

Section 5 Notices and Supports Bona Fide Notice/ACM Demo

December 4, 2013

Office of Chemical Safety and Pollution Prevention

Agenda

Speaker: Chris Gorder, Information Management Division

- Section 5 Notices and Supports Modules
 - Bona Fide
 - ACM
- Resources
- Questions and Answers



Section 5 Notices and Supports Highlights

Speakers: Casey Yeh, CGI; Joseph DeRosa, CGI

 Section 5 Notices and Supports Tool Demo for the Bona Fide and ACM modules







- CDX Login
- Chemical Information Submission System
- Home
- Section 5 Notices and Supports Forms
- Bona Fide Notice
- Alternative Control Measures (ACM)
- Resources



CSPP Primary Authorized Official



CENTRAL DATA EXCHANGE CDX

CDX Home

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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

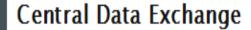
EPA will use the personal identifying information which you provide for the expressed purpose of registration to the Central Data Exchange site and for updating and correcting information in internal EPA databases as necessary. The Agency will not make this information available for other purposes unless 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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Last Login: 12/4/2012 8:39:59 PM

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Services

News and Updates

Manage Your Program Services

No news / updates.

Status Program Service Name Role(s)

CSPP: Submissions for Chemical Safety and Pesticide Programs Primary Authorized Official

Add Program Service

CDX Help Desk: 888-890-1995 | (970) 494-5500 for callers from Puerto Rico and Guam



CHEMICAL INFORMATION SUBMISSION SYSTEM

TSCA Section 5 Notices and Supports - ePMN *

OK

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

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. 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").



Forms

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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.

Items Per Page 25 +

14 items found

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Forms

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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.

Page 1 of 1

14 items found.						iten	is Pei Page.	
Alias	Type 0	Subtype \$	Case Number •	Status #	Modify Date 0	Submission Date	Copy of Record	Action
ACM-20131112-10:32:25 EST	ACM			In Progress	11/12/2013			×
Agent 1 Test	Primary PMN	PMN		In Progress	11/29/2013			×
Agent test	Primary PMN	PMN		In Progress	11/19/2013			×
Biotechnology-20131118-12:22:20 EST	Biotechnology	,		In Progress	11/20/2013	PENDING		ϔ'
Bona Fide 5329	Bona Fide			In Progress	11/29/2013			×
Bona Fide-8	Bona Fide			In Progress	11/27/2013			×
Form1	Bona Fide			In Progress	11/01/2013			×
NOC-20131113-12:52:11 EST	NOC		P-XX-XXXX	<u>₿</u> Submitted	11/20/2013	PENDING		â
NOC-20131119-16:59:01 EST	NOC		P-12-1234	In Progress	11/21/2013	11/20/2013	#	
NOC-20131120-14:34:53 EST test	NOC		P-00-0000	In Progress	11/21/2013	11/20/2013	#	
Primary PMN-20131113-12:52:33 EST	Primary PMN			In Progress	11/13/2013			×

11/29/2013

- To access and edit a form previously submitted through CDX, unlock the form by clicking the lock (in) 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.

Primary PMN

Forms

PMN

· All columns may be sorted by clicking the column header.

Agent 1 Test

Page 1 of 1 Items Per Page: 14 items found. Alias Subtype Case Status | Modify Submission Copy of Action Type : Number | Date Date Record × ACM-20131112-10:32:25 EST ACM In Progress 11/12/2013

Agent test Primary PMN PMN In Progress 11/19/2013 Biotechnology-20131118-12:22:20 Biotechnology In Progress 11/20/2013 PENDING **EST** Bona Fide 5329 Bona Fide 11/29/2013 In Progress

Bona Fide-20131129-10:30:38 EST Bona Fide In Progress 11/30/2013 Form1 Bona Fide In Progress 11/01/2013 ***** NOC-20131113-12:52:11 EST NOC P-XX-XXXX 11/20/2013 PENDING

In Progress

Submitted NOC-20131119-16:59:01 EST NOC P-12-1234 In Progress 11/21/2013 11/20/2013 **■** NOC-20131120-14:34:53 EST test NOC P-00-0000 11/29/2013 PENDING

Submitted Primary PMN-20131113-12:52:33 EST Primary PMN In Progress 12/02/2013 Support-20131113-12:52:22 EST Support In Progress 11/20/2013

Support-20131119-16:00:09 EST TestData T-23-1223 In Progress 11/19/2013 Support Support-8 Support TestData P-XX-XXXX In Progress 11/21/2013

Export options: 4 CSV | X Excel | XML | 2 PDF

Select the form type and then click Start New Form Bona Fide Form Type:

Start New Form



	CREATE PAS	SPHRASE
		better protect your form, your passphrase should contain a paces, but should not contain special characters (for example, +,
	New Passphrase: Confirm New Passphrase:	
passphrase will be used as a		passphrase and distributing it to only authorized individuals. Your of your data. As an Authorized Official, you are responsible for supports.
print, submit, or make cha	nges. You will need to complete a ne or security reasons, the system admir	e to access your Section 5 Notices and Supports Form to ew Section 5 Notices and Supports Form and create a new nistrator will not have access to your passphrase and will
	Cancel	Next

Bona Fide Notice



Bona Fide Primary Authorized Official

- General Document Information
- Primary Contact Information
- Technical Contact Information
- Statement of Intent
- Letter of Support
 - Letter of Support Submitter Information
 - Letter of Support Submission Information
- Chemical
 - Chemical Identification Information
 - - Class 1 or 2 Chemical Substances
 - Class 2 Substances
 - Use Information
 - ☐ Site Information
 - Submitter Site Identification
 - Document Management
 - Optional Cover Letter

Bona Fide (Bona Fide-20130913-21:02:16 EDT) > General Document Information GENERAL DOCUMENT INFORMATION

The form alias is a required field that allows the user to give the Bona Fide a name to be displayed in the 'Alias' field on the Section 5 Notices and Supports Forms screen. Its purpose is to make it easier for you to distinguish between multiple forms. If an alias is not selected, the field will default to the date and time the Bona Fide was created. The form alias may be changed at any time.

Form Alias:

Bona Fide-20130913-21:02:16 EDT

Please check all	applicable	checkboxes	below:
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I claim the entirety of the submission as CBI.

The technical contact is a subject matter expert (SME) who is capable of answering questions related to the chemical within the Bona Fide. The technical contact does not have to physically work at the site reported but must possess extensive knowledge on the chemical reported in order to answer EPA's questions pertaining to the submission. Please check the 'Technical Contact' checkbox below to identify a technical contact for your submission.

Technical Contact:

The 'Letter of Support' screen is used to enter contact information regarding the Letter of Support submitter who will submit information separately for the Bona Fide. The email address will be used to send the secondary submitter the unique identification number to tie the Letter of Support, completed by the secondary submitter, to the primary Bona Fide completed by the primary submitter. Please check the 'Letter of Support' checkbox below to identify a Letter of Support submitter.

