhibit 12-2 New EPA Communication CDX Inbox Notification


Home | About | Recent Announcements | Terms and Conditions | FAQ | Help

CDX Central Data Exchange

Contact Us
Logged in as JANEDOEOPPT (Log out)

MyCDX | Inbox | My Profile | Role Sponsorship | Submission History | Payment History | E-Enterprise Portal

Notice of Deficiency for CBI Claims or a Generic Chemical Name in a TSCA Submission from U.S. EPA

From noreply@epacdx.net

Date 10/25/2018 12:38:22 PM

Date: 10/25/2018 12:38:22

You have received a Notice of Deficiency communication from the EPA regarding your TSCA RER submission. You can retrieve this communication by following these steps:

1. Copy the submission alias identified below.
2. Navigate to the appropriate CSPP module for the TSCA section indicated.
3. Select the Forms/Submissions tab or link to view the table of submissions.
4. Perform a 'Find' operation by clicking 'Ctrl+F'.
5. Paste Submission Alias 'RER-20181024-14:10:06' into the navigation box and click return. The submission alias will be highlighted.
6. Click on the envelope icon found in the Action column at the end of the submission row.
7. Follow the steps to access the Copy of Record.
8. Click on the green download arrow for the desired communication within the 'Download EPA Communications' section.

If you have any difficulty locating the communication, please refer to the 'EPA Communications' section of the application user guides found in the 'Resources' tabs provided in each CSPP module or contact the CDX helpdesk between 8:00 am to 6:00 pm (EST/EDT) at 888-890-1995 (Domestic) or (970) 494-5500 (International callers).

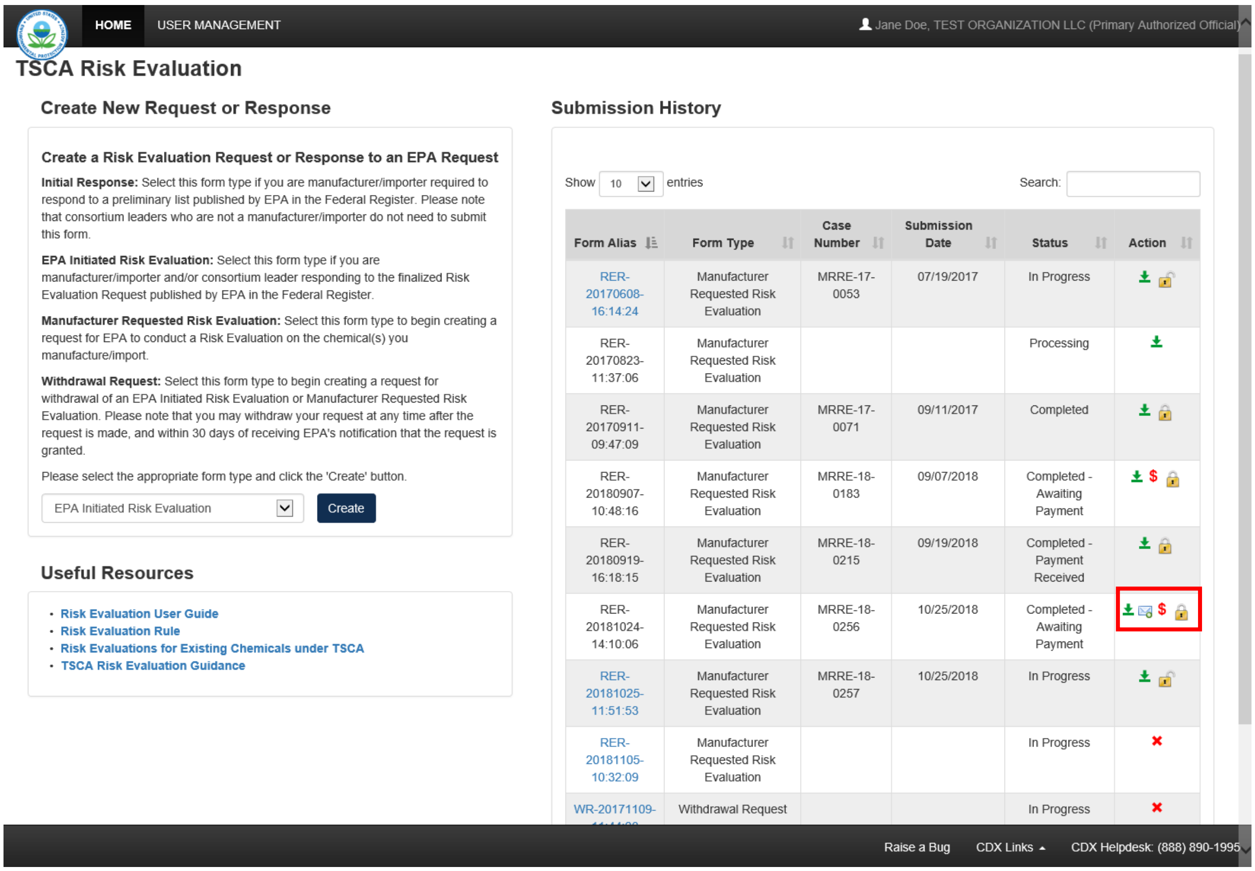
Back to Inbox | Print | Delete

Users can access EPA communications by logging into CDX and navigating to the CSPP application to which a communication applies. Within the Risk Evaluation Request application, users should navigate to the TSCA Risk Evaluation 'Home' screen, to access EPA communications. A 'Closed Envelope' icon () appears under the 'Action' column for a submission that contains a new EPA communication, and an 'Open Envelope' icon () displays for a submission that contains a previously downloaded EPA communication. To access a communication, click either the 'Closed Envelope,' 'Open Envelope,' or 'Copy of Record' icon. To ensure EPA communications are not improperly viewed, access to EPA communications is restricted to users who may access the copy of record for a submission. Additionally, EPA captures and stores CDX user and timestamp data each time an EPA communication is accessed.

