TSCA Section 5 Notice of Commencement (NOC)

EPA Form No. 7710-65

OMB Control No. 2070-0038

Expiration 12/31/2025

CHEMICAL INFORMATION SUBMISSION SYSTEM

TSCA Section 5 Notices and Supports - ePMN



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. 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"). For questions regarding TSCA Section 5 Notices, a pre-submission inquiry can be submitted.

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.

Paperwork Reduction Act Notice

Paperwork Reduction Act Notice

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., and assigned OMB Control No. 2070-0038. Responses to this collection of information are mandatory for certain persons who engage in the covered activities as specified in section 5 of the Toxic Substances Control Act and EPA implementing regulations (40 CFR parts 720 through 725). 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, which varies based on the activity, is estimated to be between 17 to 526 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 Director of the Information Engagement Division, Office of Mission Support, 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.

Authority

The Government Paperwork Elimination Act (GPEA) (44 U.S.C. 3504) provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3) (Ref. 2), provides that any requirement in title 40 of the CFR to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency published a document in the Federal Register announcing that EPA is prepared to receive certain documents in electronic form. For more information about CROMERR, go to http://www.epa.gov/cromerr.

Forms

The TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting rule requires anyone who intends to manufacture (which includes import) a new chemical substance (i.e., one not listed on the TSCA Inventory) for a non-exempt commercial purpose or to manufacture or process a chemical substance for a significant new use previously designated by EPA to provide EPA with notice before initiating the activity.

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

To determine if a substance is on the TSCA inventory, and therefore excluded from the requirement to provide premanufacturing notification, a submitter may submit a Bona Fide Intent to Manufacture notice ('Bona Fide Notice'). For questions regarding TSCA Section 5 Notices, a pre-submission inquiry can be submitted.

User Management

Manage the access rights of Support persons (including Agents/Consultants) for each Section 5 Notices and Support form.

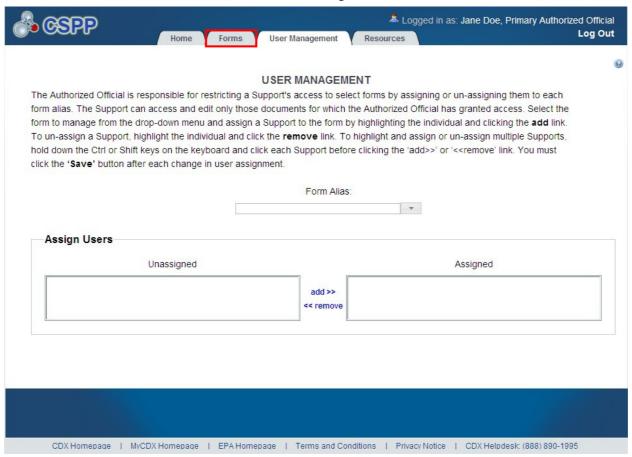
Resources

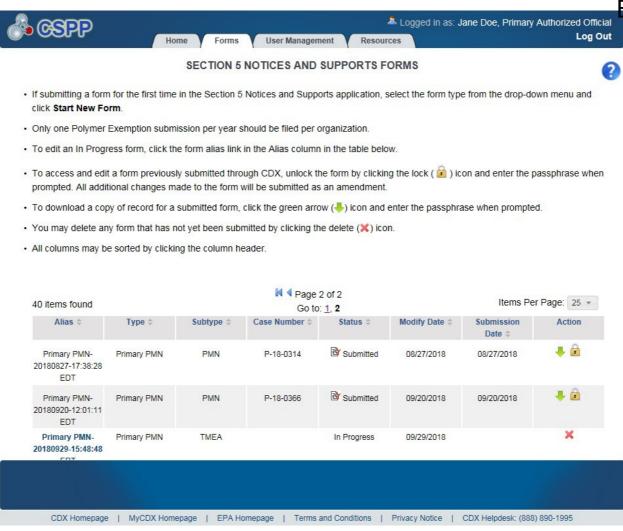
Displays links to helpful guidance documents and websites for TSCA and Section 5.

