

# PMN/Joint/Letter of Support Demo

December 5, 2013

Office of Chemical Safety and Pollution Prevention

# **Agenda**

Speaker: Chris Gorder, Information Management Division

- Welcome and Overview
- Roles
- PMN 2.0 highlights
  - PMN Demo
- Resources
- Questions and Answers



# **Overview of ePMN Role Changes**

Speaker: Chris Gorder, Information Management Division

- Old eTSCA CDX Registration Roles
  - Authorized Official (AO)
  - Support Registrant (SR)
- New CDX Registration Roles (CSPP workflow)
  - Primary Authorized Official (Primary AO)
  - Primary Agent/Consultant
  - Primary Support
  - Secondary Authorized Official (Secondary AO)
  - Secondary Agent/Consultant
  - Secondary Support



# **PMN Highlights**

- PMN Tool Demo
- Joint Submission
- Letter of Support





# Section 5 Notices and Supports Tool Demo

Office of Chemical Safety and Pollution Prevention

CENTRAL DATA EXCHANGE CDX

**CDX Home** 

About CDX

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Help

# Central Data Exchange

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## Welcome

Welcome to the Environmental Protection Agency (EPA) Central Data Exchange (CDX) - the Agency's electronic reporting site. The Central Data Exchange concept has been defined as a central point which supplements EPA reporting systems by performing new and existing functions for receiving legally acceptable data in various formats, including consolidated and integrated data.

### Notices

RADNET: For more information on radiation and accessing radiation monitoring data click here

CDX: Welcome CDR users. As a reminder, please register using the CSPP flow.

# Warning Notice and Privacy Policy

## Warning Notice

EPA's Central Data Exchange Registration procedure is part of a United States Environmental Protection Agency (EPA) computer system, which is for authorized use only. Unauthorized access or use of this computer system may subject violators to criminal, civil, and/or administrative action. All information on this computer system may be monitored, recorded, read, copied, and disclosed by and to authorized personnel for official purposes, including law enforcement. Access or use of this computer system by any person, whether authorized or unauthorized, constitutes consent to these terms.

### Privacy Statement

EPA will use the personal identifying information which you provide for the expressed purpose of registration to the Central Data Exchange site and for updating and correcting information in internal EPA databases as necessary. The Agency will not make this information available for other purposes unless required by law. EPA does not sell or otherwise transfer personal information to an outside third party. [Federal Register: March 18, 2002 (Volume 67, Number 52)][Page 12010-12013].



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Logged in as JANEDOEOPPT (Log out)

# Central Data Exchange

**⊠**Contact Us

Last Login: 11/29/2013 12:24:52 PM

MyCDX

Inbox

My Profile Submission History

# Services

# News and Updates

Manage Your Program Services

No news/updates.

Status	Program Service Name	Role(s)
8	CROMERRTEST: CROMERR Test Sandbox	Development Sandbox
8	CSPP: Submissions for Chemical Safety and Pesticide Programs	Primary Authorized Official
8	CSPP: Submissions for Chemical Safety and Pesticide Programs	Primary Support
8	CSPP: Submissions for Chemical Safety and Pesticide Programs	Secondary Authorized Official
8	TSCA: TSCA	PMN Client Download and View Support Registrants

Add Program Service



## CHEMICAL INFORMATION SUBMISSION SYSTEM

TSCA Section 5 Notices and Supports - ePMN

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

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

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



Forms

User Management

Resources

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# HOME

# Forms

The TSCA Section 5 Notices and Supports Reporting rule requires anyone who plans to manufacture or import a new chemical substance (i.e. one not listed on the TSCA inventory) for a non-exempt commercial purpose is required by section 5 of TSCA to provide EPA with notice before initiating the activity.

Use the following forms to report new chemicals to EPA: Premanufacture Notice form (EPA Form 7710-25) should be used to submit PMNs, LVEs, SNUNs, LOREXs, TMEAs, Modifications for LVEs and LoREX submissions; Biotechnology Notice form (EPA Form 6300-14) should be used to submit MCANs, TERAs, Tier I Exemptions, Tier 2 Exemptions, and Biotechnology TMEAs; or Notice of Commencement form (NOC, EPA Form 7710-56) should be used to submit Notices of Commencement for PMNs and MCANs. The Support Document form will be used to submit supplemental information for Premanufacture and Biotechnology notices, such as Test Data, Correspondences, and Amendments to older submissions.

# **User Management**

Manage the access rights of Support persons for each Section 5 Notices and Support document.

# Resources

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

# **Authorized Official**

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

# SECTION 5 NOTICES AND SUPPORTS FORMS

If submitting a form for the first time in the Section 5 Notices and Supports application, select the form type from the drop-down menu and click Start New Form.

To edit an In Progress form, click the form alias link in the Alias column in the table below.

Forms

To access and edit a form previously submitted through CDX, unlock the form by clicking the lock ( i ) icon and enter the passphrase when prompted. All additional changes made to the form will be submitted as an amendment.

To download a copy of record for a submitted form, click the green arrow (--) icon and enter the passphrase when prompted.

You may delete any form that has not yet been submitted by clicking the delete (X) icon.

All columns may be sorted by clicking the column header.

Page 1 of 1

7 items found.			Page 1 of 1			Ite	ms Pe <mark>r P</mark> age:	25 🕶
Alias \$	Type \$	Subtype \$	Case Number \$	Status \$	Modify Date	Submission Date	Copy of Record	Action
ACM-20130913-22:23:38 EDT	ACM			In Progress	11/29/2013	11/29/2013		
ACM-20131129-18:46:05 EST	ACM			In Progress	11/29/2013			×
Biotechnology-20130913-22:22:52 EDT	Biotechnology			In Progress	11/17/2013			×
Bona Fide-20130913-21:02:16 EDT	Bona Fide			In Progress	11/29/2013			×
NOC-20130913-22:22:18 EDT	NOC		P-12-3456	In Progress	09/13/2013			×
Primary PMN-20131129-11:33:26 EST	Primary PMN	PMN		In Progress	12/04/2013			×
Support-20130913-22:21:59 EDT	Support	Amendment	P-12-3456	In Progress	11/15/2013			×

Select the form type and then click Start New Form

Premanufacture Notice (PMN) Form Type:

Start New Form





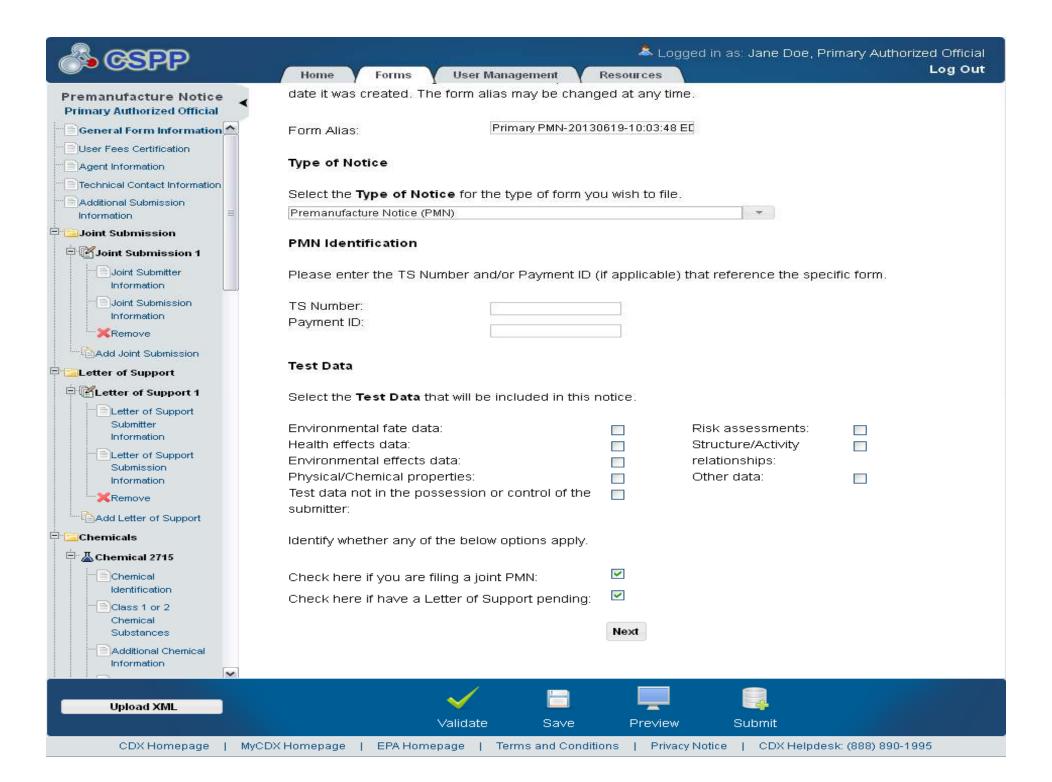
CREATE P.	ASSPHRASE
Please create a passphrase that is at least 8 characters in length. T	o better protect your form, your passphrase should contain a
combination of letters and numbers. Your passphrase may include s	spaces, but should not contain special characters (for example, +, and
*)-	
New Passphrase:	
Confirm New Passphrase:	