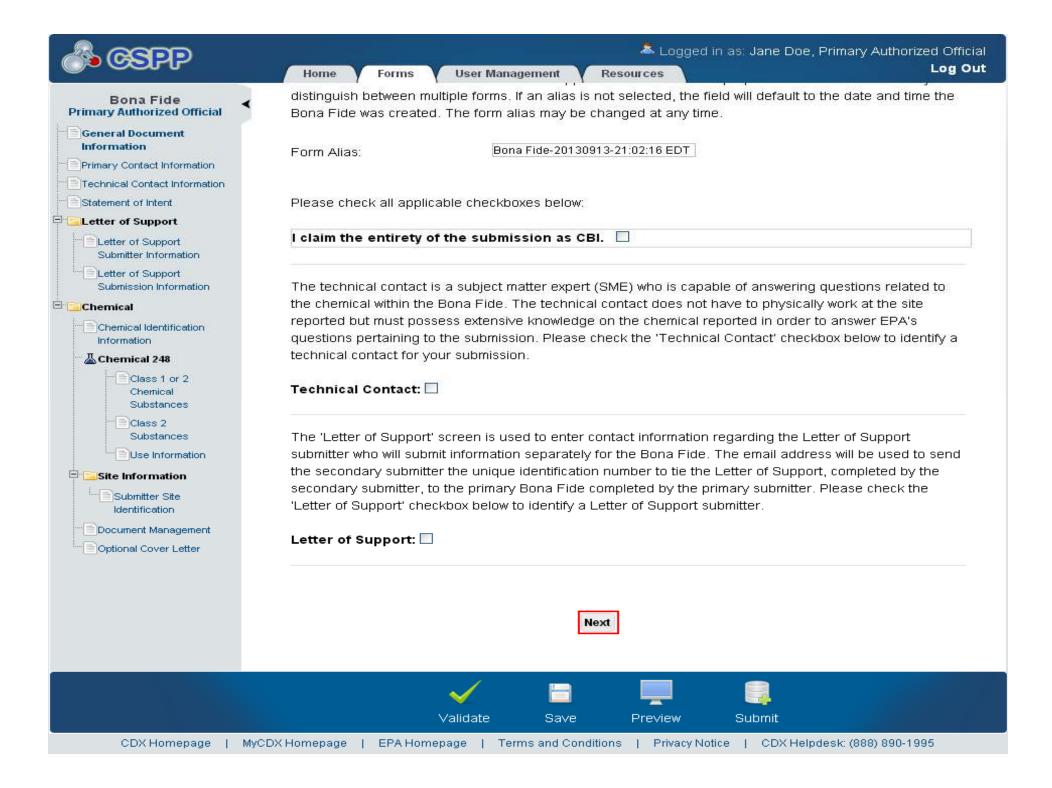
Letter of Support: 🗌



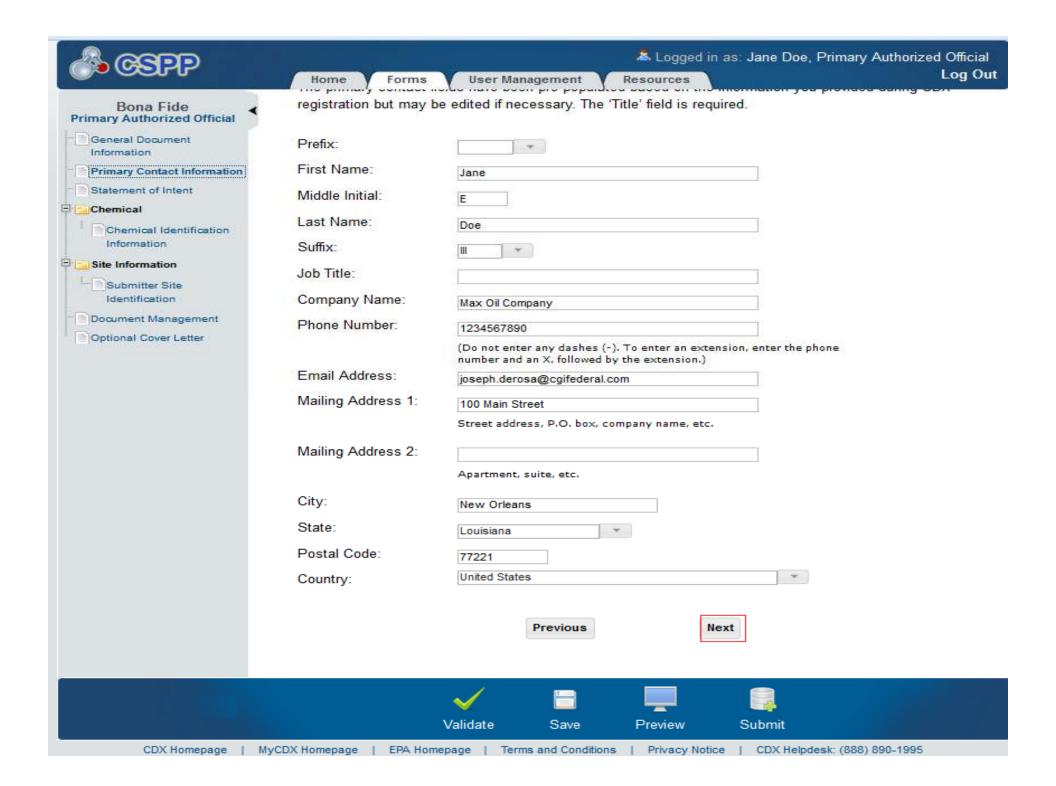






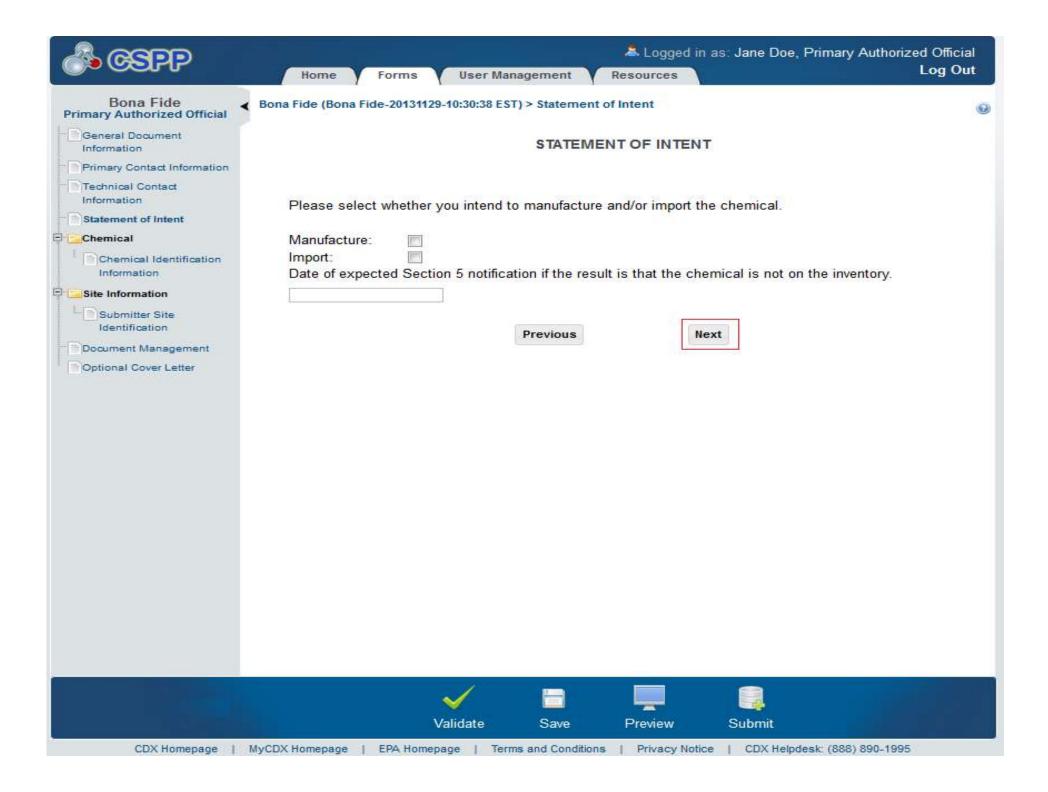


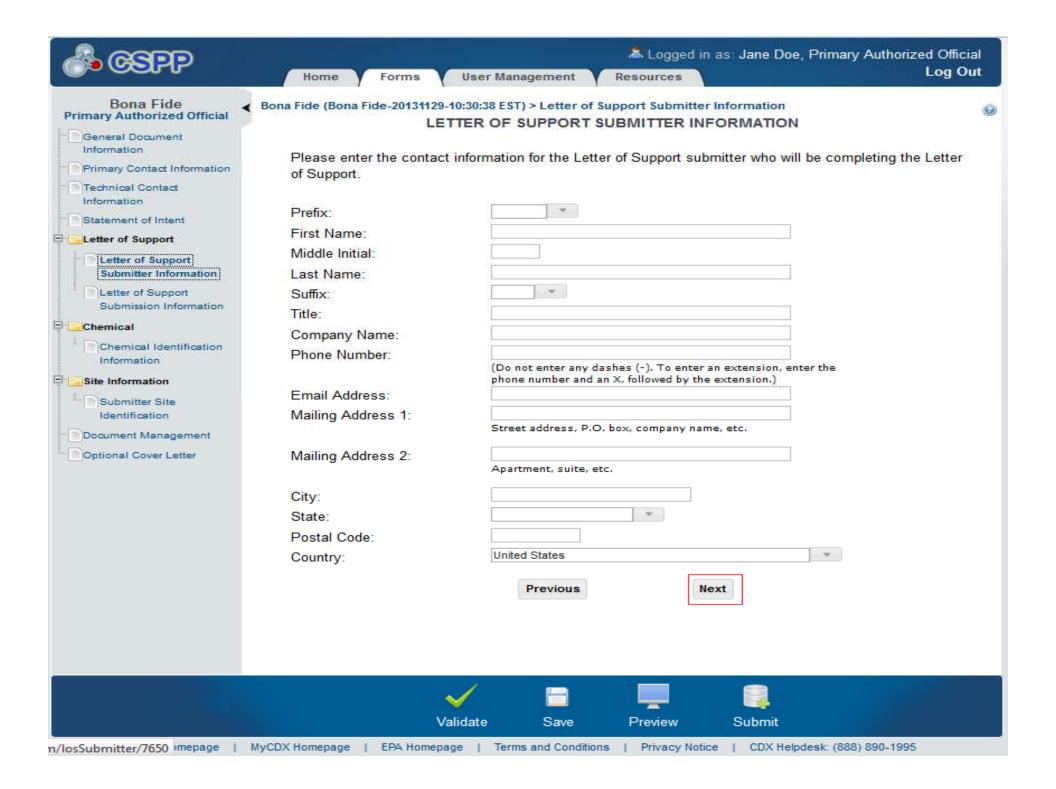
CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

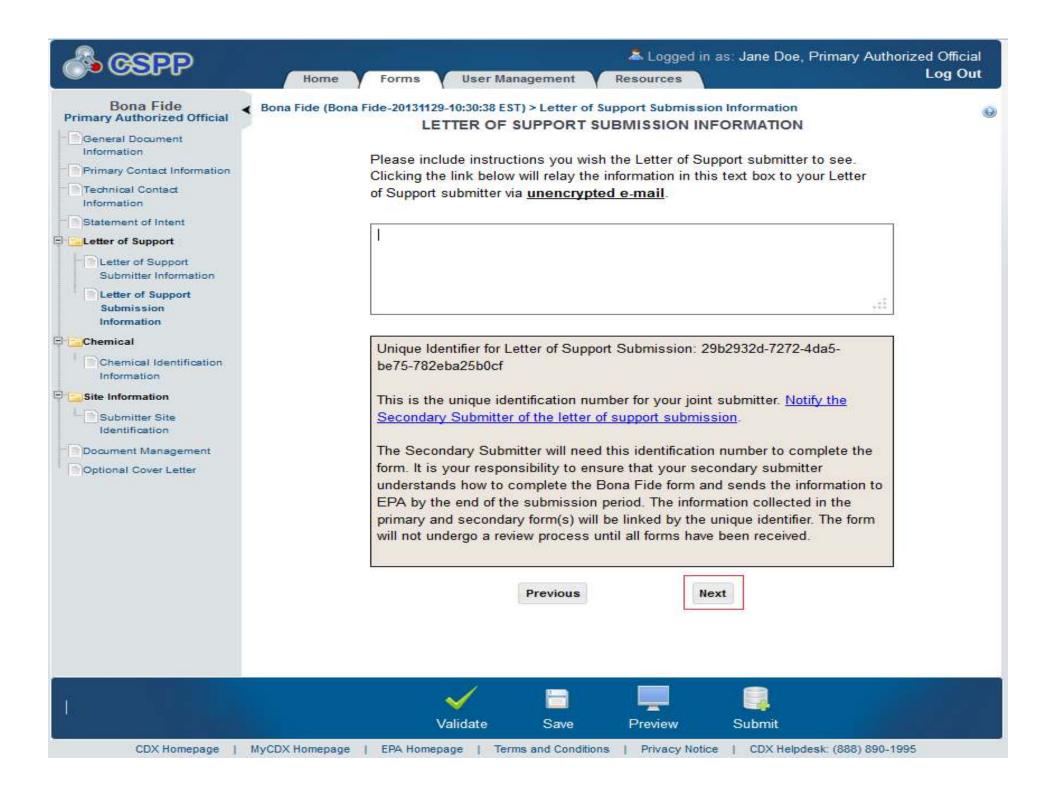


CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

A CSPP		🚨 Logged in as: Jane Doe, Primary Authorized Official
	Home Forms	User Management Resources Log Out
Bona Fide	information if required.	
Primary Authorized Official		
General Document	Prefix:	
Primary Contact Information	First Name:	
Technical Contact	Middle Initial:	
Statement of Intent	Last Name:	
Chemical	Suffix:	
Chemical Identification	Title:	
Site Information	Company Name:	
Submitter Site	Phone Number:	
Document Management		(Do not enter any dashes (-). To enter an extension, enter the phone number and an X, followed by the extension.)
Optional Cover Letter	Email Address:	
	Mailing Address 1:	
		Street address, P.O. box, company name, etc.
	Mailing Address 2:	
		Apartment, suite, etc.
	City:	
	State:	w
	Postal Code:	
	Country:	United States
		Previous
		Validate Save Preview Submit
CDX Homepage My	CDX Homepage EPA Home	nepage Terms and Conditions Privacy Notice CDX Helpdesk: (888) 890-1995









CC:

From: Jane.Doe@Test.com

Jane.Doe@Test.com

To:

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

Subject: 2013 Bona Fide

addresses.