Users can also access the invoice sent by personnel on the TSCA Risk Evaluation Home' screen. A red 'Unpaid Invoice' icon ($) appears within the 'Action column for a submission that is awaiting payment. The invoice icon no longer appears after an invoice has been paid.

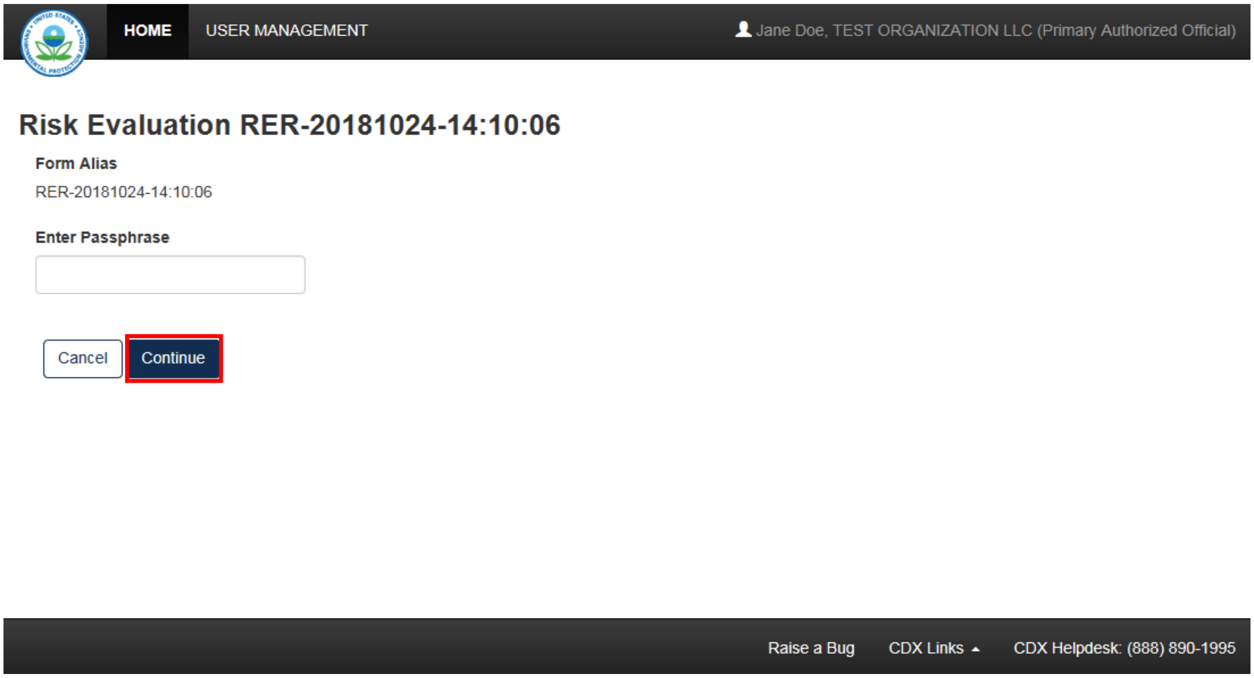
Exhibit 12-3 shows a screen capture of the TSCA Risk Evaluation 'Home' screen:

Exhibit 12-3 TSCA Risk Evaluation Home Screen



Navigation: Click the 'Copy of Record' or 'Unpaid Invoice' icon to navigate to the 'Enter Passphrase' screen.Exhibit 12-4 shows a screen capture of the 'Enter Passphrase' screen:

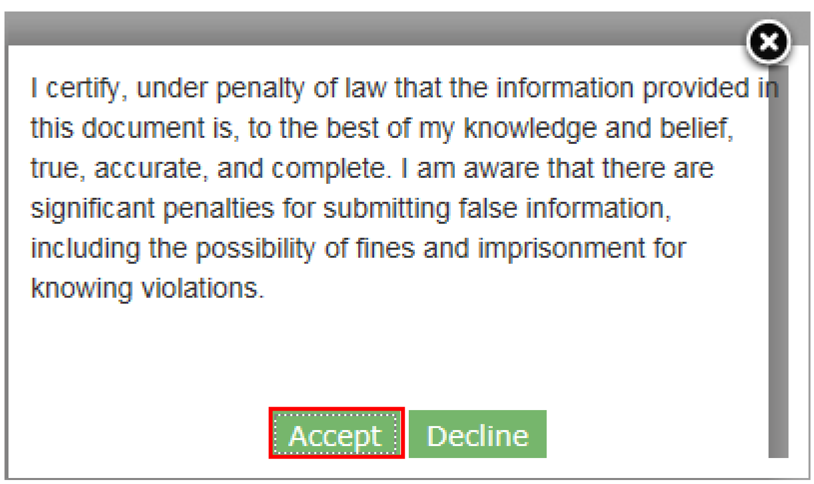
Exhibit 12-4 Enter Passphrase Screen



Navigation: Enter the passphrase associated to this submission and click the 'Continue' button to generate the 'CROMERR Certification' window.