Authorized Official

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

Exhibit 3-5 User Management Screen





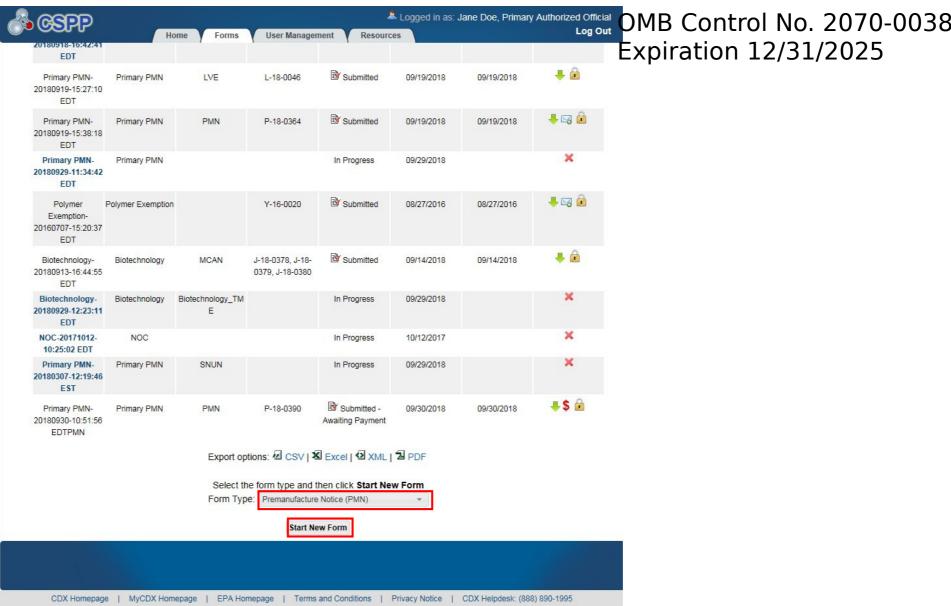


Exhibit 3-8 Create Passphrase Screen

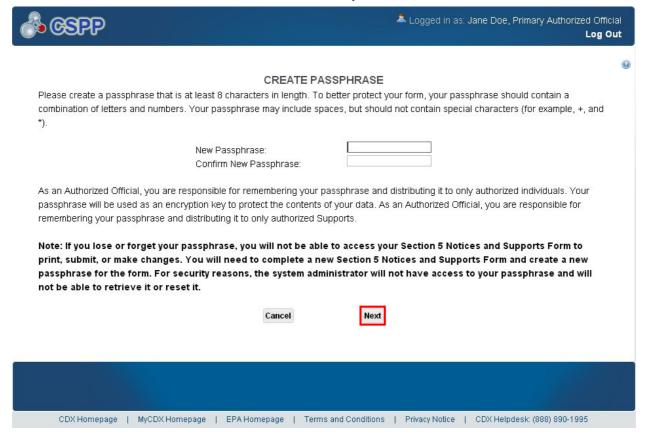
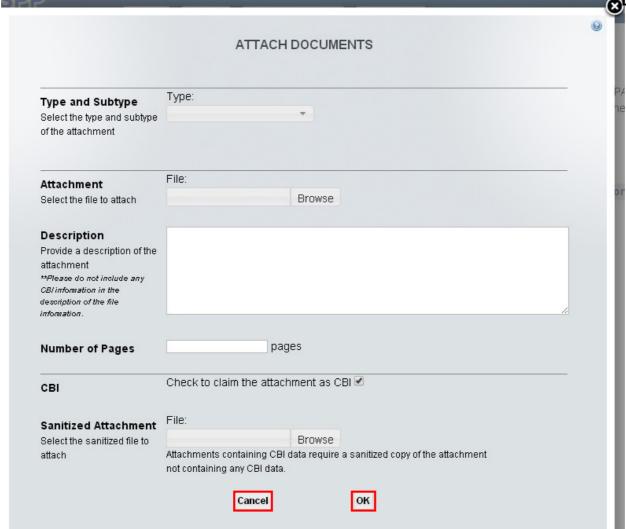


Exhibit 3-10 Attach Documents Pop-Up Window

OMB Control No. 2070-0038

Expiration 12/31/2025



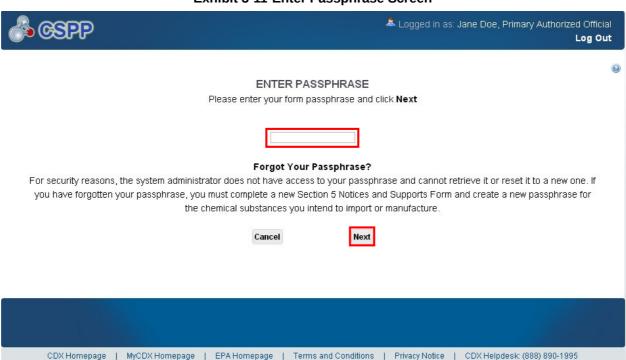
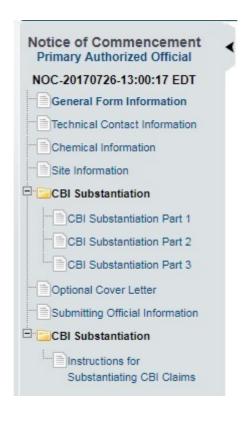
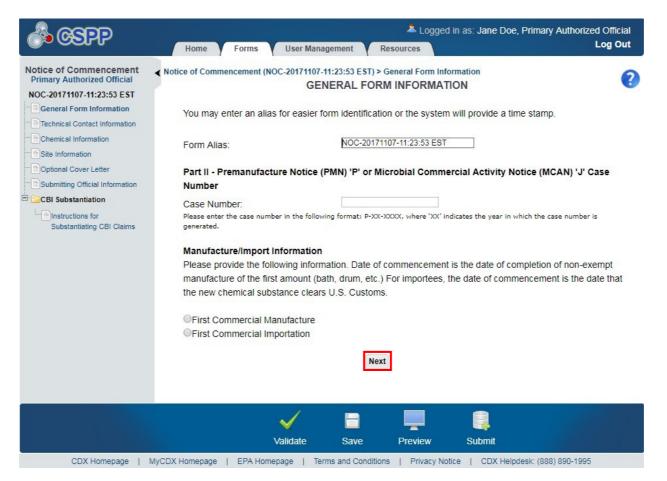
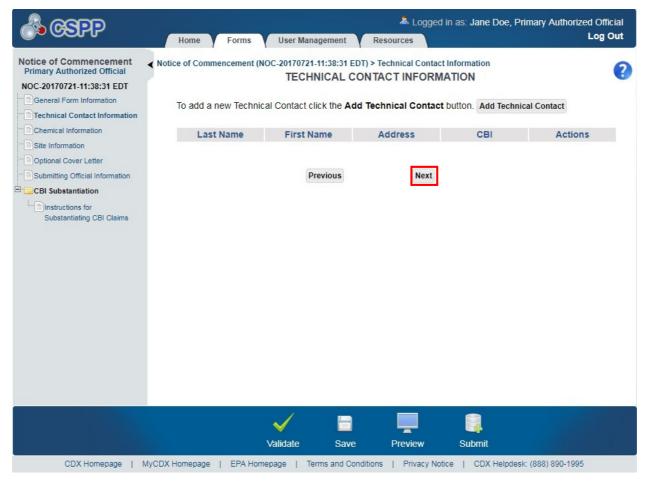