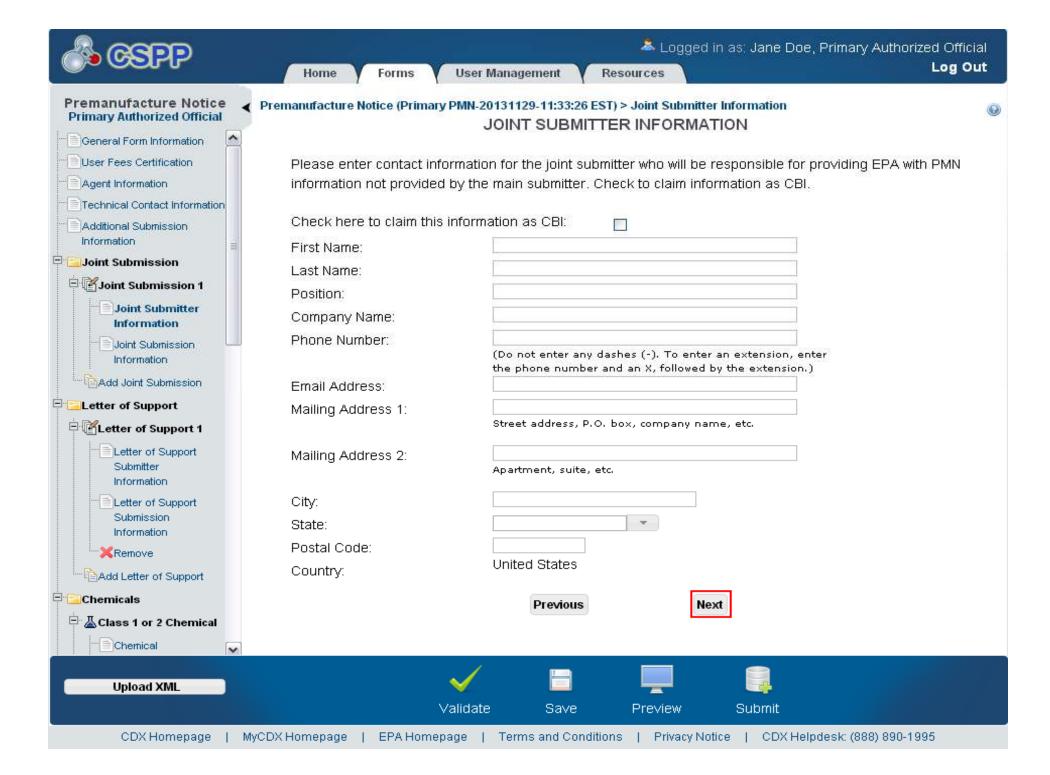
As an Authorized Official, you are responsible for remembering your passphrase and distributing it to only authorized individuals. Your passphrase will be used as an encryption key to protect the contents of your data. As an Authorized Official, you are responsible for remembering your passphrase and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

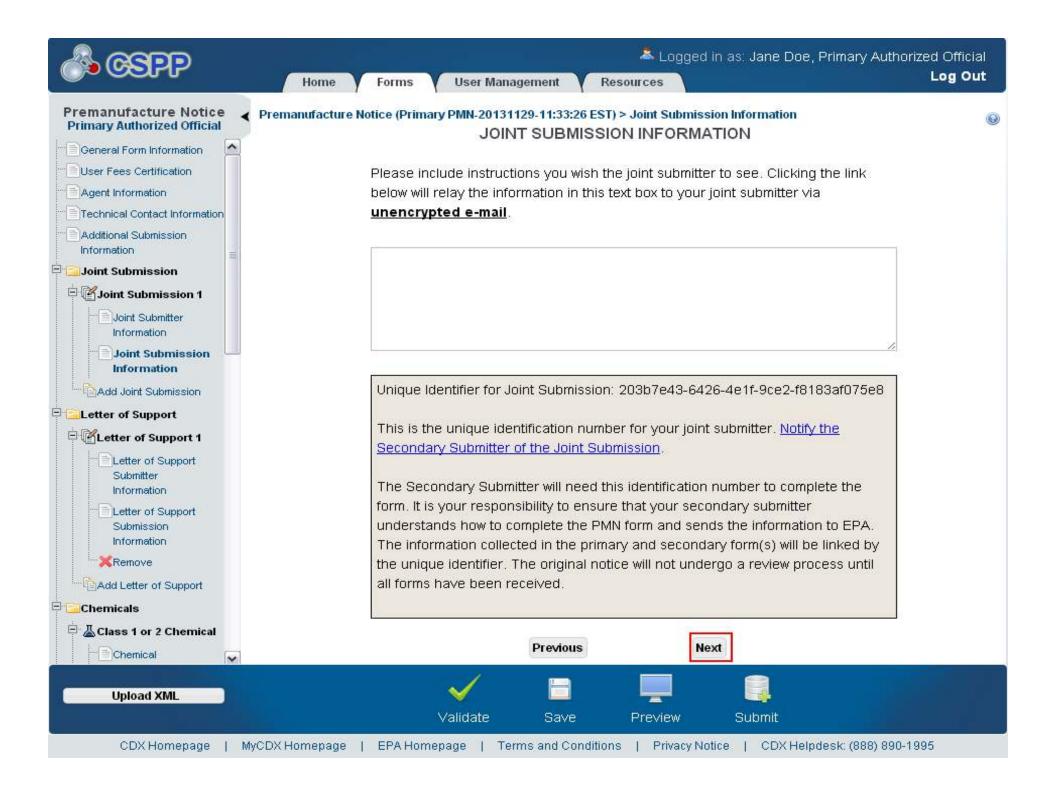
Note: If you lose or forget your passphrase, you will not be able to access your Section 5 Notices and Supports Form to print, submit, or make changes. You will need to complete a new Section 5 Notices and Supports Form and create a new passphrase for the form. For security reasons, the system administrator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

Cancel











The same

User Fees

CC:

Technica

Additional

Joint Sub

- Joint

Subject:

Message:

From:

To:

(RSP)

Jane.Doe@test.com

Jane.Doe@test.com

Enter email addresses separated by semicolons (;) or commas (,). Click in this box to start entering email addresses.

2013 Primary PMN

As the Authorized Official of CGI TEST COMPANY, I have identified you as a Secondary Submitter of a joint submission for this 2013 Premanufacture Notice (PMN) form. Please use the Section 5 Notices and Supports application to provide the correct information for the necessary items in this form. See the instructions below for accessing the Section 5 Notices and Supports application. You will need to use the unique identification number to access and complete the Premanufacture Notice (PMN) form for the joint submission.

Unique Identifier 203b7e43-6426-4e1f-9ce2f8183af075e8

Information about the Section 5 programs, how to access the Section 5 Notices and Supports application, and instructions for reporting under the Section 5 rule are available at <a href="https://www.epa.gov/oppt/newchems/">www.epa.gov/oppt/newchems/</a>. For