Exhibit 12-5 shows a screen capture of the 'CROMERR Certification' window:

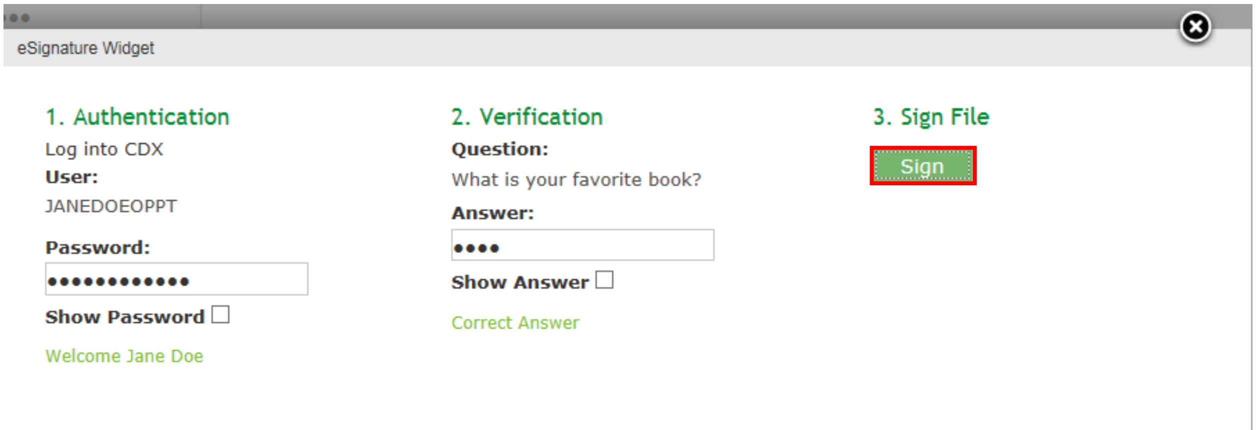
Exhibit 12-5 Cross-Media Electronic Reporting Regulation (CROMERR) Certification Window



Navigation: Click the ‘Accept’ button to generate the ‘eSignature Widget’ window.

Exhibit 12-6 shows a screen capture of the ‘eSignature Widget’ window:

Exhibit 12-6 eSignature Widget



Navigation: Click the ‘Sign’ button on the ‘eSignature Widget’ window to navigate to the ‘Download Copy of Record page.

The ‘Download Communication Documents’ table is located in the middle of the ‘Download Copy of Record’ screen and displays EPA communications associated with all versions of the selected submission. The ‘Download Communication Documents’ table includes the following columns of information:

- **Communication Type:** Displays the type of EPA communication.
- **File Name:** Displays the file name of the EPA communication.
- **File Size:** Displays the file size of the EPA communication.
- **Status:** Displays the status of the EPA communication. The ‘Closed Envelope’ icon ( ) indicates an un-accessed EPA communication, and the ‘Open Envelope’ icon ( ) indicates an accessed EPA communication.
- **Download:** Click the ‘Download’ icon ( ) to download an EPA communication. The communication file downloads as a PDF.

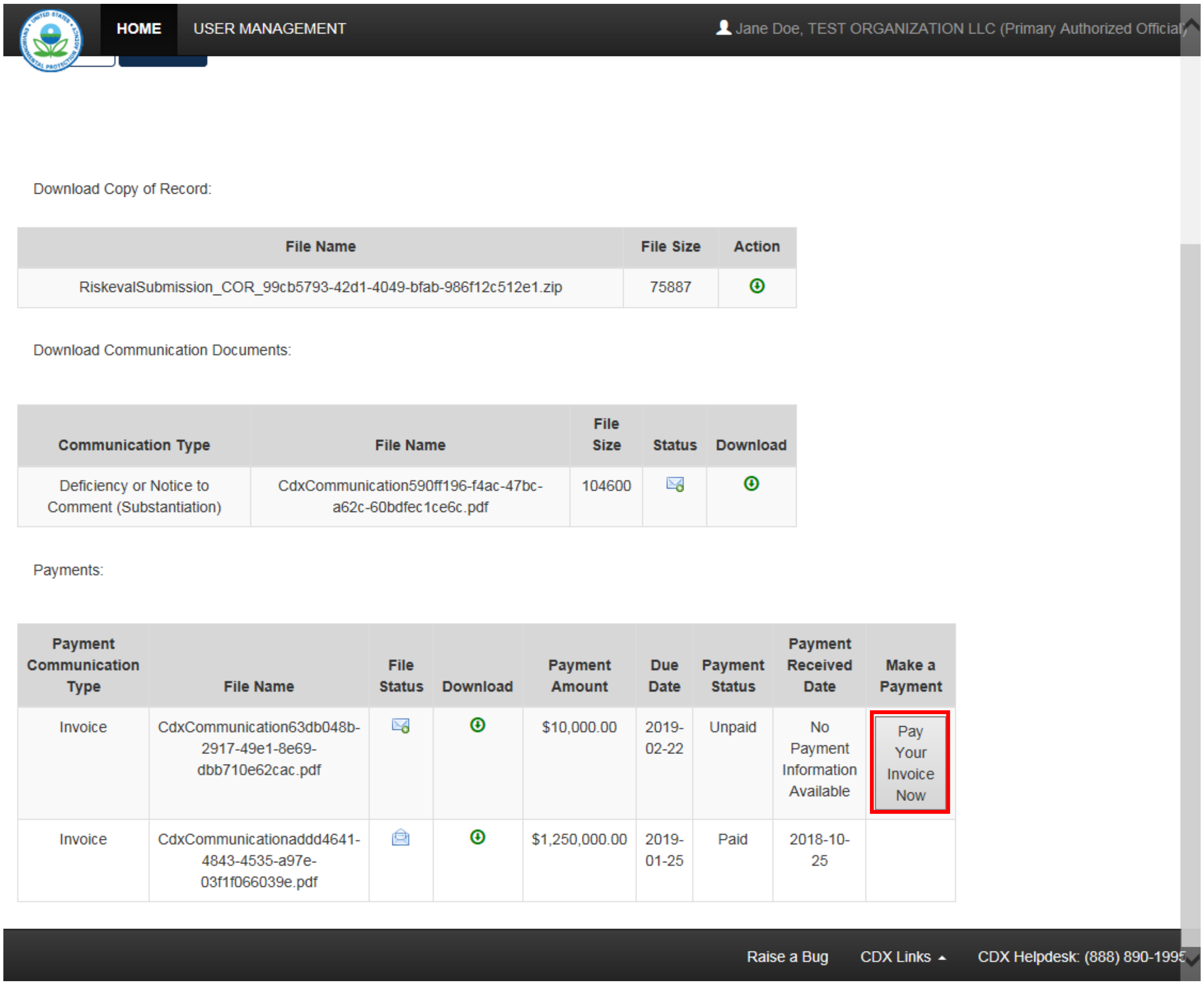
The ‘Payments’ table is located at the bottom of the ‘Download Copy of Record’ screen and displays invoices sent to a Risk Evaluation Request. The ‘Payments’ table displays ‘Payment Communication Type,’ ‘File Name,’ ‘File Status,’ ‘Download,’ ‘Payment Amount,’ ‘Due Date,’ ‘Payment Status,’ Payment Received Date,’ and Make a Payment’ columns.