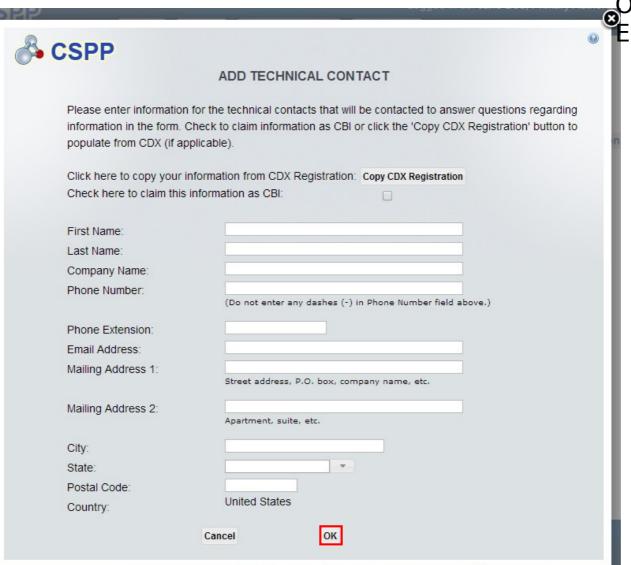
Exhibit 3-11 Enter Passphrase Screen











EPA Form No. 7710-56

Exhibit 6-4 Chemical Information Screen (NOC)

**Logged in as: Jane Doe, Primary Authorized Official*

OMB Control No. 2070-0038

Expiration 12/31/2025

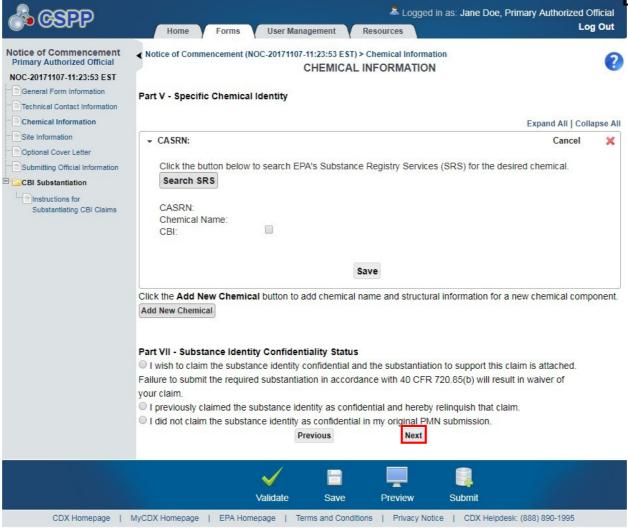


Exhibit 6-5 Site Information Screen (NOC)



Expiration 12/31/2025 **Premanufacture Notice** ◆ Premanufacture Notice (Primary PMN-20231218-09:54:49 EST) > CBI Claims and Substantiation. **Primary Authorized Official** CBI CLAIMS AND SUBSTANTIATION Primary PMN-20231218-09:54:49 Click the Expand icon 🔾 to view and populate the substantiation answers for the CBI claims made. A green checkmark 🔾 indicates that substantiation answers have been provided and is complete. A substance that is missing an icon indicates an incomplete set of **EST** substantiation answers. Add Consolidated Chemical Note: Please do not copy/paste CBI Substantiations from external applications to prevent issues with form validation, and result in not being able to complete the submission or migration process. If you need to copy/paste from an external application, paste the Site Information substantiations into Notepad, then copy from Notepad into the reporting application. Site Information Sites Controlled By Selected Chemical Identifier: N/A Search: Others Show 150 ✓ entries Selected Chemical Claim: Prenotice Communication Number Data Element Chemical Identifier Operations Status Action A APPLICABLE ONLY TO GENERAL CBI CLAIMS Operation 1 Agent Information (PMN) A person may assert a claim of confidentiality for the specific chemical identity of a chemical substance as Submitter described in § 711.15(b)(3) of this part only if the identity of that chemical substance is treated as confidential in the Operation Technical Contact Information (PMN) Information Master Inventory File as of the time the report is submitted for that chemical substance. Generic chemical identities Occupational and accession numbers may not be claimed as confidential. To assert a claim of confidentiality for the identity of a Additional Submission Information (PMN) Exposures reportable chemical substance, you must submit with the report detailed written answers to the questions from Environmenta subsection (b) and to the following questions. 4 Prenotice Communication Number N/A Releases *X Remove æ Previously Submitted Notice Number N/A Add Operation 1. Please specifically explain what harm to the competitive position of your business would be likely to result ď٦ Bona Fide Intent Notice Number N/A Operations Controlled by from the release of the information claimed as confidential. How would that harm be substantial? Why is the Others substantial harm to your competitive position likely (i.e., probable) to be caused by release of the information Class 1 Or 2 Chemical (PMN) Add Operation rather than just possible? If you claimed multiple types of information to be confidential (e.g. site information, exposure information, environmental release information, etc.), explain how disclosure of each type of Optional Pollution Prevention Class 1 Or 2 Additional Chemical (PMN) information would be likely to cause substantial harm to the competitive position of your business. Additional Attachments Class 1 Or 2 Production Information (PMN) □ CBI Attachment Summary Optional Cover Letter Showing 1 to 20 of 20 entries Previous Next 2980 characters remaining Submitting Official Information CBI Substantiation