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Letter

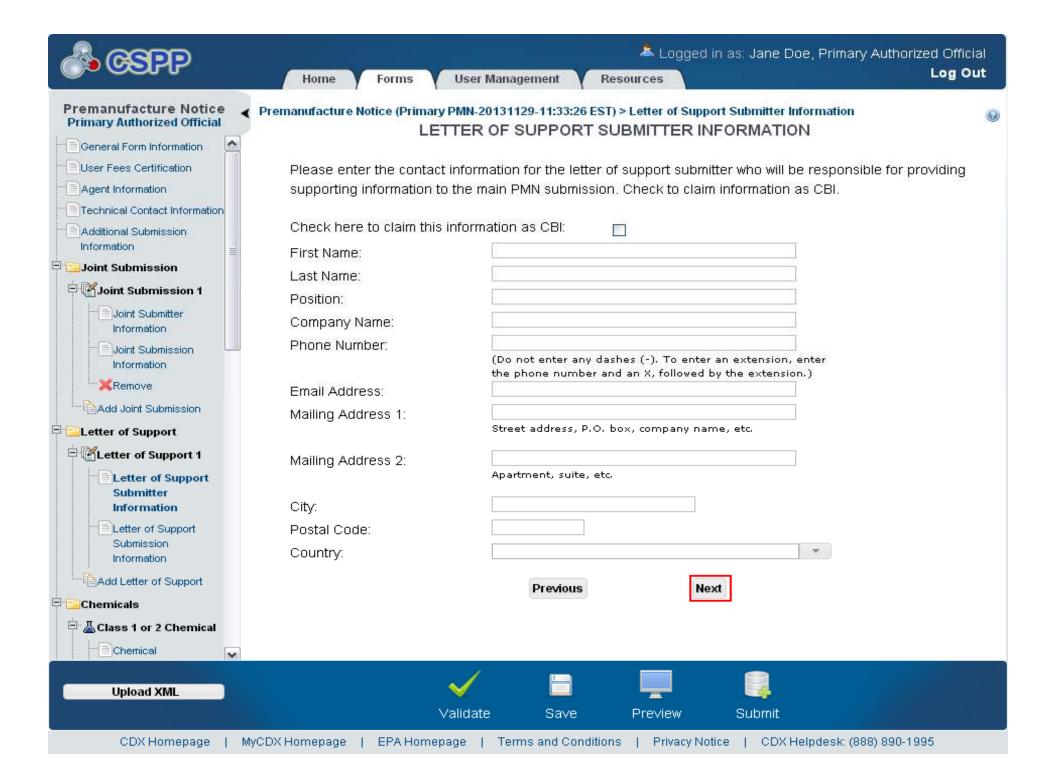
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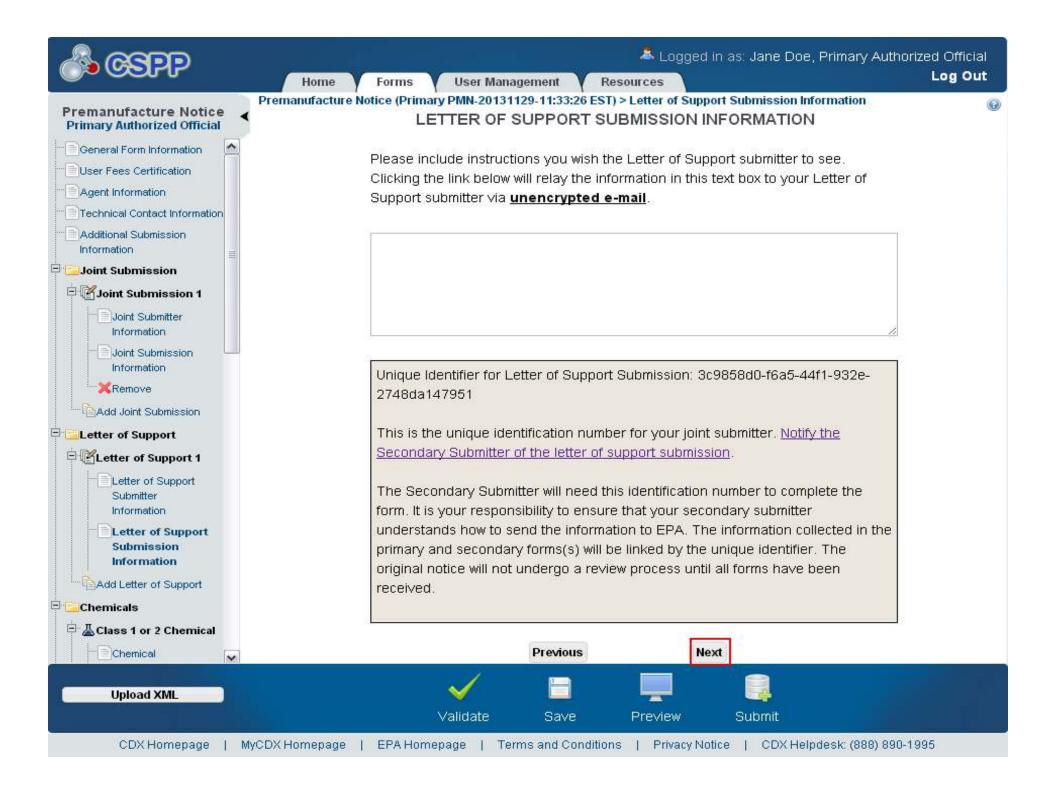
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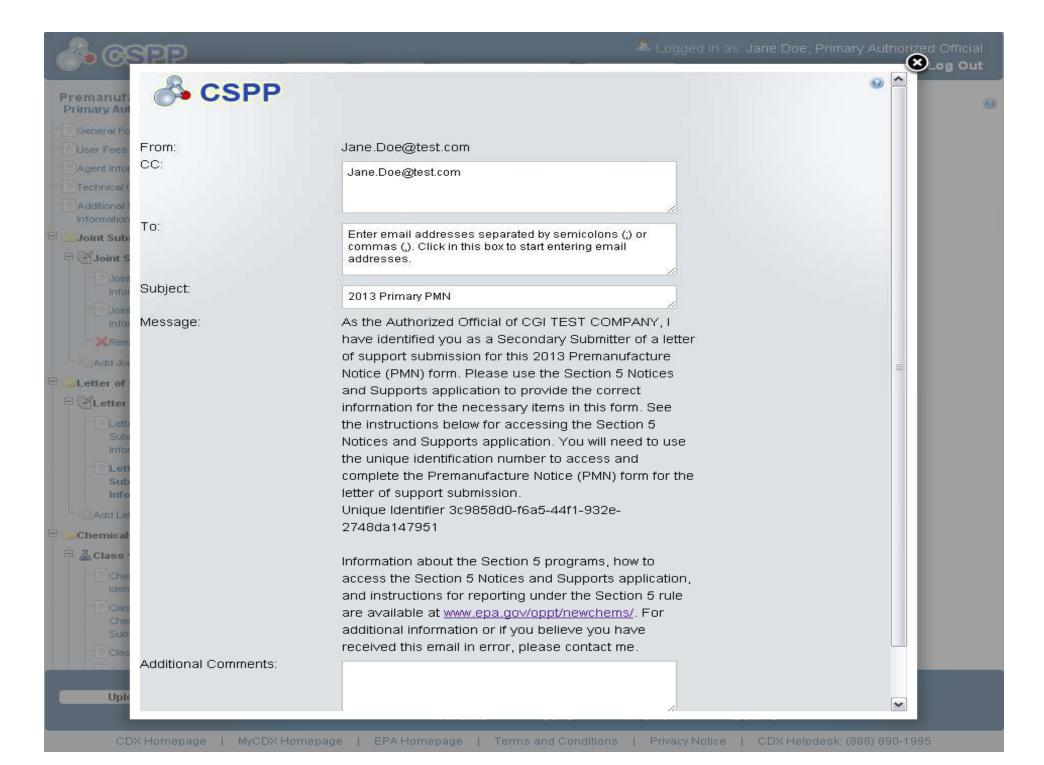