- **Payment Communication Type:** Displays ‘Invoice’ or ‘Cancelled Invoice.’
- **File Name:** Displays the file name of the fee invoice PDF.

- **File Status:** Displays an icon that indicates the status of the invoice; a closed envelope icon displays with a status of ‘New Communication Documents’ when a user initially accesses the ‘Download Copy of Record’ page.
- **Download:** Displays a green arrow for a user to download the invoice PDF.
- **Payment Amount:** Displays the amount of the invoice.
- **Due Date:** Displays the invoice due date.
- **Payment Status:** Displays the status of the payment; i.e. ‘Unpaid,’ ‘Payment Received,’ or ‘Invoice Cancelled.’ The status displays ‘Invoice Cancelled’ if an invoice has been cancelled by EPA personnel.
- **Payment Received Date:** Displays the date of payment, if the invoice has been paid. ‘No Payment Information Available’ displays if an invoice is unpaid
- **Make a Payment:** Displays a ‘Pay Your Invoice Now’ button; click the ‘Pay Your Invoice Now’ button to generate the ‘CSPP Payment Processor’ window to remit a payment to the invoice. The ‘Pay Your Invoice Now’ button is not displayed if a user has paid the invoice or the invoice was cancelled.

Exhibit 12-7 shows a screen capture of the ‘Download Copy of Record’ screen:

Exhibit 12-7 Download Copy of Record Screen


HOME USER MANAGEMENT

Jane Doe, TEST ORGANIZATION LLC (Primary Authorized Official)

Download Copy of Record:

File Name	File Size	Action
RiskevalSubmission_COR_99cb5793-42d1-4049-bfab-986f12c512e1.zip	75887	

Download Communication Documents:

Communication Type	File Name	File Size	Status	Download
Deficiency or Notice to Comment (Substantiation)	CdxCommunication590ff196-f4ac-47bc-a62c-60bdfec1ce6c.pdf	104600		

Payments:

Payment Communication Type	File Name	File Status	Download	Payment Amount	Due Date	Payment Status	Payment Received Date	Make a Payment
Invoice	CdxCommunication63db048b-2917-49e1-8e69-dbb710e62cac.pdf			$10,000.00	2019-02-22	Unpaid	No Payment Information Available	Pay Your Invoice Now
Invoice	CdxCommunicationaddd4641-4843-4535-a97e-03f1f066039e.pdf			$1,250,000.00	2019-01-25	Paid	2018-10-25	

Raise a Bug CDX Links CDX Helpdesk: (888) 890-1995

Navigation: Click the ‘Download’ icon ( ) under the ‘Download Communication Documents’ table to download an EPA communication file. Click the ‘Pay Your Invoice Now’ button to generate the ‘CSPP Payment Processor’ window.

12.1 CSPP Payment Processor

The ‘CSPP Payment Processor’ window provides functionality for you to remit your fee via debit/credit card or Automatic Clearing House (ACH) payment.

- **Credit/Debit Card:** Select the radio button to display the credit/debit card fields. This option is only available for payment amounts less than or equal to $24,999.99.
- **Payment Amount:** Displays the fee amount the user will be paying.

- **Card Number:** Enter the credit/debit card number. This is a required field.
- **Expiration Date:** Select the month and date of the expiration date of the credit/debit card. This is a required field.
- **Security Code:** Enter the security code/CCV of the credit/debit card. This is a required field.
- **First Name:** Enter the first name of the cardholder. This is a required field.
- **Last Name:** Enter the last name of the cardholder. This is a required field.
- **Billing Address 1:** Enter line 1 of the billing address. This is a required field.
- **Billing Address 2:** Enter line 2 of the billing address, if applicable.
- **City:** Enter the city of the billing address. This is a required field.
- **State:** Select the state of the billing address from the drop-down menu. This is a required field.
- **Zip:** Enter the zip code of the billing address. This is a required field.
- **ACH Payment:** Select the radio button to display the ACH fields.
- **Account Type:** Select 'Business Checking,' 'Business Savings,' 'Personal Checking,' or 'Personal Savings' to indicate the account type that will be used to remit the fee. This is a required field.
- **Check Number:** Enter the check number.
- **Use a Company Name:** Check the check box to generate a 'Company Name' field and pay on behalf of the reporting company's name.
- **Company Name:** Enter the name of the company that is submitting the payment. This is a required field.
- **Routing Number:** Enter the routing number of the bank account. This is a required field.
- **Account Number:** Enter the account number of the bank account. This is a required field.
- **Confirm Account Number:** Re-enter the account number of the bank account. This is a required field.
- **Submit Payment:** Click the button to submit the payment credentials.