OMB Control No. 2070-0038

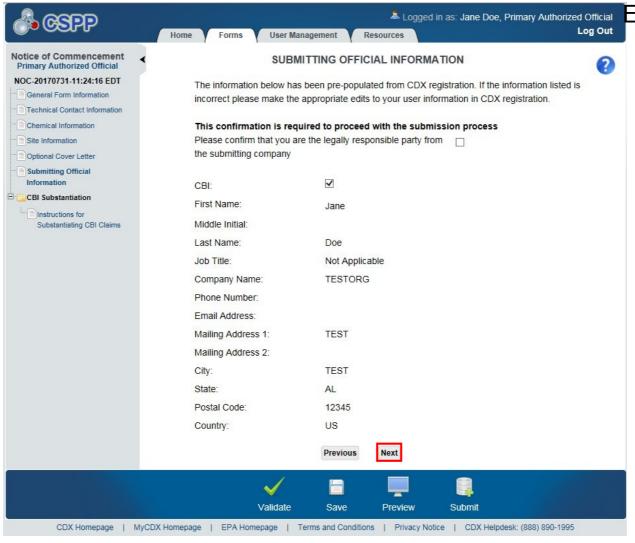
CBI Claims and Substantiation

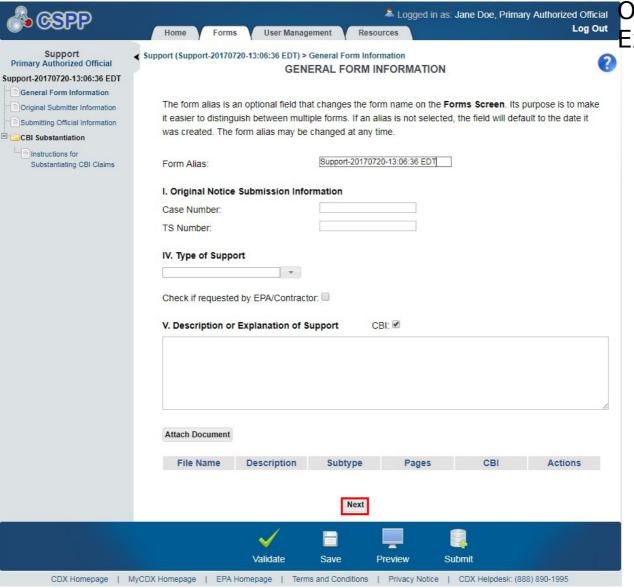
& CSPP	Home Forms Use	Log	ged in as: Jane Doe, Prima	Log Out	OMB Control No	
Support Primary Authorized Official Support-20170731-12:13:21 EDT	■ Support (Support-20170731-12:13:2	1 EDT) > Original Submitter Informat PRIGINAL SUBMITTER INFO		?	Expiration 12/3	1/2025
General Form Information Original Submitter Information	Please enter the information form for which you are filing	of the Authorized Official who su a Support document.	bmitted the original PMN/B	iotech/Bona Fide		
Submitting Official Information	Click here to copy your infor	mation from CDX Registration:	Copy CDX Registration			
□ CBI Substantiation	Check here to claim this info	and the state of t				
Substantiating CBI Claims	First Name: Last Name: Position: Company Name: Phone Number: Phone Extension: Email Address: Mailing Address 1: Mailing Address 2:	(Do not enter any dashes (-) in Pho Street address, P.O. box, company				
	City: State: Postal Code: Country:	Apartment, suite, etc. United States Previous Next				
CDX Homepage	Valida MyCDX Homepage EPA Homepage	ate Save Preview Terms and Conditions Privace	Submit y Notice CDX Helpdesk: (388) 890-1995		

Navigation: Click the 'Validate' icon () located in the bottom action bar to validate the form. Click the 'Save' icon () located in the bottom action bar to save the overall form. Click the EPA Form No. 7710-56 Preview' icon () located in the bottom action bar to generate a PDF preview of the form.