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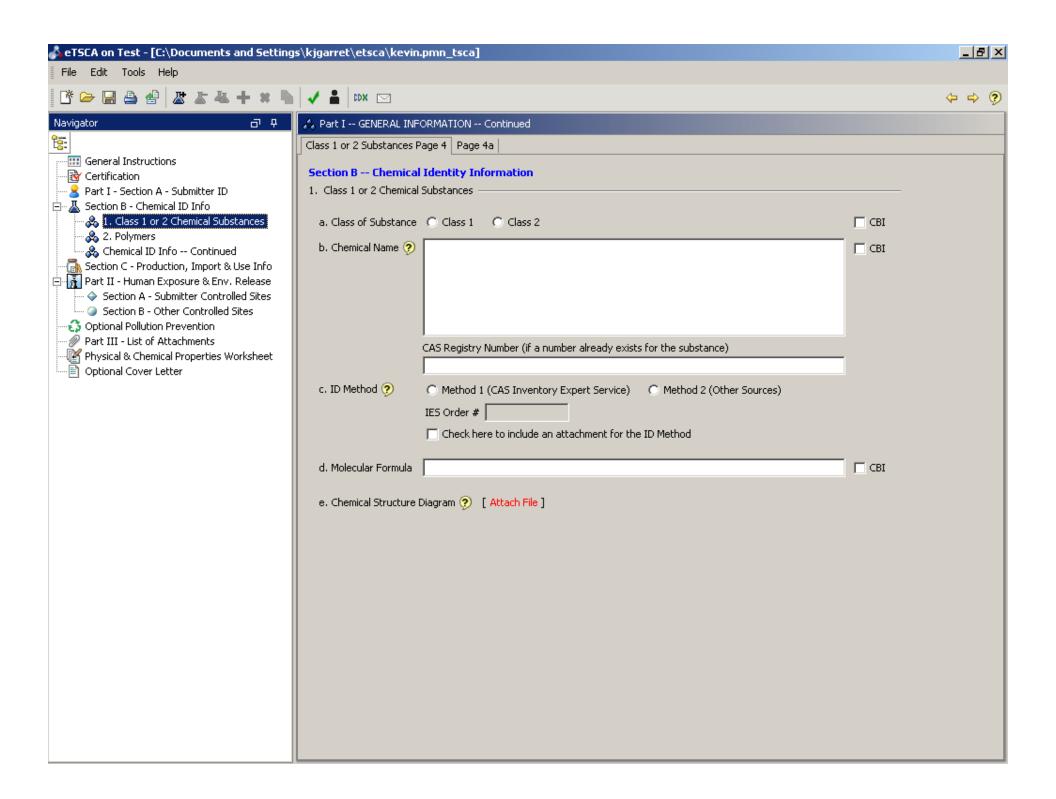
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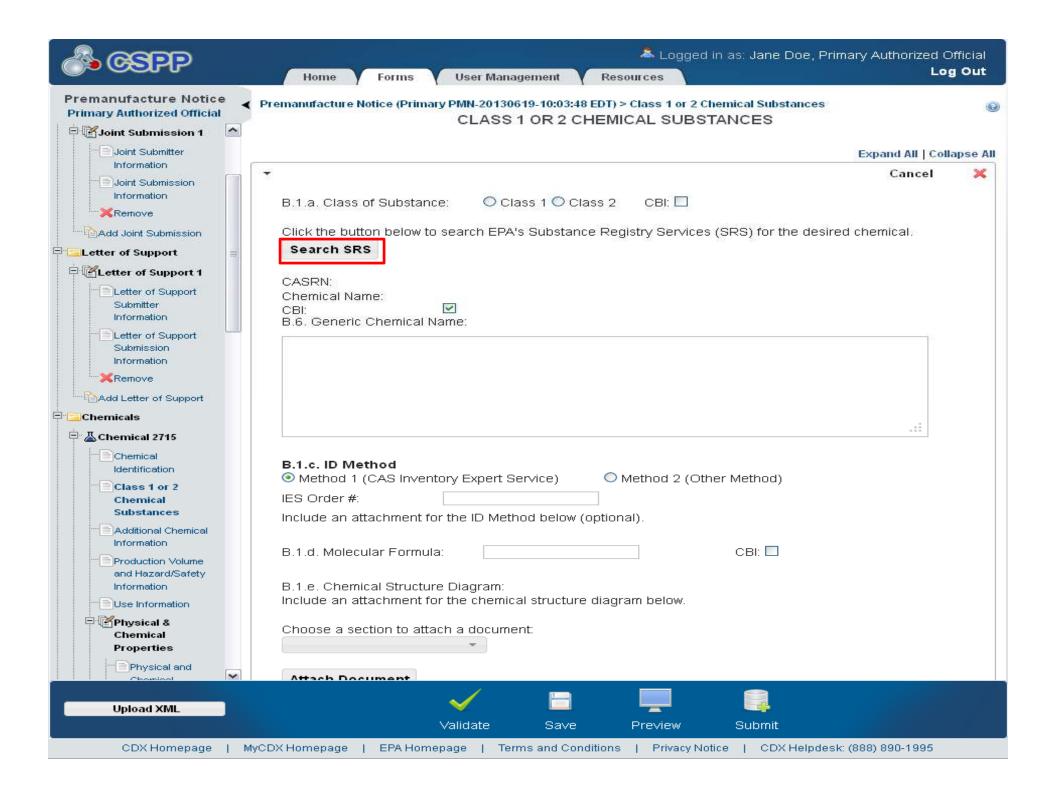
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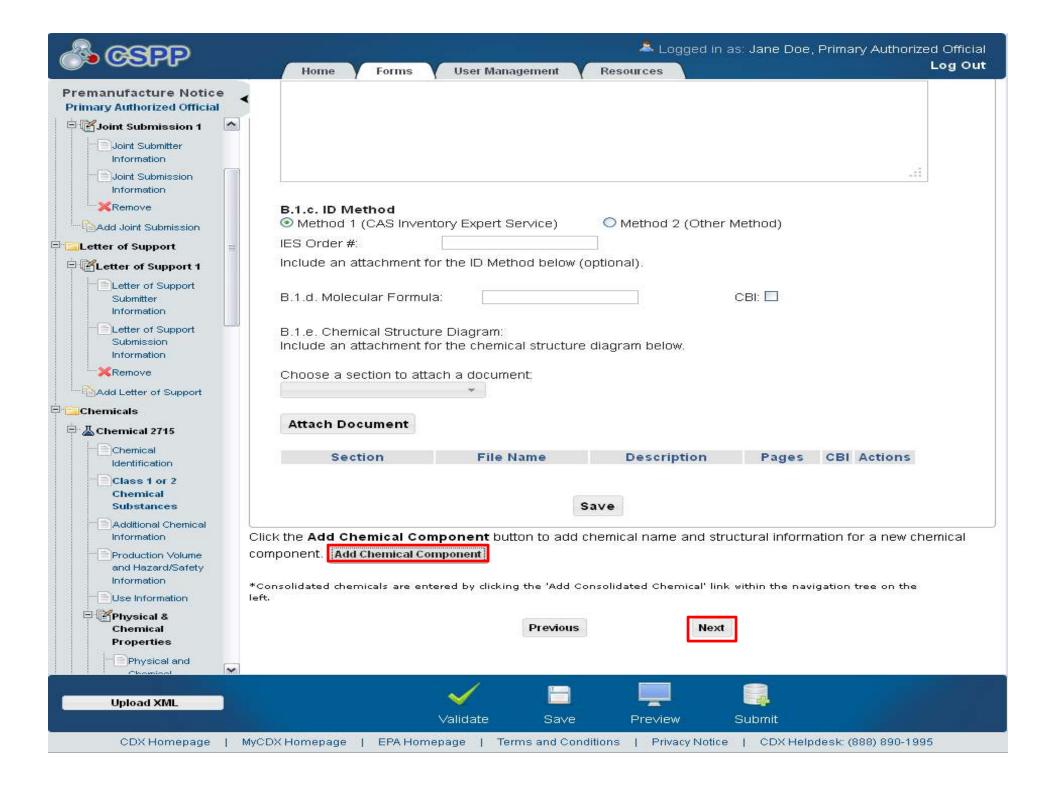