Message: As the Authorized Official of Max Oil Company, I have identified you as a Secondary Submitter of a letter of

support submission for this 2013 Bona Fide form.

Please use the Section 5 Notices and Supports application to provide the correct information for the necessary items in this form. See the instructions below for accessing the Section 5 Notices and

Supports application. You will need to use the unique identification number to access and complete the

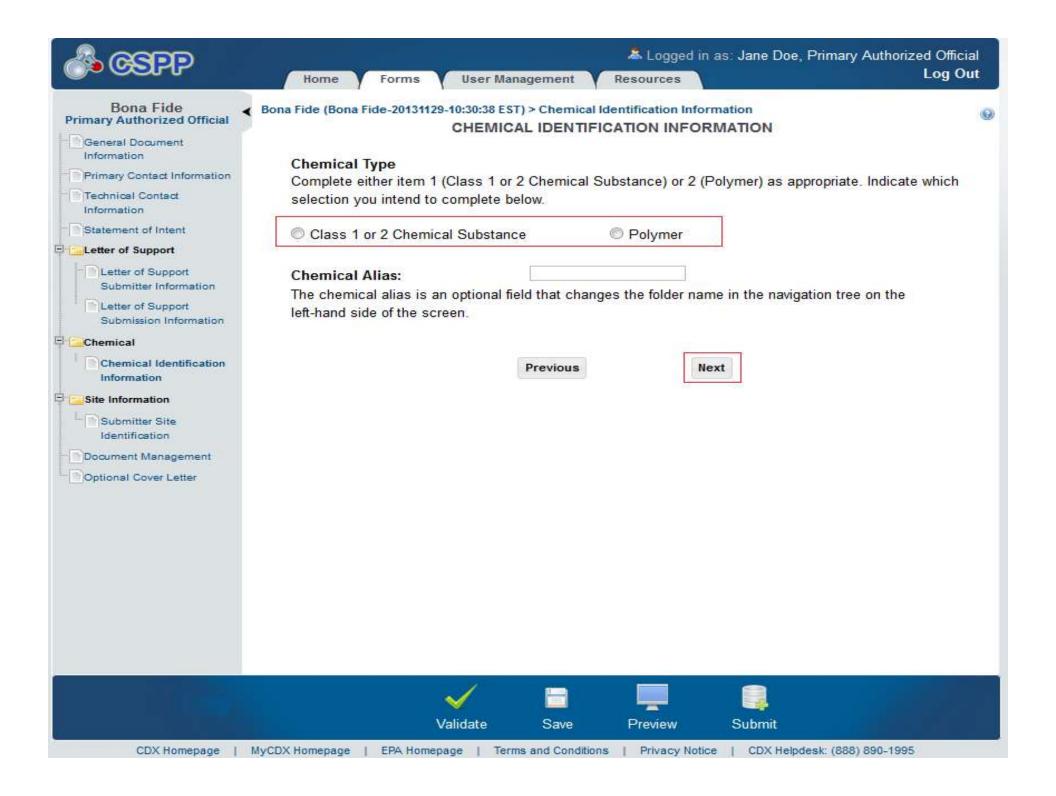
Bona Fide form for the letter of support submission.