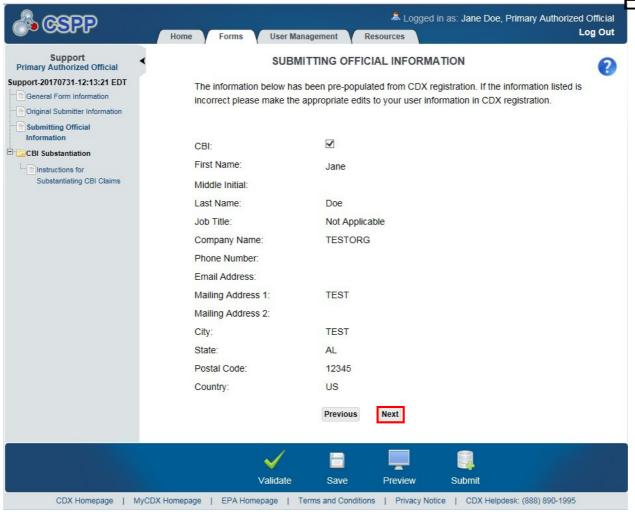
& CSPP	Home	Forms	User Manage	ement R	Logged i	in as: Jane Doe, Primary Authorize	ed Official Log Out
Notice of Commencement Primary Authorized Official NOC-20170721-11:38:31 EDT General Form Information Technical Contact Information Chemical Information CBI Substantiation CBI Substantiation Part 1 CBI Substantiation Part 3 Optional Cover Letter Submitting Official Information Instructions for Substantiating CBI Claims	If you wo	uld like to inc		TIONAL Co	Optional Cover Let OVER LETTER ere. Next		?
			Validate	Save	Preview	Submit	
CDX Homepage	MyCDX Homepage	EPA Home	epage Terms	s and Condition	s Privacy Notic	ce CDX Helpdesk: (888) 890-1995	

Navigation: Click the 'Validate' icon () located in the bottom action bar to validate the form. Click the 'Save' icon () located in the bottom action bar to save the overall form. Click the 'Preview' icon () to generate a PDF preview of the form. Click the 'Next' button to navigate to the 'Submitting Official Information' screen.





EPA Form No. 7710-56



CBI SUBMISSION Form Approved. O.M.B. No. 2070-0012 NOC2014P1 U.S. Environmental Protection Agency Report Number NOTICE OF COMMENCEMENT OF MANUFACTURE OR IMPORT (40CFR6720.102) Part I - SUBMITTER IDENTIFICATION Name of Authorized Official Mailing Address (number and street) CBI* Manu-(first) facturer/ Importer Company Name City State Zip (in U.S.) Telephone Number Technical Name Contact (in U.S.) Part II - Premanufacture Notice (PMN) "P" Case Number: Part III - Check the appropriate box and provide the exact date of manufacture or importation: First Commercial Manufacture** First Commercial Importation*** Date: ""Date of commencement is the date of completion of non-exempt manufacture of the first amount (bath, drum, etc.) ***For importees, the date of commencement is the date that the new chemical substance clears U.S. customs Part IV - Manufacturing Plant Site(s) or Importing Site(s): (Importers, provide street address of destination) Part V - Specific Chemical Identity: (For Consolidated submissions, each substance must have a separate NOC form with the specific identity of each chemical substance.) Part VI - Generic Chemical Name (if chemical identity is claimed CBI*): Part VII - Substance Identity Confidentiality Status: I wish to continue to claim the substance identity confidential and the substantiation to support this claim is attached. Failure to submit the required substantiation in accordance with 40 CFR 720.85(b) will result in a waiver of your claim. I previously claimed the substance identity as confidential and hereby relinquish that claim. I did not claim the substance identity as confidential in my original PMN submission. The public reporting and recordkeeping burden for this collection of information 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 7710-56 to this address. You must submit your completed notice no later than 30 calendar days after the first date of commercial manufacture/importation to the address

U.S. Environmental Protection Agency

Note: CBI" - refers to the term "Confidential Business Information". Mark (X) in the box if the information is to be held Confidential.

OPPT Document Control Office (7407M) 1200 Pennsylvania Ave., NW Washington, D.C. 20460 ATTN: Notice of Commencement

Date

EPA Form No. 7710-56

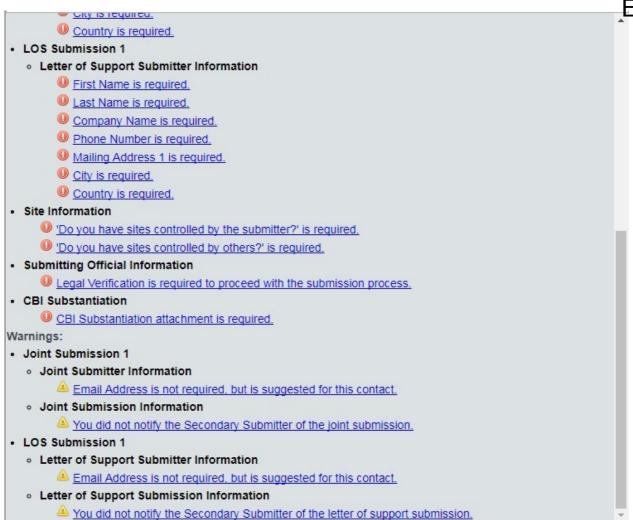
EPA Form 7710-56 (6-09)

Signature of authorized official

shown below:

SUP2014P1					oved. O.M.B. N	lo. 2070-01	73.		
		EPA S	Suppo	rt For	m				
Support Form Report Number			Mark (X) if anything is CBI			BI			
I. ORIGINAL N	OTICE SUBMISSION	ON IDE	NTIFICA	ATION					
Report Number			TS Number			Case Numb	per		
Original Sul	bmission Date	33							
Original Sul	bmission Media Typ	e							
II. ORIGINAL N	NOTICE SUBMITTE	ER IDEN	TIFICA	TION			CI	31	100
Authorized Offi Name	icial (first)			(1	ast)	1),		
Position				Compar	ny Name				
Mailing Addres (Number & Stre				4	5				
City			State		Postal 0	Code			
e-mail				Telepi (inclu	hone de area cod	le)			
III. CURRENT	SUPPORT DOCUM	ENT ID	ENTIFI	CATION	INFORM	ATION	CI	31	200
Name	(first)	0	1	(1	ast)		8	- 525	
Position				Compar	ny Name				
Mailing Addres (Number & Str	and the second s								
City	: 0		State		Postal (Code			
Province	KO			Country					
e-mail				Telepi (inclu	hone de area cod	le)			
IV. TYPE OF SU	UPPORT (Check On	ıe)		(IIICIG	de area coe				
457	Transfer of Own	ership							
Suspension Request									
Withdrawal Request									
Other Correspondence									
TEST DATA (Health/Eco/Fate)					6400000000				
	Amendment (Cl properties)	nanges m	nade to F	MN pag	es 1-13, M	SDS or l	Physical/	Che	mical
Check if requeste	d by EPA/ contracto	r							
EPA person/ con	tractor								
Submitter Signature									





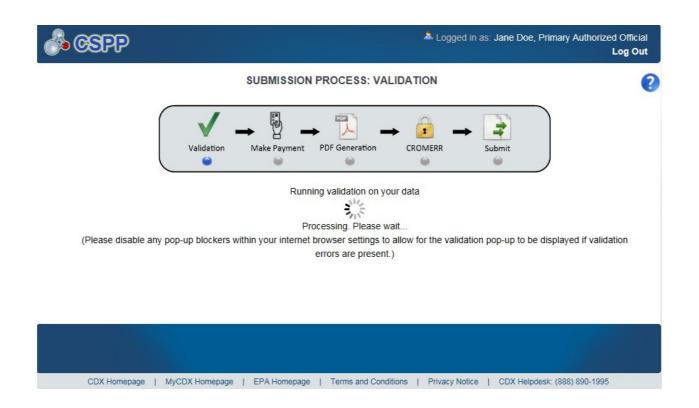
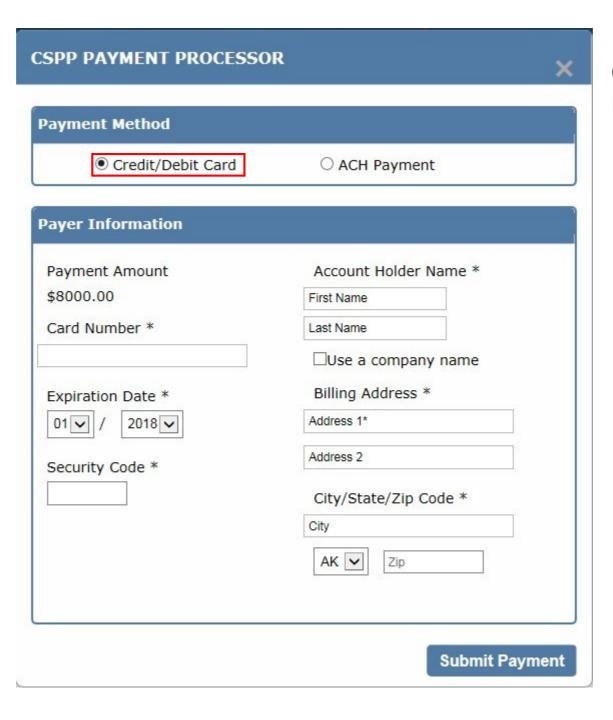