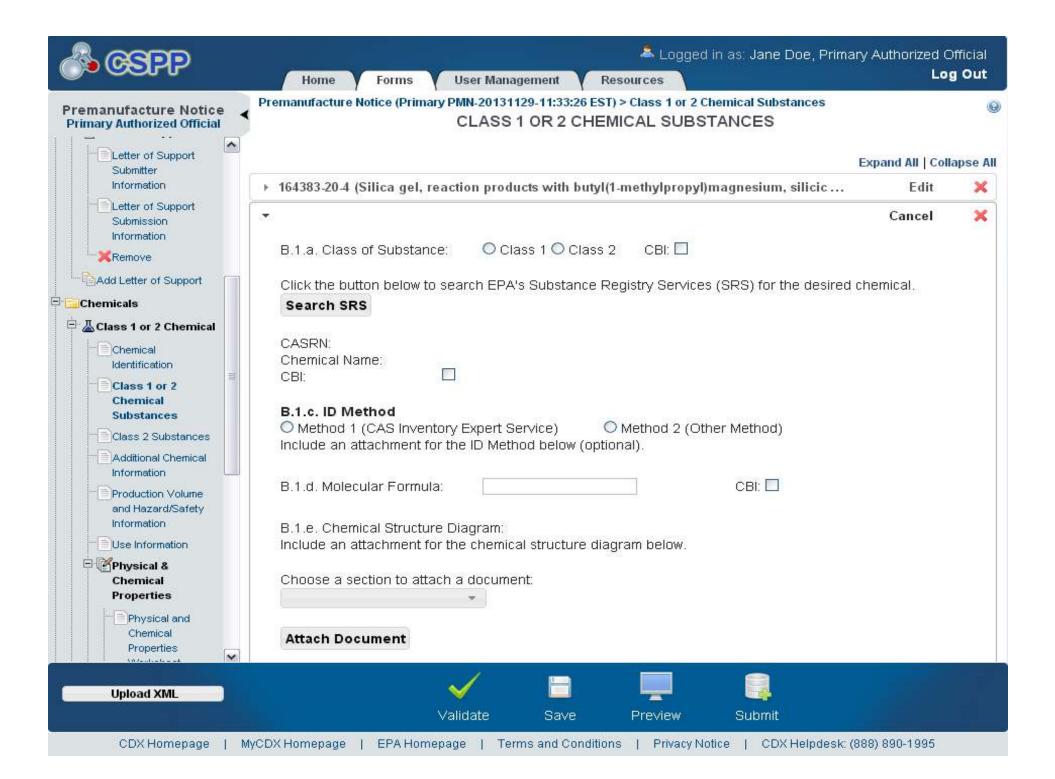


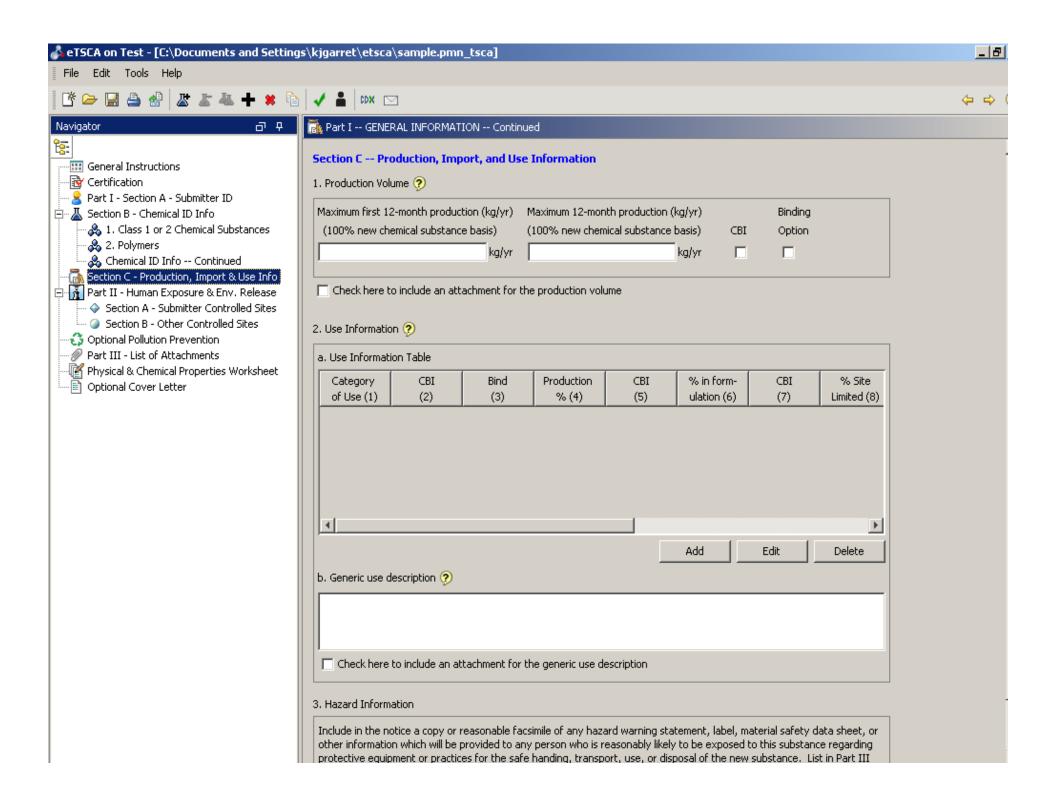


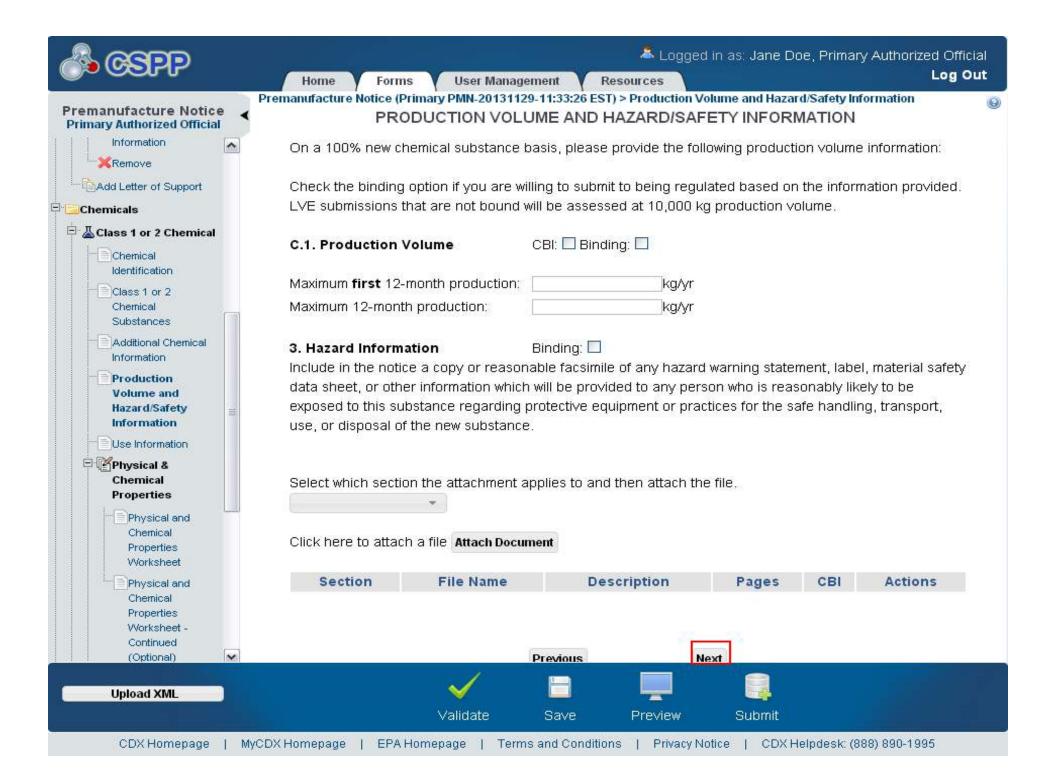


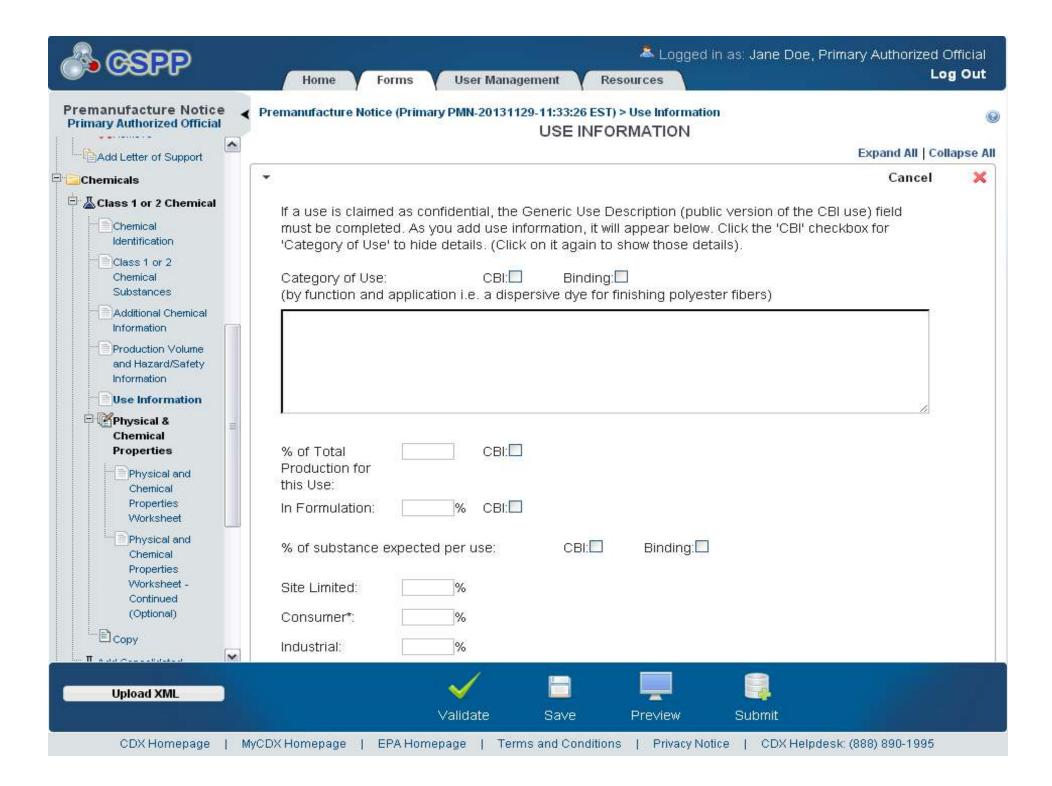


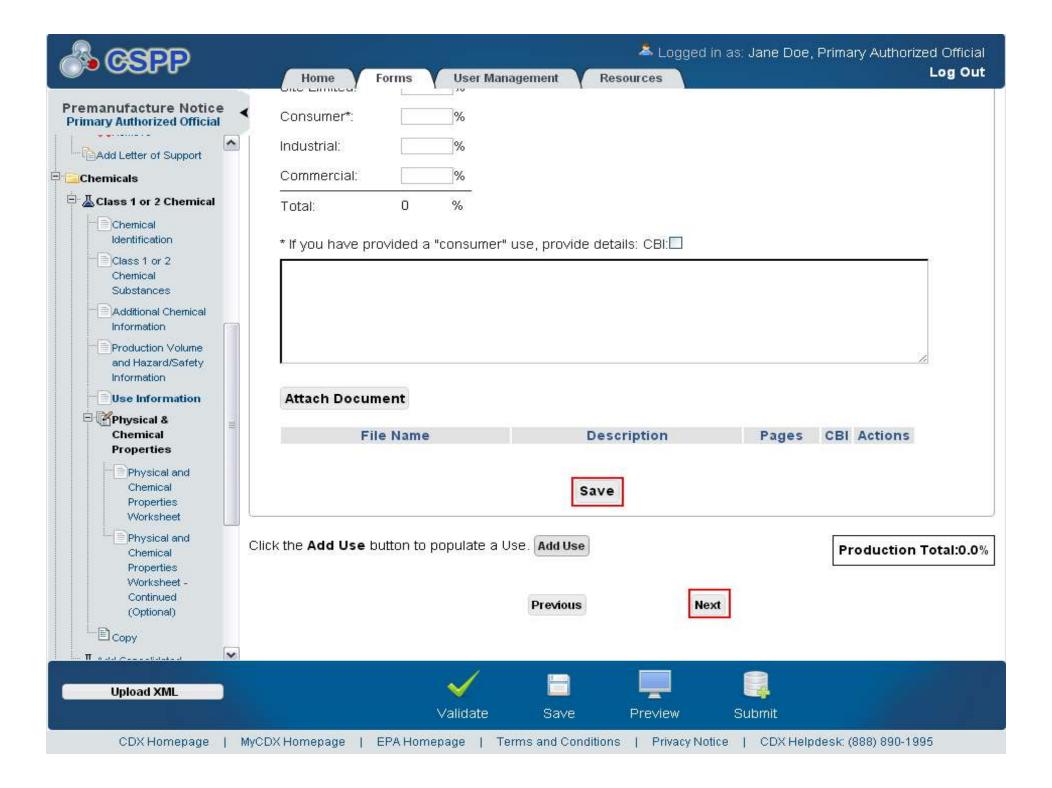


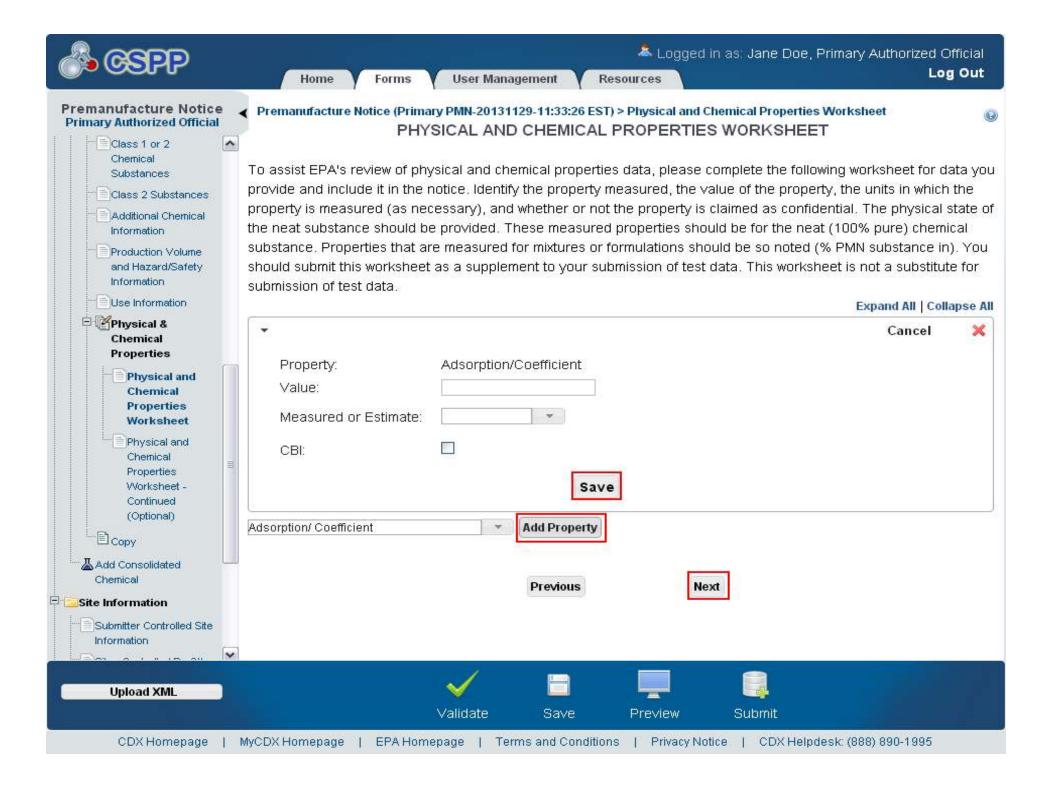


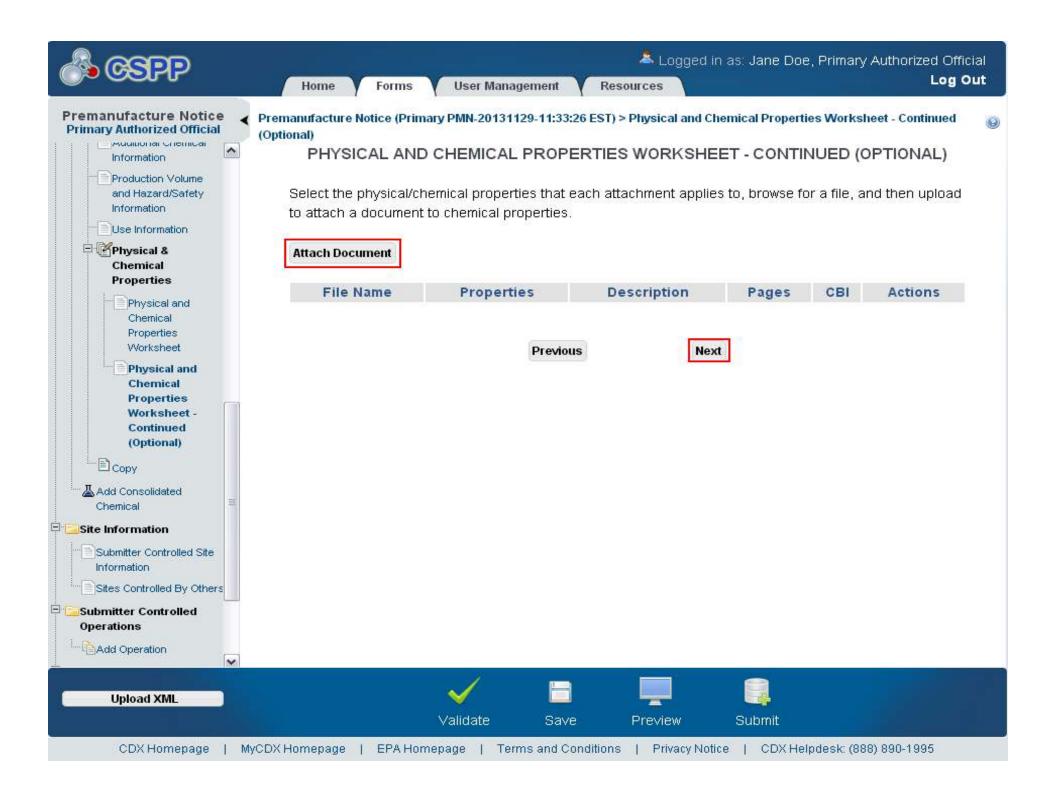