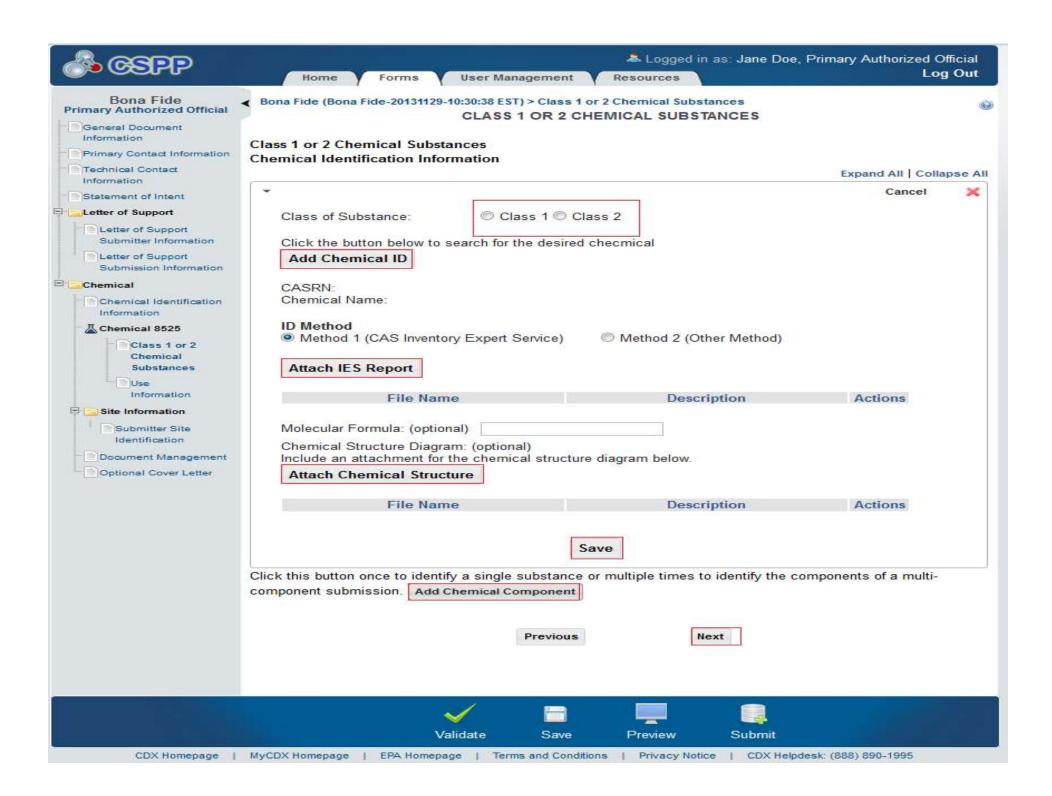
Unique Identifier 29b2932d-7272-4da5-

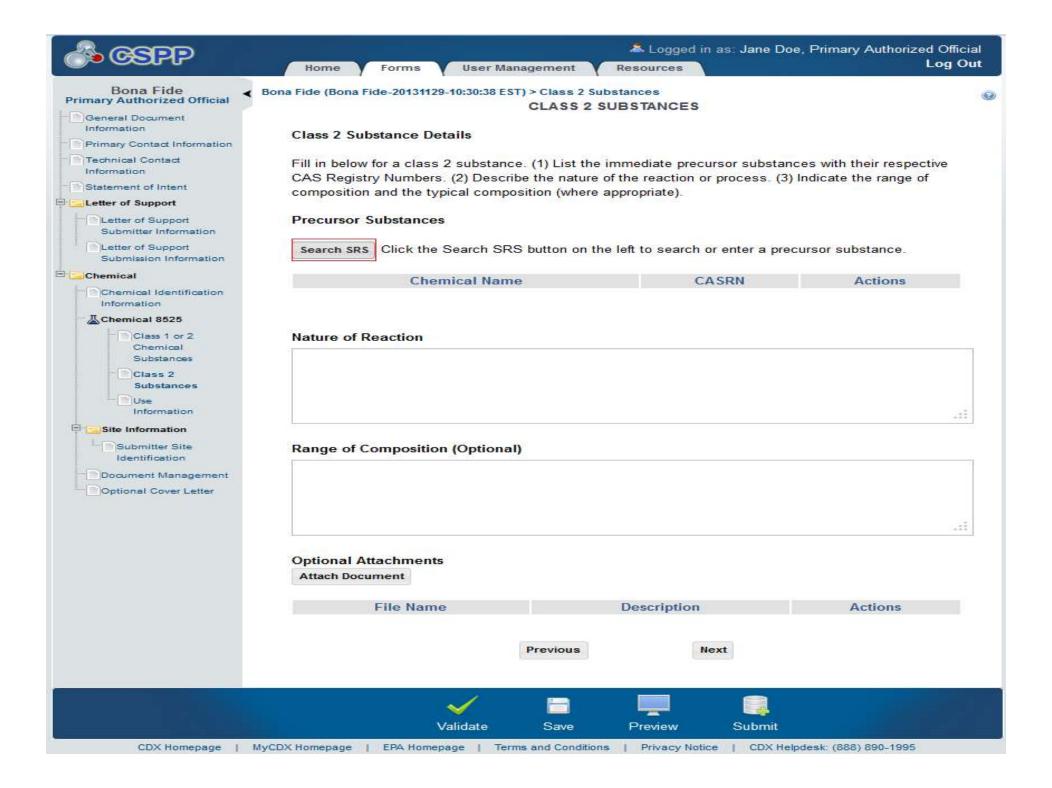
be75-782eba25b0cf

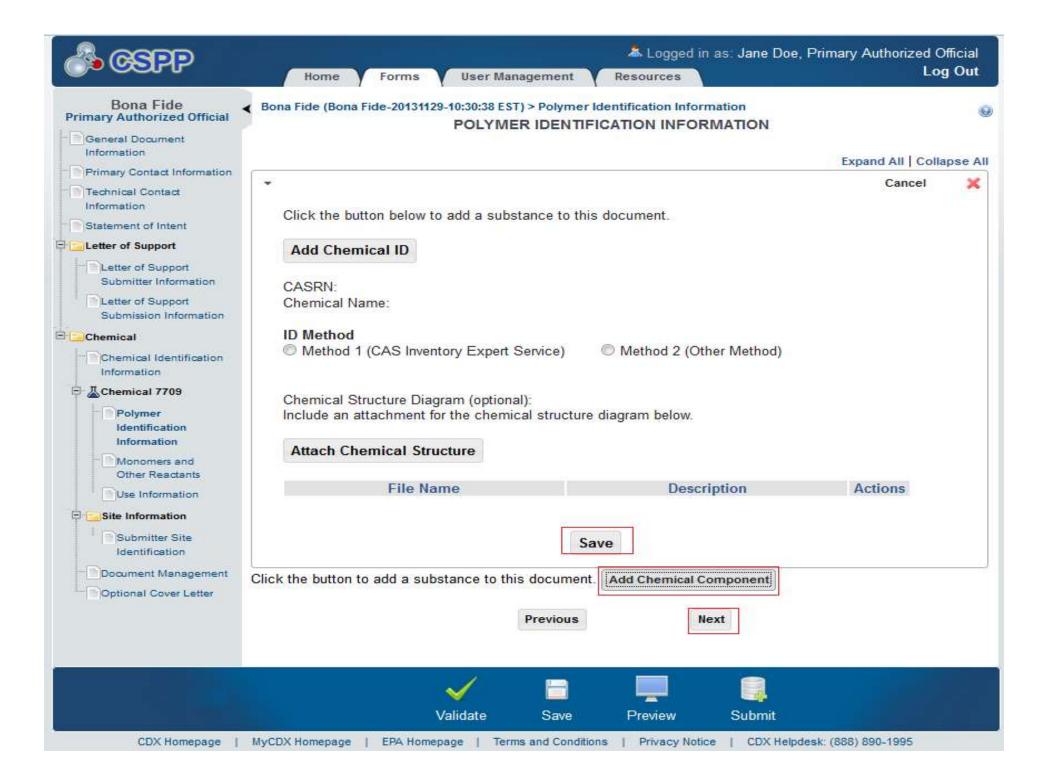
Information about the Section 5 programs, how to access the Section 5 Notices and Supports application, and instructions for reporting under the Section 5 rule are available at www.epa.gov/oppt/newchems/. For additional information or if you believe you have received this email in error, please contact me.

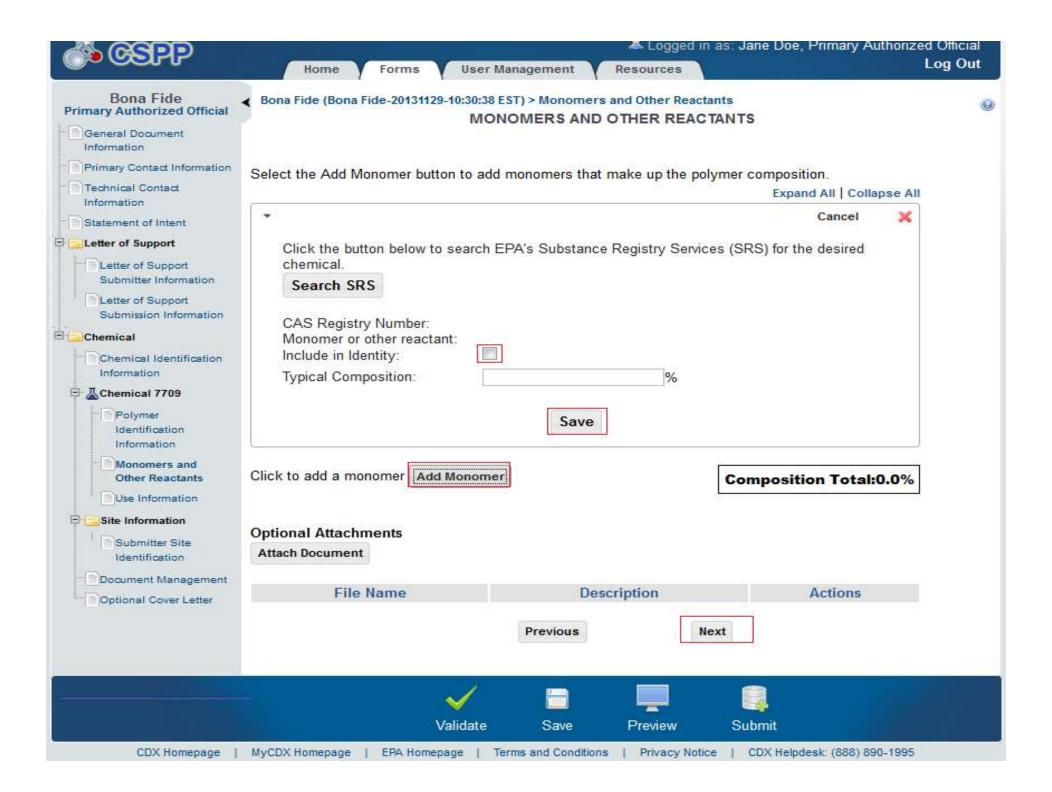
Additional Comments:

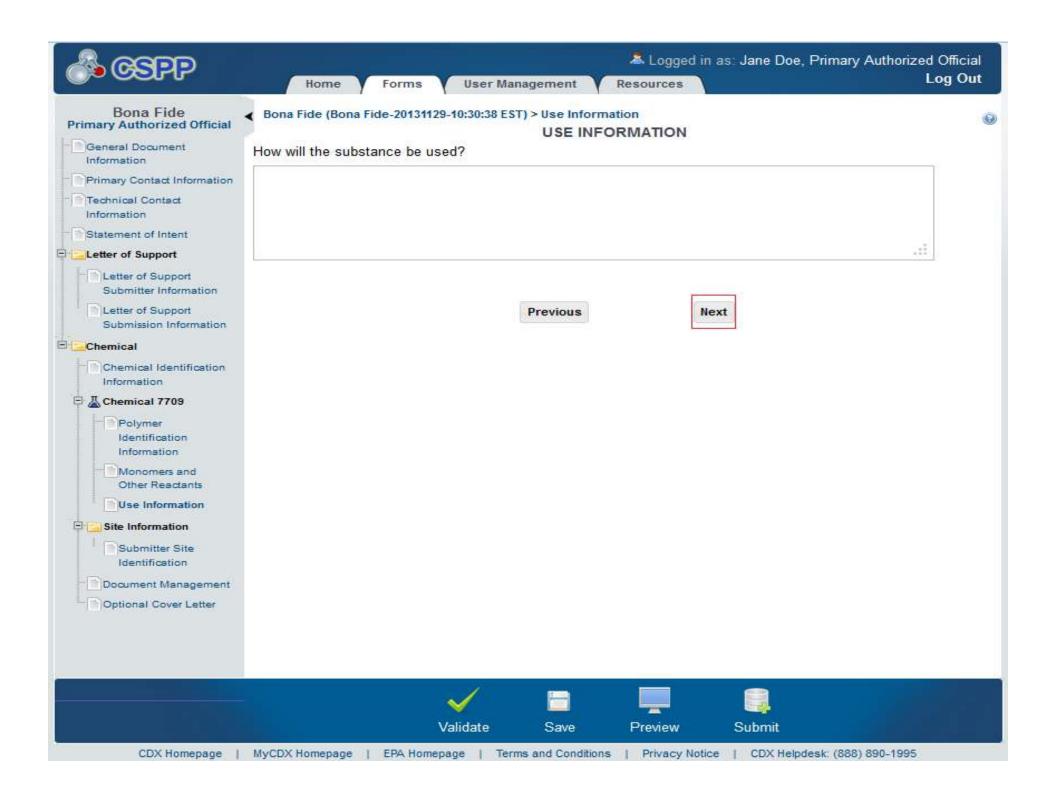


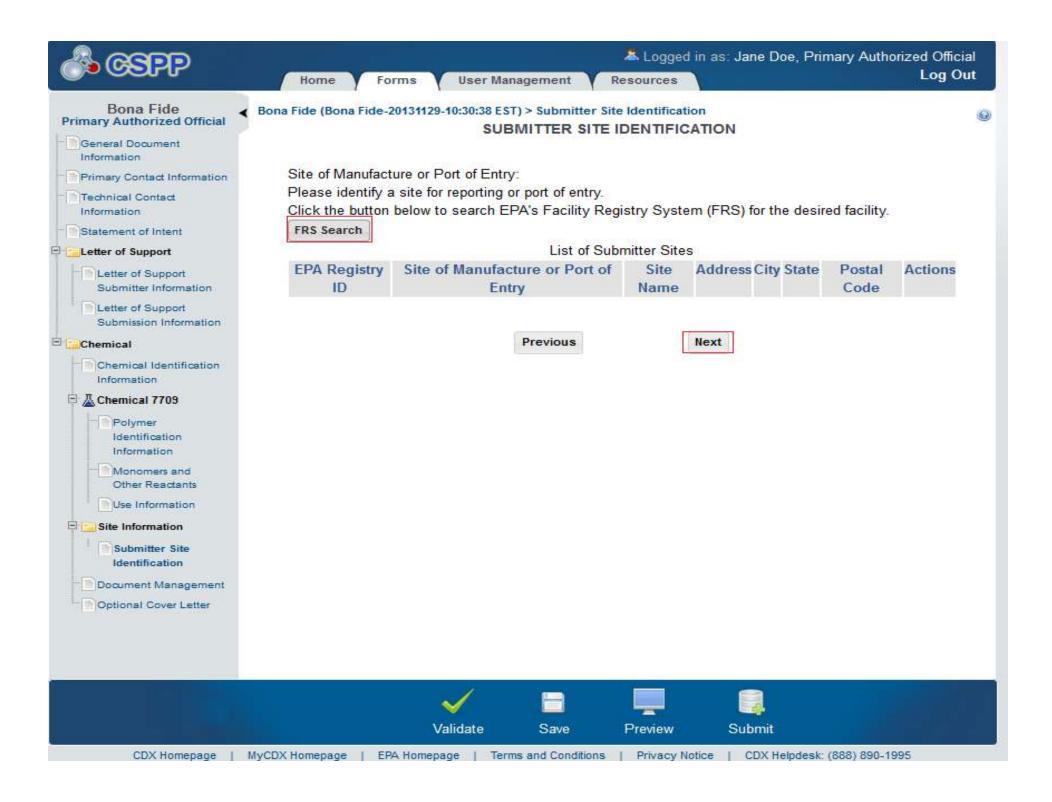


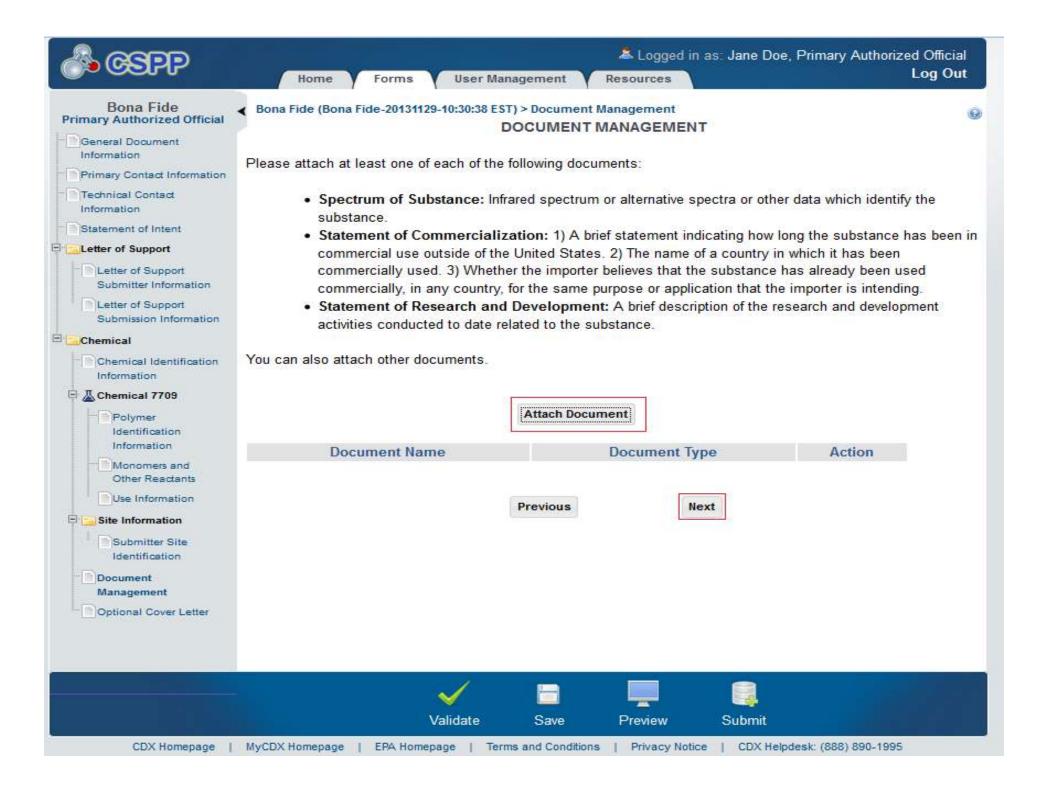


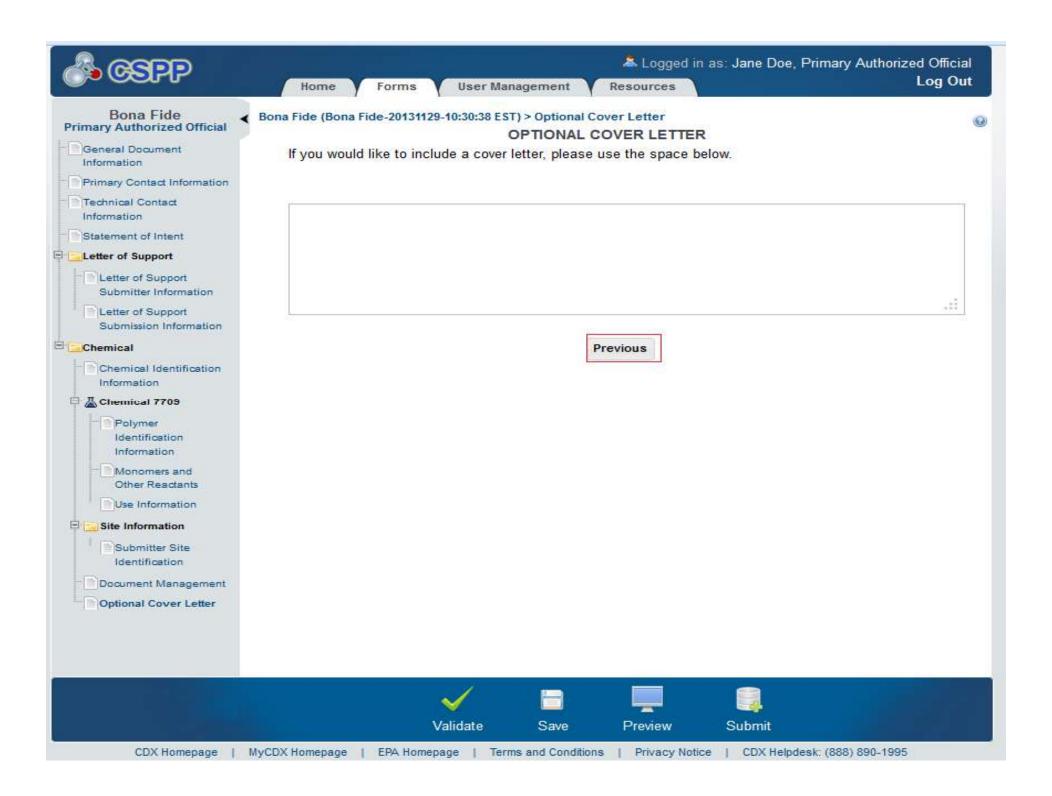












Alternative Control Measures (ACM)



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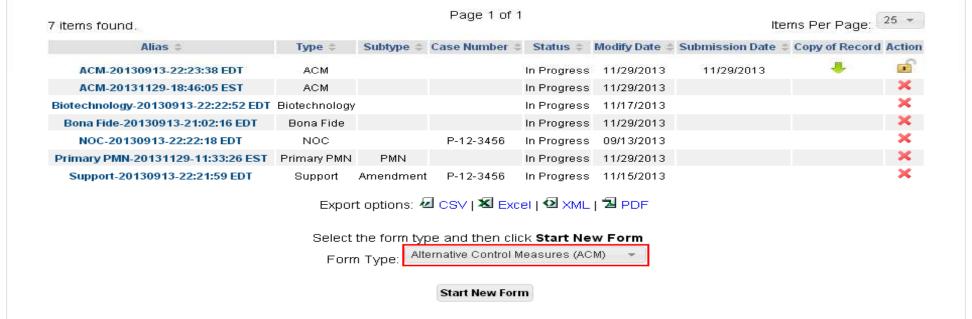