Exhibit 14-5 Make a Payment Screen





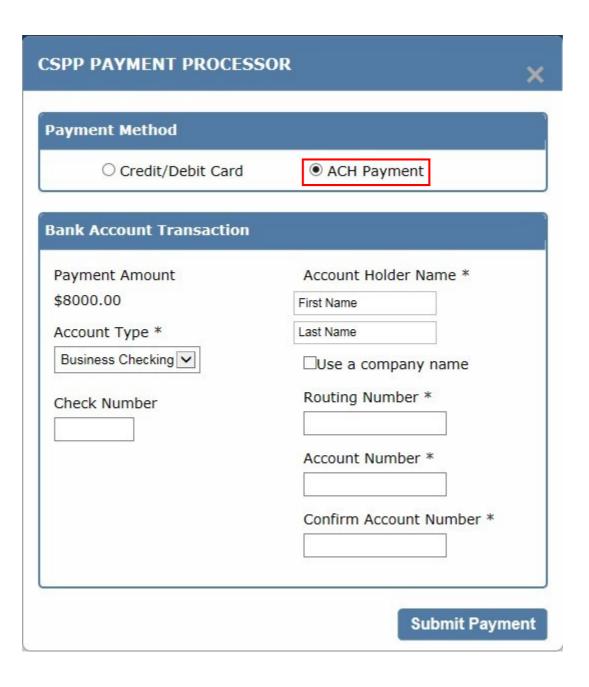
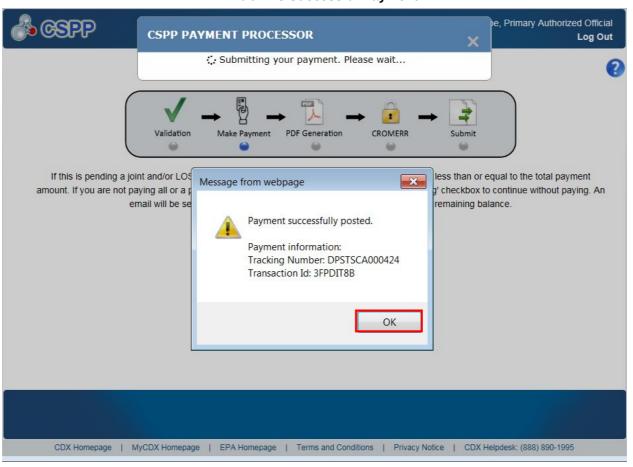
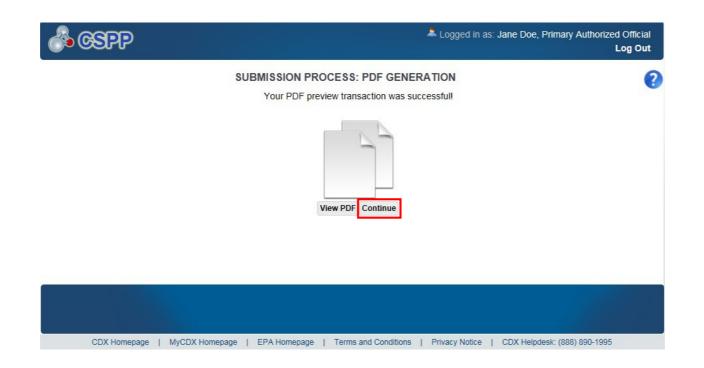


Exhibit 14-8 Successful Payment





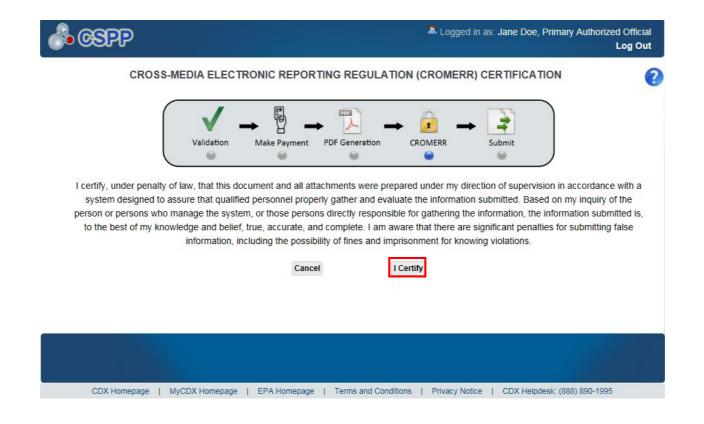


Exhibit 14-17 Submit to CDX Screen

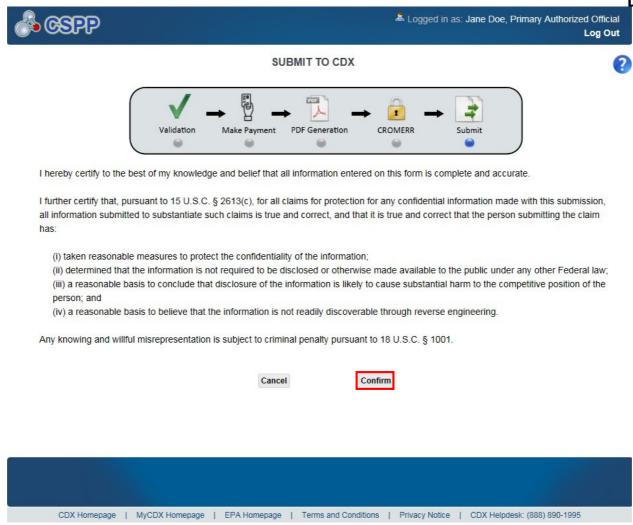
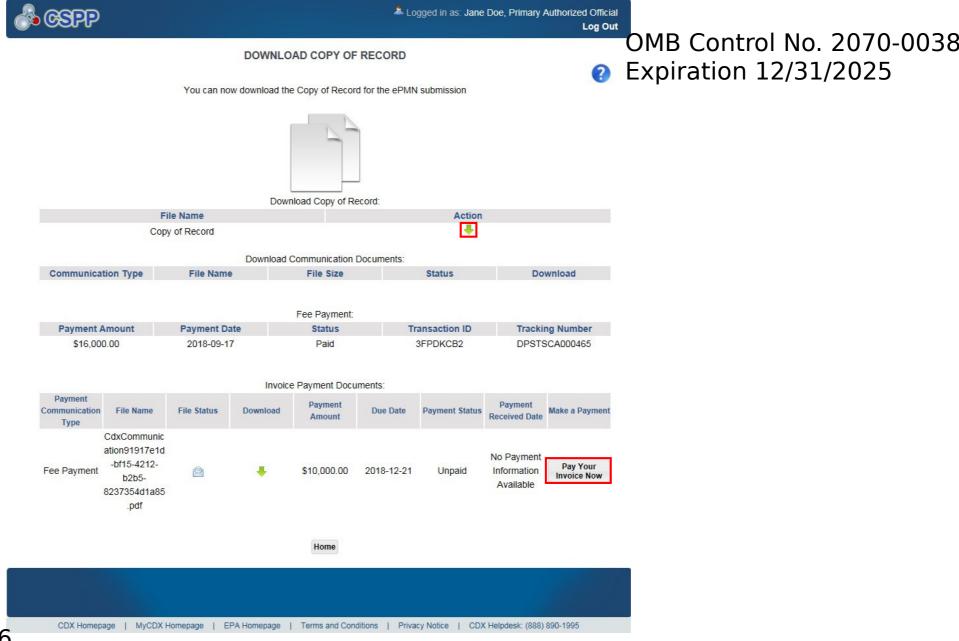