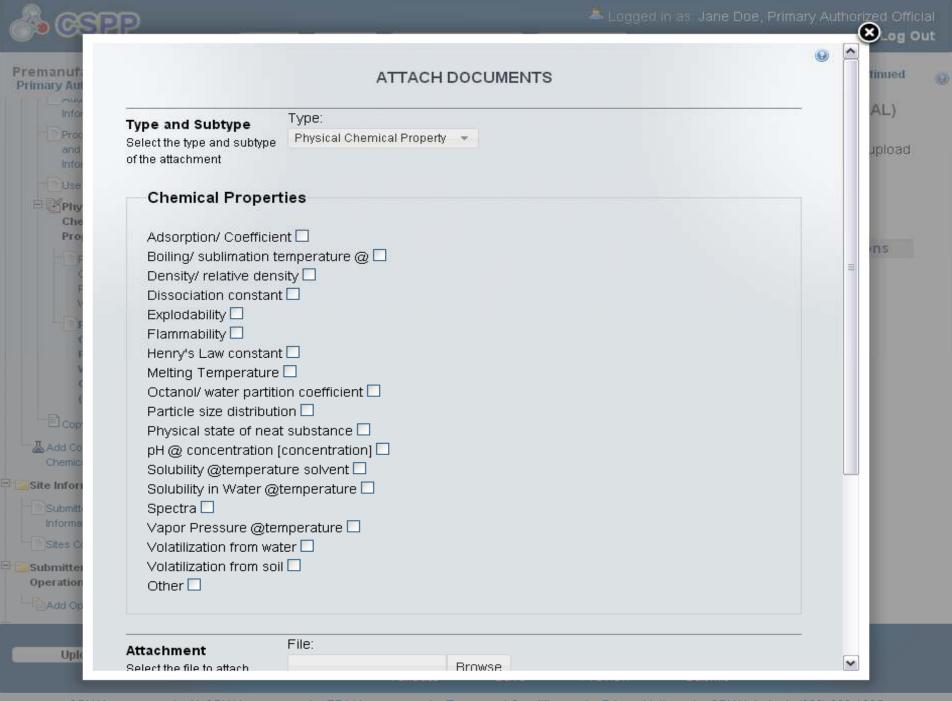










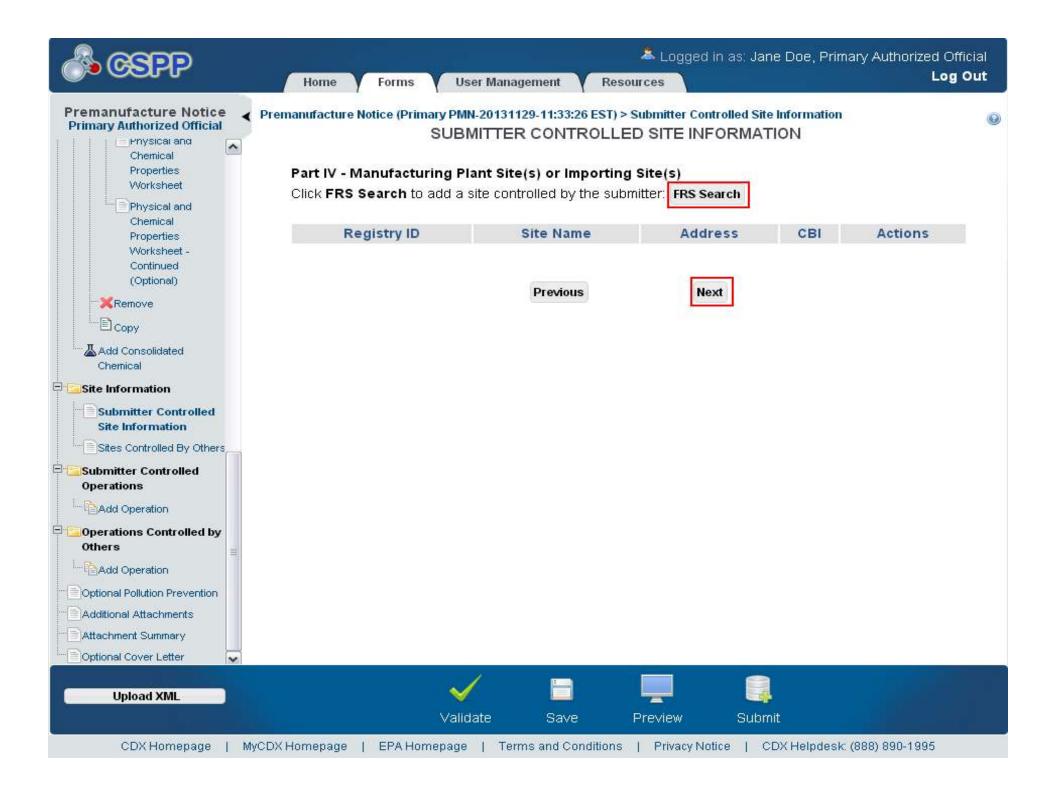


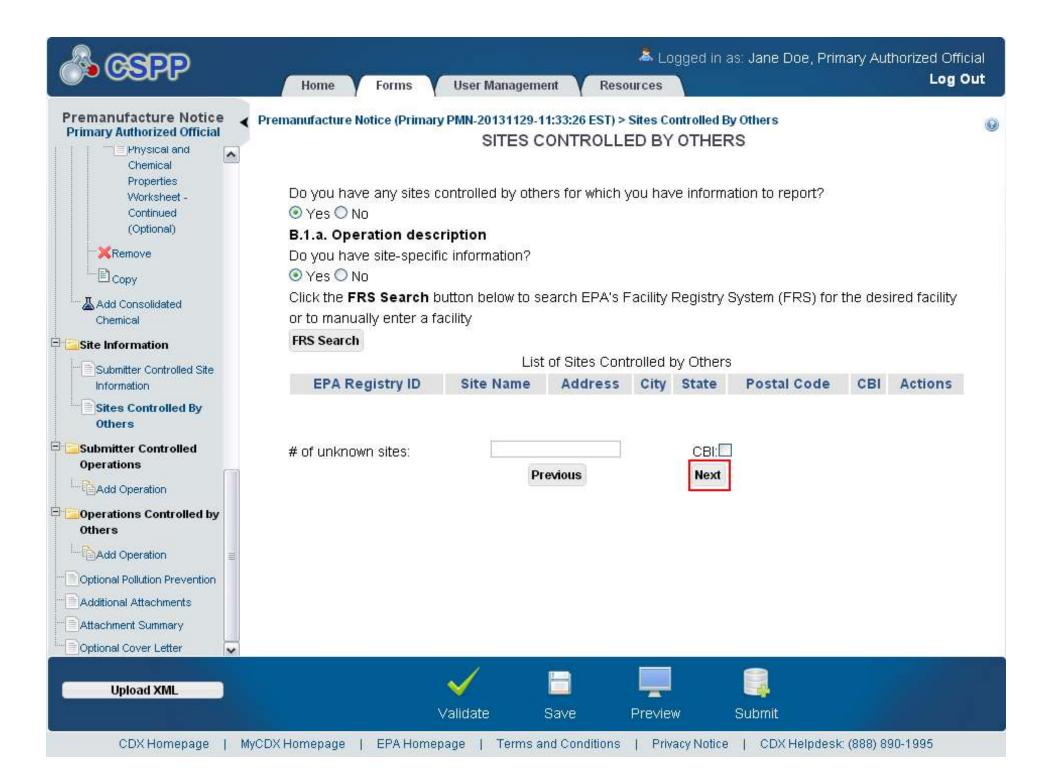
CDX Homepage | MyCDX Homepage |

EPA Homepag

Ferms and Conditions

Jotice | CDX Helpdesk: (888) 890





# **Joint/Letter of Support**

# Secondary