Exhibit 12-8 shows a screen capture of the ‘CSPP Payment Processor’ window (ACH Payment):

Exhibit 12-8 CSPP Payment Processor (ACH Payment)

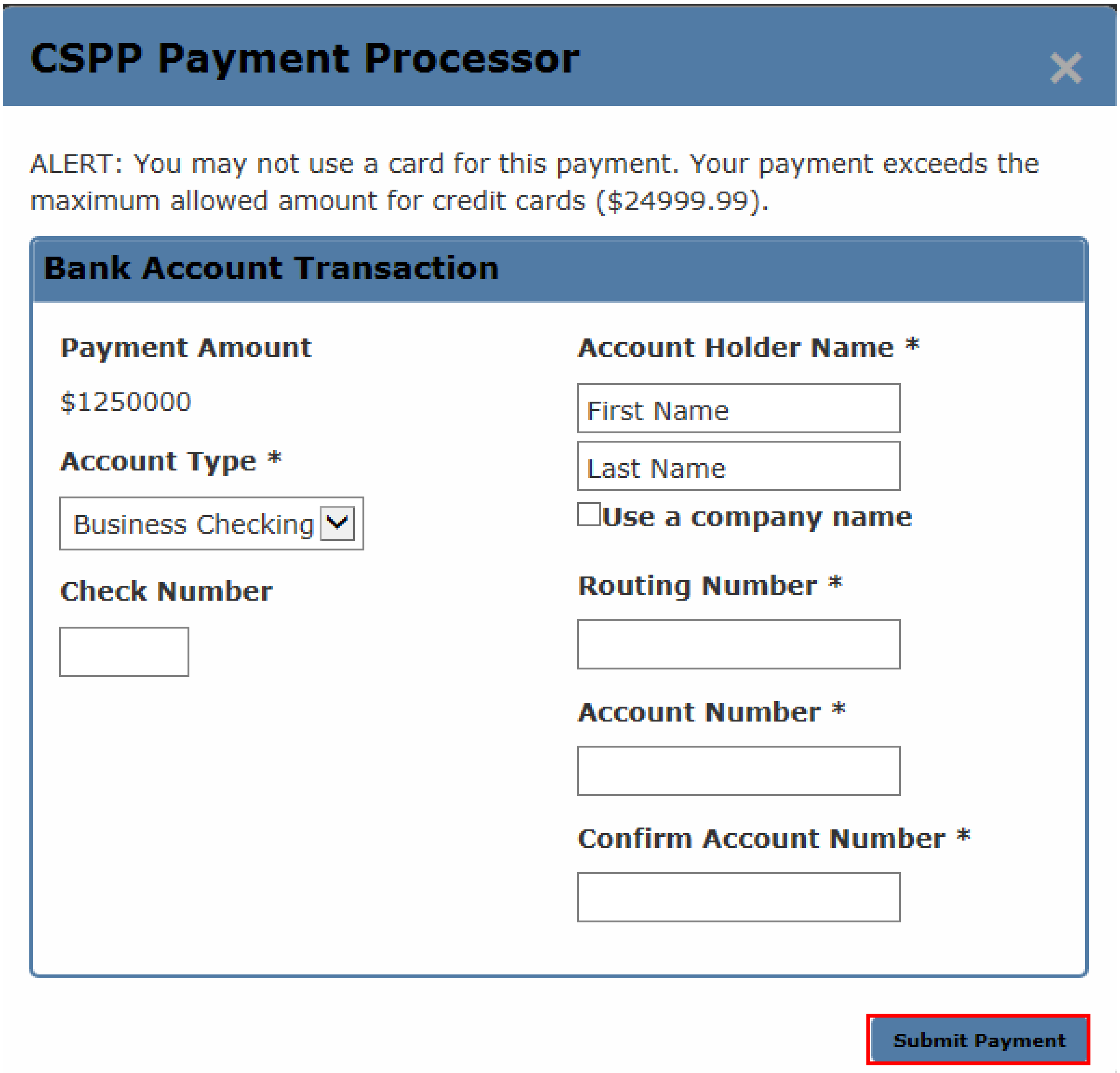


Exhibit 12-9 shows a screen capture of the 'CSPP Payment Processor' window (Credit/Debit Card):

Exhibit 12-9 CSPP Payment Processor (Credit/Debit Card)