Resources

SECTION 5 NOTICES AND SUPPORTS FORMS

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







CREATE PASSPHRASE

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

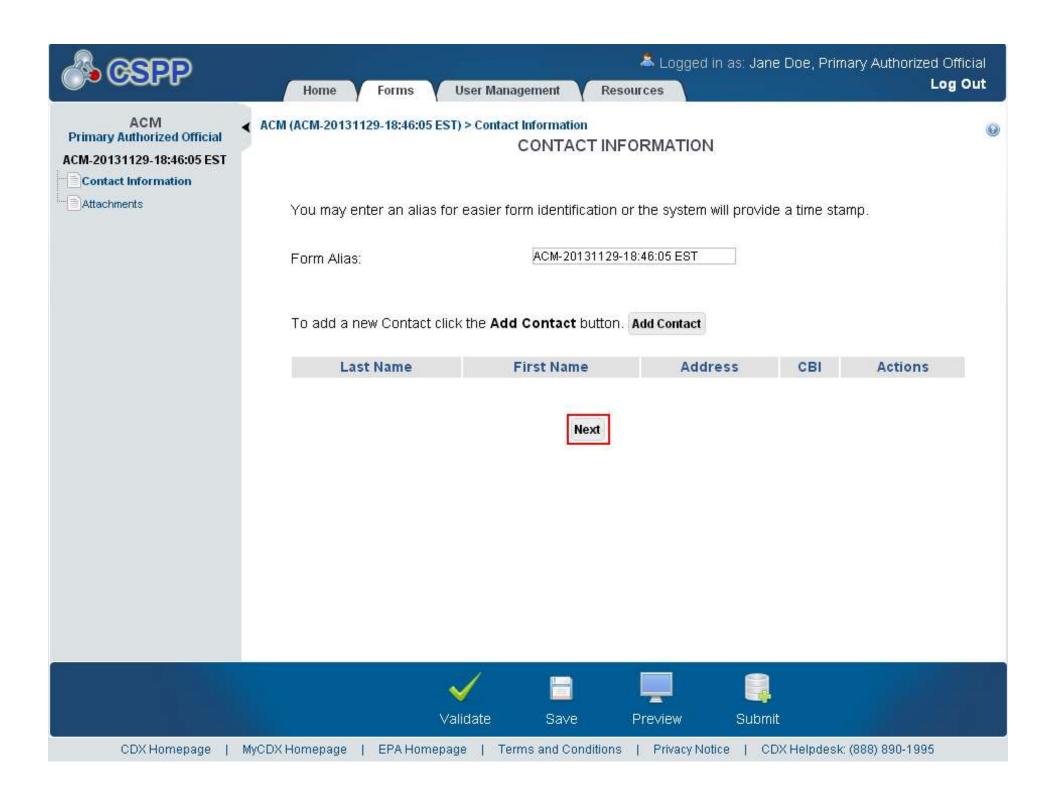
New Passphrase: Confirm New Passphrase:

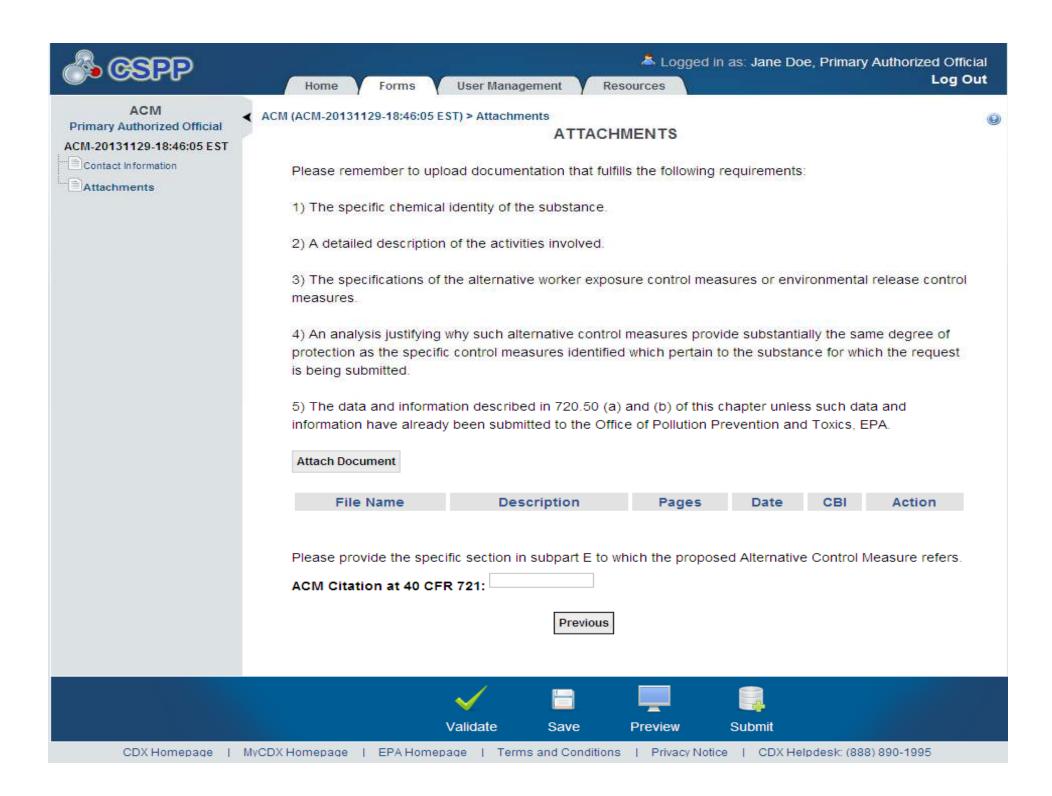
As an Authorized Official, you are responsible for remembering your passphrase and distributing it to only authorized individuals. Your passphrase will be used as an encryption key to protect the contents of your data. As an Authorized Official, you are responsible for remembering your passphrase and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

Next





Demo of Section 5 Notices and Supports Web Tool

Submission Process





SUBMITTING OFFICIAL INFORMATION

0

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

This confirmation is required to proceed with the submission process
Please confirm that you are the legally responsible party from the submitting
company

1

First Name: Jane

Middle Initial:

Last Name: Doe

Job Title: Boss

Company Name: Max Oil Company

Phone Number: 1234567890

Email Address: joseph.derosa@cgifederal.com

Mailing Address 1: 100 Main Street

Mailing Address 2:

City: New Orleans

State: LA Postal Code: 77221

Country: US

Cancel

Next



BONA FIDE INTENT TO MANUFACTURE OR IMPORT



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

 The submitter of this notice intends to manufacture or import the identified substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 720.25.

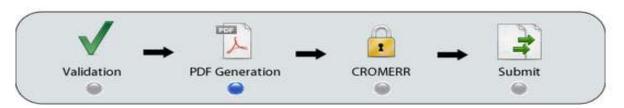
Cancel



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SUBMISSION PROCESS: PDF GENERATION



Generating a finalized PDF file of your submission

= =

Processing. Please wait...



SUBMISSION PROCESS: PDF GENERATION

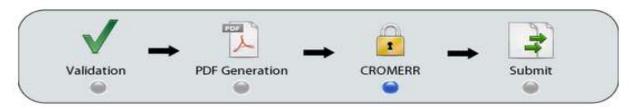
Your PDF preview transaction was successful!







CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) CERTIFICATION



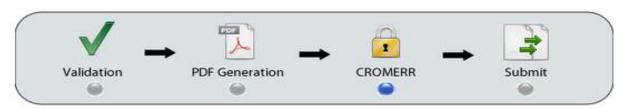
I certify, under penalty of law, that this document and all attachments were prepared under my direction of supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage 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



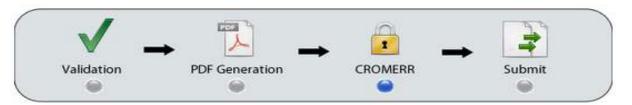
Please login with your CDX password:

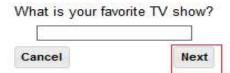


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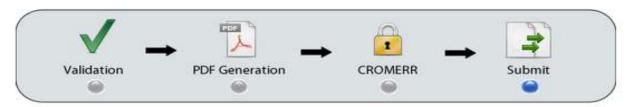
CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) SECURITY QUESTION







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.

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User Management

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

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RESOURCES

Section 5 Notices and Supports User Guide

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

User Guide

Helpful Web Links

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

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

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

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

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

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

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

CDX Homepage

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

TSCA Chemical Substances Inventory

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

TSCA Chemical Substances Inventory

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

Substance Registry Services (SRS)

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

Facility Registry System (FRS)

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

CAS Inventory Expert Services

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

National Pollutant Discharge Elimination System (NPDES)

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

New Chemicals Program Homepage

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

Status of Section 5 Notices

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

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 helpdesk@epacdx.net
- Industry Beta Testing
 - Email <u>etscareporting@epa.gov</u> to participate
 - December 16 20, 2013
- CDX Registration Walkthrough (December 17, 2013)
- The slides and audio will be made available at: http://epa.gov/oppt/newchems/epmn/epmn-index.htm



Questions & Answers