Authorized Official



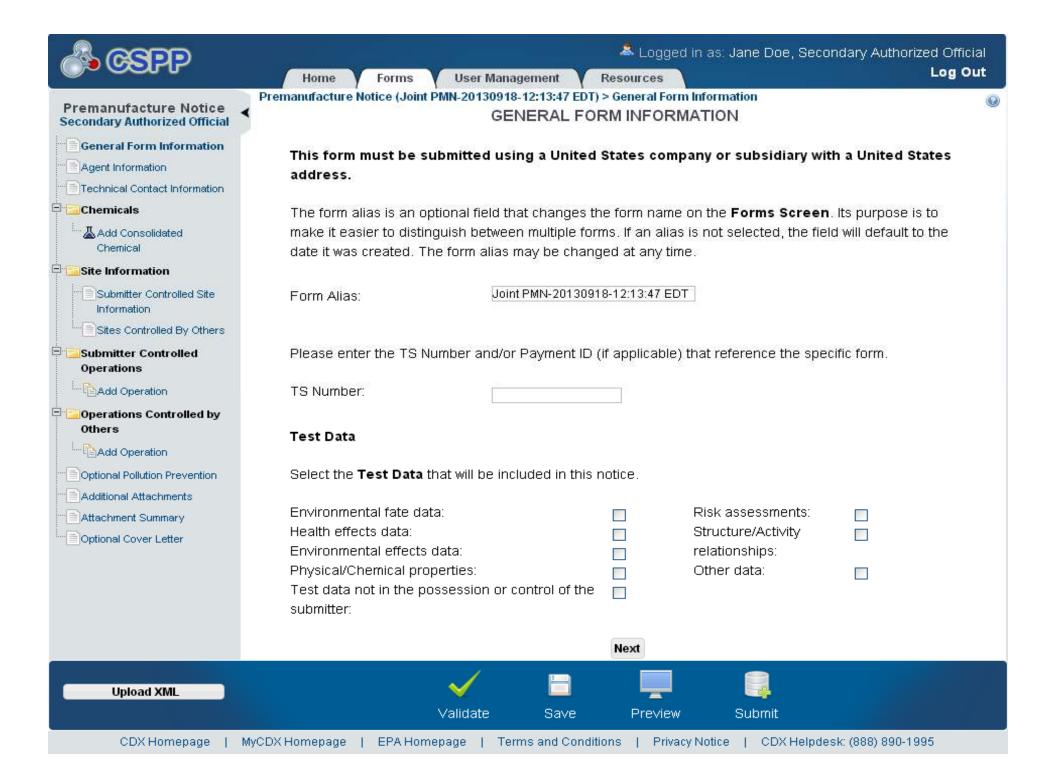


# Section 5 Notices and Supports Tool Demo: Joint Submission

Office of Chemical Safety and Pollution Prevention



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# Section 5 Notices and Supports Tool Demo: Letter of Support