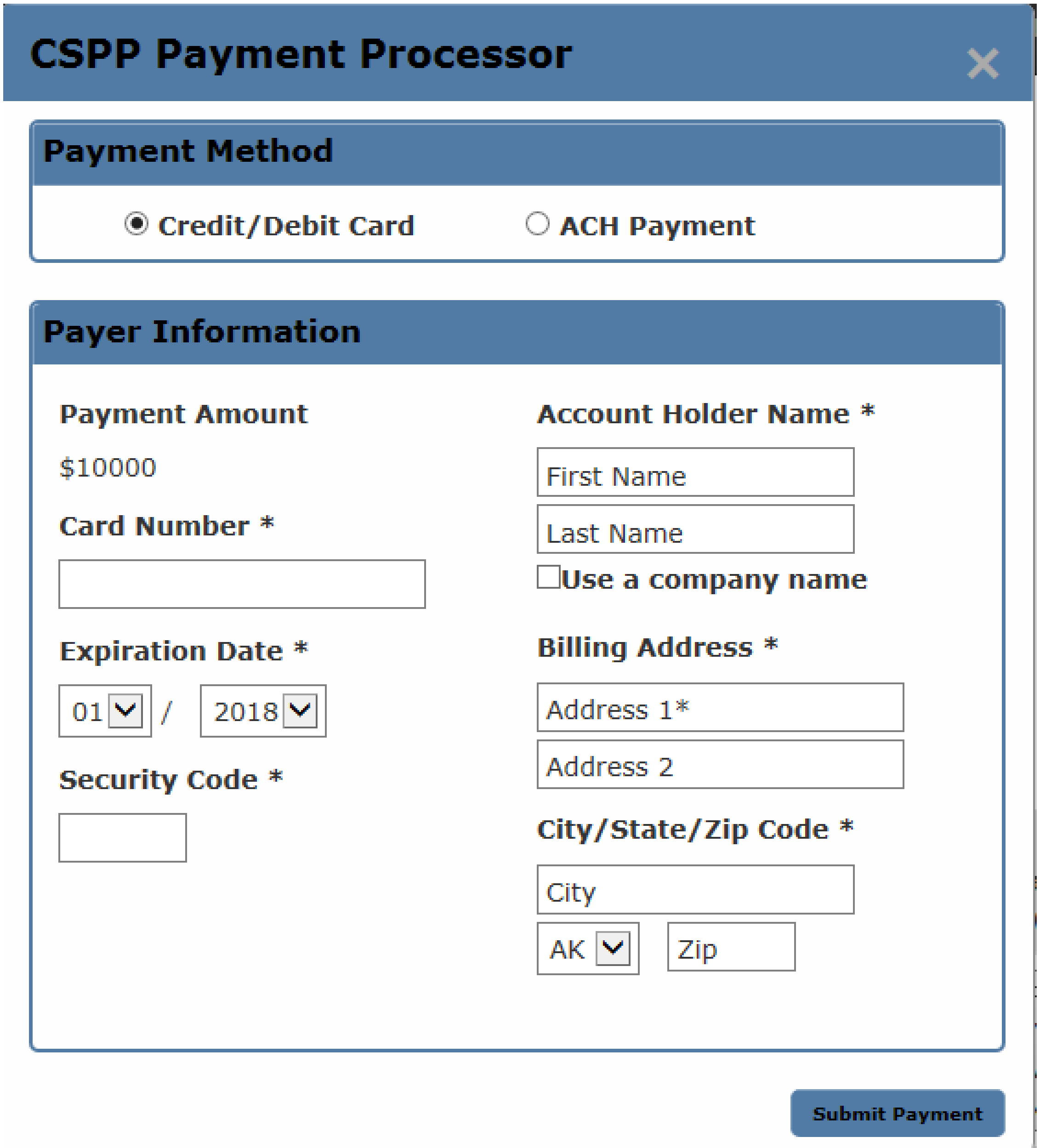
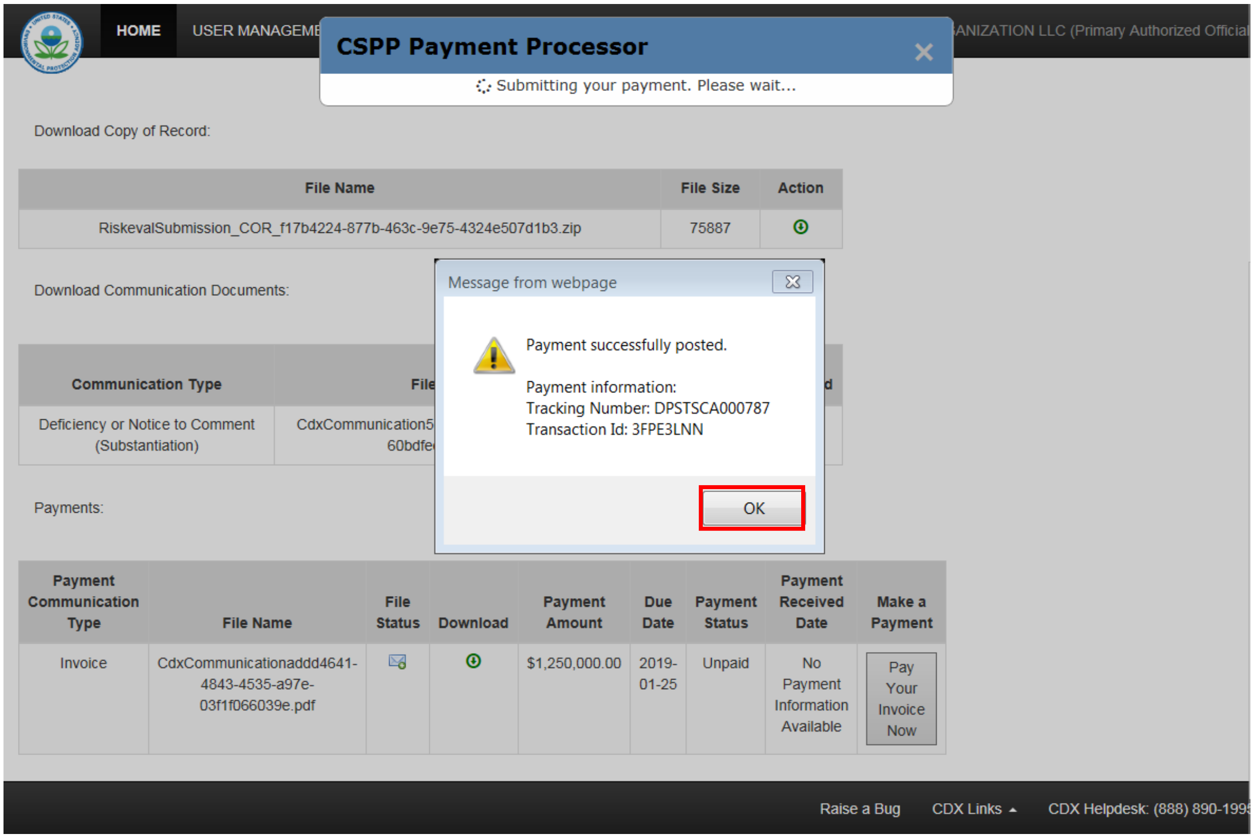


Exhibit 12-10 shows a screen capture of the payment successful message:

Exhibit 12-10 Successful Payment



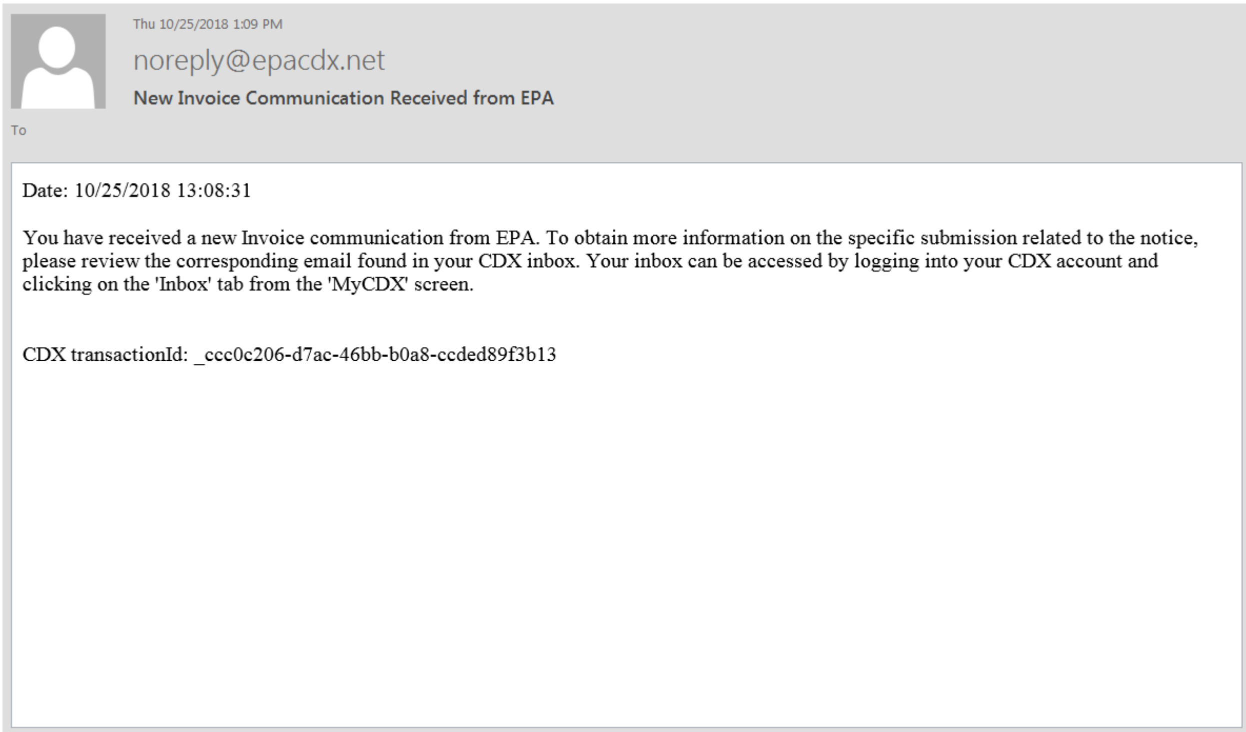
Navigation: Click the ‘Submit Payment’ button to submit the payment. The application displays a payment successful message and sends a payment receipt to the submitter. Click the ‘OK’ button on the payment successful message to return to the ‘CSPP Payment Processor’ window. Click the ‘Close Widget’ button on the ‘CSPP Payment Processor’ window to navigate back to the ‘Copy of Record’ screen.

12.2 Invoice Communications

EPA may send an invoice communication related to a specific CDX submission. In the event EPA sends an electronic communication, the original submitter will receive a notification to both their registered email address and inbox within CDX. The notification will inform the user that there is a new, submission-specific invoice communication sent from EPA.

Exhibit 12-11 shows a screen capture of the email for Risk Evaluation Request Invoice Email:

Exhibit 12-11 Invoice Communication Email



Thu 10/25/2018 1:09 PM

noreply@epacdx.net

New Invoice Communication Received from EPA

To

Date: 10/25/2018 13:08:31

You have received a new Invoice communication from EPA. To obtain more information on the specific submission related to the notice, please review the corresponding email found in your CDX inbox. Your inbox can be accessed by logging into your CDX account and clicking on the 'Inbox' tab from the 'MyCDX' screen.

CDX transactionId: _ccc0c206-d7ac-46bb-b0a8-ccded89f3b13

Exhibit 12-12 shows a screen capture of the CDX Inbox text for Risk Evaluation Request Invoices:

Exhibit 12-12 CDX Inbox Invoice Communication

Central Data Exchange

Contact Us
Logged in as JANEDOEOPPT (Log out)

MyCDX | Inbox | My Profile | Role Sponsorship | Submission History | Payment History | E-Enterprise Portal

New Invoice Communication Received from EPA

From noreply@epacdx.net

Date 10/25/2018 1:08:31 PM

Date: 10/25/2018 13:08:31

You are receiving this message because the U.S. Environmental Protection Agency delivered an invoice communication to your Central Data Exchange (CDX) account associated with a Toxic Substances Control Act (TSCA) submission. The invoice communication can be accessed within the Risk Evaluation reporting module. You can retrieve this communication by following these steps:

1. Copy the submission alias identified below.
2. Navigate to the appropriate CSPP module for the TSCA section indicated.
3. Select the Forms/Submissions tab or link to view the table of submissions.
4. Perform a 'Find' operation by clicking 'Ctrl+F'.
5. Paste Submission Alias 'RER-20181024-14:10:06' into the navigation box and click return. The submission alias will be highlighted.
6. Click on the dollar sign icon found in the Action column at the end of the submission row.
7. Follow the steps to access the Copy of Record.
8. Click on the green download arrow for the desired communication within the 'Payments' section.