Office of Chemical Safety and Pollution Prevention

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& CSP	Ð	A Logged In as: Jane Doe, Secondary Auth	orized Official
Premanufi Secondary A		ATTACH DOCUMENTS	
General Fo Agent Infor Technical Chemical Add Co	Type and Subtype Select the type and subtype of the attachment	Type:	PA ney
Site Inform	Attachment Select the file to attach	File:  Browse	on
Sites Co Submitter Operation Add Operation Others	Description Provide a description of the attachment  **Please do not include any CBI information in the description of the file information.		
Add Op	Number of Pages	pages	
Attachmen Optional Co	СВІ	Check to claim the attachment as CBI	
		Cancel	
Upk			
CDX Hom	iepage   MyCDX Homepag	e   EPA Homepage   Terms and Conditions   Privacy Notice   CDX Helpdesk: (888) 890	)-1995

## **Submission Process**





## SUBMITTING OFFICIAL INFORMATION

The information below has been pre-populated from CDX registration. If the information listed is incorrect please make the appropriate edits to your user information in CDX registration.					
CBI:					
This confirmation is required to proceed with the submission process  Please confirm that you are the legally responsible party from the submitting company					
First Name:	Jane				
Middle Initial:	E				
Last Name:	Doe				
Job Title:					
Company Name:	TEST COMPANY				
Phone Number:	7034349615				
Email Address:	Jane.Doe@test.com				
Mailing Address 1:	12601 FAIR LAKES CIRCLE				
Mailing Address 2:					
Citv:	FAIRFAX				



## This confirmation is required to proceed with the submission process

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

First Name: Jane

Middle Initial:

Last Name: Doe

Job Title:

Company Name: TEST COMPANY

Phone Number: 7034349615

Email Address: Jane.Doe@test.com

Mailing Address 1: 12601 FAIR LAKES CIRCLE

Mailing Address 2:

City: FAIRFAX

State: VA

Postal Code: 22033

Country: US

Cancel

Next



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Log Out

## LVE CERTIFICATION

I certify, under penalty of law, that the following is true:

- The manufacturer submitting this notice intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 723.50.
- The manufacturer is familiar with the terms of this section and will comply with those terms.
- The new chemical substance for which the notice is submitted meets all applicable exemption conditions.
- In accordance with 40 CFR 723.50(c)(1), the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30 day review period.

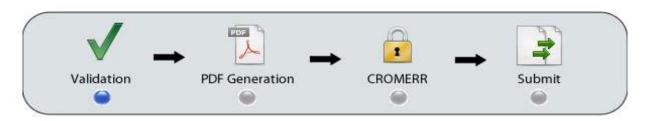
Cancel



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## SUBMISSION PROCESS: VALIDATION



Running validation on your data



Processing. Please wait...

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



## SUBMISSION PROCESS: PDF GENERATION

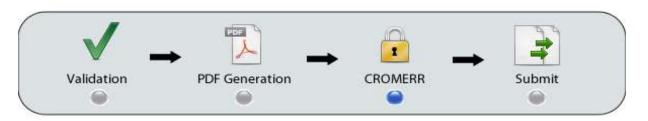
Your PDF preview transaction was successful!







## CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) CERTIFICATION



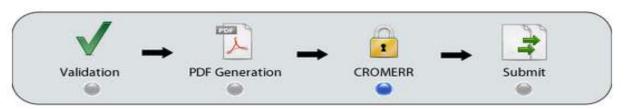
I certify, under penalty of law, that this document and all attachments were prepared under my direction of supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.



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## CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) LOGIN

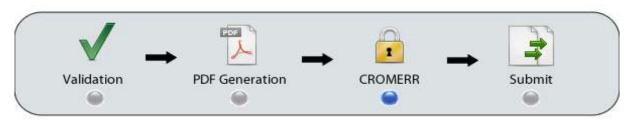


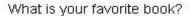
Please login with your CDX password:

Cancel



## CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) SECURITY QUESTION

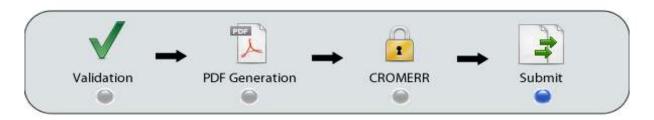








## SUBMIT TO CDX

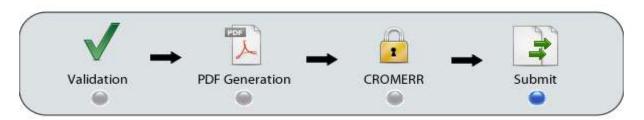


I hereby certify to the best of my knowledge and belief that (1) all information entered on this form is complete and accurate; and (2) any confidentiality claims are true and correct as to that information for which they have been asserted. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 USC 1001





## CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) SUBMISSION



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





#### Forms

The TSCA Section 5 Notices and Supports Reporting rule requires anyone who plans to manufacture or import a new chemical substance (i.e. one not listed on the TSCA inventory) for a non-exempt commercial purpose is required by section 5 of TSCA to provide EPA with notice before initiating the activity.

Use the following forms to report new chemicals to EPA: Premanufacture Notice form (EPA Form 7710-25) should be used to submit PMNs, LVEs, SNUNs, LOREXs, TMEAs, Modifications for LVEs and LoREX submissions; Biotechnology Notice form (EPA Form 6300-14) should be used to submit MCANs, TERAs, Tier I Exemptions, Tier 2 Exemptions, and Biotechnology TMEAs; or Notice of Commencement form (NOC, EPA Form 7710-56) should be used to submit Notices of Commencement for PMNs and MCANs. The Support Document form will be used to submit supplemental information for Premanufacture and Biotechnology notices, such as Test Data, Correspondences, and Amendments to older submissions.

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

#### **User Management**

Manage the access rights of Support persons for each Section 5 Notices and Support document.

#### Resources

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

#### **Authorized Official**

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

## (6)

#### SECTION 5 NOTICES AND SUPPORTS FORMS

If submitting a form for the first time in the Section 5 Notices and Supports application, select the form type from the drop-down menu and click **Start New Form**.

To edit an In Progress form, click the form alias link in the Alias column in the table below.

To access and edit a form previously submitted through CDX, unlock the form by clicking the lock ( 📵 ) icon and enter the passphrase when prompted. All additional changes made to the form will be submitted as an amendment.

To download a copy of record for a submitted form, click the green arrow (--) icon and enter the passphrase when prompted.

You may delete any form that has not yet been submitted by clicking the delete (X) icon.

All columns may be sorted by clicking the column header.



Select the form type and then click Start New Form

Form Type: Premanufacture Notice (PMN)

Start New Form



Log Out

### **ENTER PASSPHRASE**

Please enter your user passphrase and click Next

## Forgot Your Passphrase?

For security reasons, the system administrator does not have access to your passphrase and cannot retrieve it or reset it to a new one. If you have forgotten your passphrase, you must complete a new Section 5 Notices and Supports Form and create a new passphrase for the chemical substances you are intending to import or manufacture.

Cancel

Next



## CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) LOGIN @

Please login with your CDXweb password:

Cancel

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## CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) SECURITY QUESTION @

What is the first and middle name of your oldest sibling?

Cancel



## DOWNLOAD COPY OF RECORD®

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



Download Copy of Record:

File Name

Copy of Record

Action



Home



#### RESOURCES

Section 5 Notices and Supports User Guide

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

#### User Guide

### Helpful Web Links

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

Regulatory Impact Analysis for the Regulation of Microbial Products of Biotechnology: Government Costs

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

Microbial Products of Biotechnology: Final Rule (62 FR 17910)

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

Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms

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

CDX Homepage

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

<u>TSCA Chemical Substances Inventory</u>

click the link provided below to access additional information related to the Toxic <mark>Substances control Act (TSCA) Chemical Substances inventory.</mark>

## TSCA Chemical Substances Inventory

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

Substance Registry Services (SRS)

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

Facility Registry System (FRS)

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

CAS Inventory Expert Services

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

National Pollutant Discharge Elimination System (NPDES)

Click the link provided below to access additional information related to the New Chemicals Program.

New Chemicals Program Homepage

Click the link provided below to access information related to the status of Section 5 Notices.

Status of Section 5 Notices

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

## Resources

- Resources
  - Resources screen within Section 5 Notices and Supports web application provides useful links and user guides
- Contacts
  - TSCA Hotline: 202-564-3011, or <u>TSCA-Hotline@epamail.epa.gov</u>
  - CDX Helpdesk: 888-890-1995, or <a href="helpdesk@epacdx.net">helpdesk@epacdx.net</a>
- Industry Beta Testing (for TSCA Section 5 Bona Fide & ACM)
  - Email <u>Gorder.Chris@epa.gov</u> to participate
  - − December 16 20, 2013
- CDX Registration Walkthrough (December 17, 2013)
- The slides and audio will be made available at: <a href="http://epa.gov/oppt/newchems/epmn/epmn-index.htm">http://epa.gov/oppt/newchems/epmn/epmn-index.htm</a>



## **Questions & Answers**