If you have any difficulty locating the communication, please refer to the 'EPA Communications' section of the application user guides found in the 'Resources' tabs provided in each CSPP module or contact the CDX helpdesk between 8:00 am to 6:00 pm (EST/EDT) at 888-890-1995 (Domestic) or (970) 494-5500 (International callers).

CDX transactionId: _ccc0c206-d7ac-46bb-b0a8-ccded89f3b13
Submission Alias: RER-20181024-14:10:06

Back to Inbox | Print | Delete

Exhibit 12-13 shows a screen capture of the Risk Evaluation Request Invoice PDF:

Exhibit 12-13 Risk Evaluation Request Fee Invoice PDF

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON D.C. 20460

October 25, 2018

Office of
Chemical Safety and
Pollution Prevention

Fee Invoice

Jane Doe
TEST ORGANIZATION LLC
1025 LEESBURG PIKE
FALLS CHURCH, VA 22033 US

Subject: Fee Invoice Notice

Dear Submitter,

As required by 40 CFR 700.45, your organization is subject to a fee in the amount of $1,250,000.00 for the manufacture (including import) of a chemical substance that is the subject of a risk evaluation under TSCA section 6(b). Payment in full is due by January 25, 2019.

You may make a payment by clicking the Pay Your Invoice Now button on the Copy of Record screen within the TSCA Risk Evaluation application. To access the Copy of Record screen, click the payment communication icon associated with your submission within the TSCA Risk Evaluation application in CDX.

TEST

CBI	Case Number	Chemical ID
N		437-17-2 - Methylium, triphenyl-, hexafluorophosphate(1-) (1:1)

Exhibit 12-14 shows a screen capture of the Payment Receipt:

Exhibit 12-14 Risk Evaluation Request Payment Receipt

Thu 10/25/2018 2:07 PM

noreply-dev <noreply-dev@epacdx.net>

Payment Receipt

To

Payment Receipt

Payee Information

- John Doe

Receipt Details

Your payment has been submitted.

- Date: 10/25/2018 2:06 PM
- Tracking Number: DPSTSCA000787

Total: $1,250,000.00

13 Create An Amendment

To amend a submitted Risk Evaluation request, navigate to the Risk Evaluation 'Home' screen and locate a submission that you previously submitted with a status of 'Completed' within the 'Submission History' table. In addition to displaying a status of 'Completed' 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.

A pop-up window will appear after clicking the 'Lock' icon ( ), confirming that you wish to begin the amendment process. After you click the 'OK' button, you will be taken to the 'Enter Passphrase' screen. You must enter the passphrase originally associated with the submission to start the amendment process. After you enter the passphrase and click the 'Next' button, you will be taken to the first screen in the specific Risk Evaluation request. Refer to **Section 3.6** for further instructions on the 'Enter Passphrase' screen.

After a submission has been unlocked, the Risk Evaluation 'Submission History' 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 Risk Evaluation 'Submission History' screen. The only way to lock the submission again is by resubmitting it to EPA.

- Refer to **Section 4** through **Section 4.11** for instructions on editing a revised Risk Evaluation request.
- Refer to **Section 5** through **Section 5.5** for instructions on editing a revised Risk Evaluation request.
- Refer to **Section 6** through **Section 6.9** for instructions on editing a revised Risk Evaluation request.
- Refer to **Section 7** through **Section 7.10** for instructions on editing a revised Risk Evaluation request.

14 Appendix A. Document Types and Subtypes

The following appendix displays the document types and document subtypes available within the 'Attach Document' window.

Document Type	Document Subtype
Aquatic Ecotoxicity	Algae Toxicity Fish Acute Toxicity Fish Chronic Toxicity Invertebrate Acute Toxicity Invertebrate Chronic Toxicity
Chemical Category Rationale	N/A
Chemical Category Substance List	N/A
Chemical Structure Diagram	N/A
Condition of Use Rationale	N/A
Construct	Construct Data Construct Methodology Gene Sequence Data
Correspondence	N/A
Effects	Antibiotic Resistance Environmental Effects Human Health Effects Metabolism Pathogenicity Data
Fate	BCF/BAF Biodegradation Fugacity Hydrolysis Monitoring Data (e.g., air, water, soil, biota, human) Partitioning (e.g., Koc, Kd, Kow, Koa, Henry's law constant) Photolysis
Genetic Toxicity	Chromosomal Aberrations Assay Unscheduled DNA Synthesis Genetic Mutation Assay
GPC	N/A
Health Toxicity	Acute Toxicity

Document Type	Document Subtype
	Carcinogenicity Combined Repeated-Dose/Development/Reproductive Toxicity Dermal Irritation Developmental Toxicity Eye Irritation Immunotoxicity Neurotoxicity Pharmacokinetics/Metabolism Repeated-Dose Toxicity Reproductive Toxicity Sensitization
i5Z IUCLID	N/A
i6Z IUCLID	N/A
ID	ID Sequence Data Other ID Data Strain History
IES Report	N/A
Inactivation Data	N/A
Interstate Commerce	N/A
Main Submission	N/A
Manufacturing Details	N/A
MSDS	N/A
OECD Harmonized Templates	N/A
Other	A free text field generates for a user to provide a description of the document type.
Process Diagram-Other	N/A
Process Diagram-Submitter	N/A
Published Literature	N/A
Regs and Certifications	N/A
Safety Datasheet (MSDS)	MSDS/SDS Technical Datasheet
Terrestrial Ecotoxicity	Avian Toxicity Invertebrate Toxicity Plant Toxicity

Document Type	Document Subtype
Use Details	N/A