Exhibit 15-1 Download Copy of Record Screen





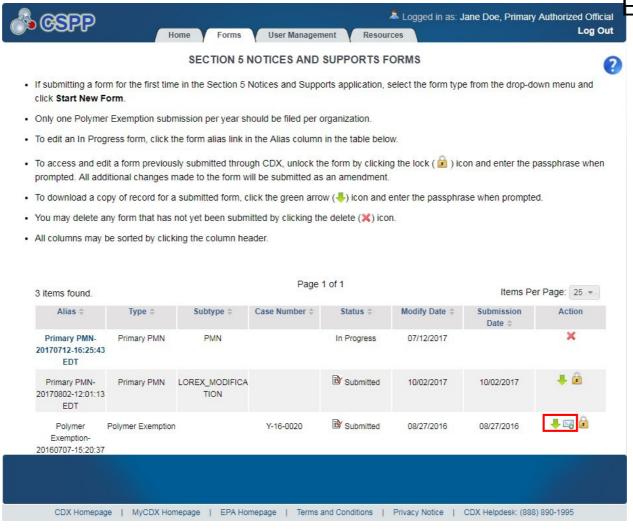
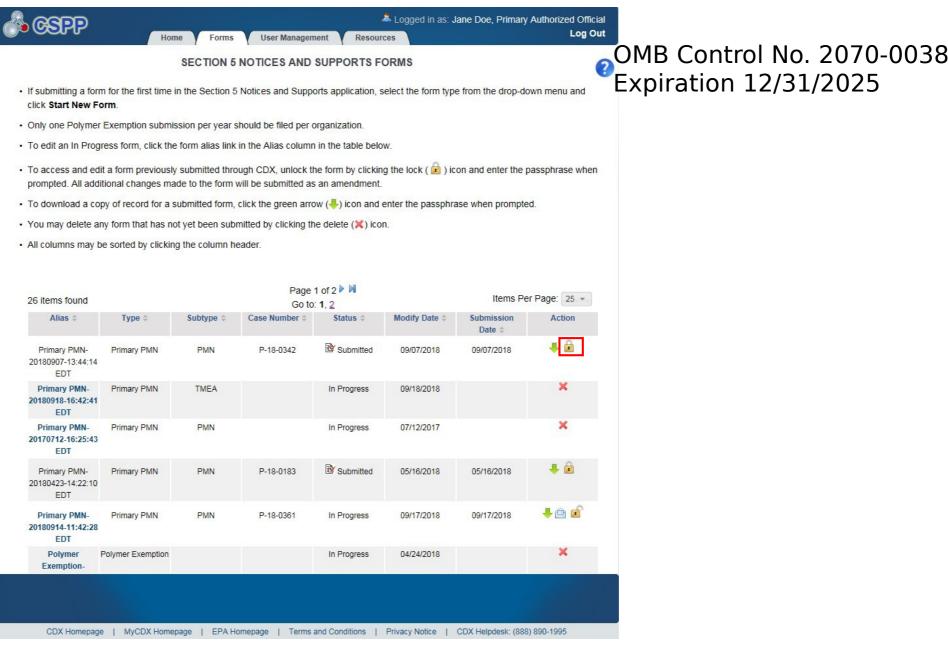


Exhibit 16-4 Enter Passphrase Screen

& COSPP	Logged in as: Jane Doe, Primary Authorized Official Log Out
	2
ENTER PASSPHE	RASE
Please enter your form passphra	ase and click Next
Forgot Your Passph	nrase?
For security reasons, the system administrator does not have access to you	
you have forgotten your passphrase, you must complete a new Section 5 No	tices and Supports Form and create a new passphrase for the
chemical substances you intend to in	mport or manufacture.
Cancel	Next
CDX Homepage MyCDX Homepage EPA Homepage Terms and Con	ditions Privacy Notice CDX Helpdesk: (888) 890-1995

& CSPP	👗 Logged in as: Jane Doe, Primary Authorize	ed Official Log Out
		0
	CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) LOGIN	
	Please login with your CDXweb password:	
	Cancel	
CDX Homepag	e MyCDX Homepage EPA Homepage Terms and Conditions Privacy Notice CDX Helpdesk: (888) 890-1995	

& CORP	Logged in as: Jane Doe, Primary Authorized Official
	⊌
	CROSS-MEDIA ELECTRONIC REPORTING REGULATION (CROMERR) SECURITY QUESTION
	What is the first and middle name of your oldest sibling?
	Cancel
CDX	Homepage MyCDX Homepage EPA Homepage Terms and Conditions Privacy Notice CDX Helpdesk: (888) 890-1995



EPA Form No. 7710-56

Navigation: After clicking the 'Lock' icon (), a prompt will display to confirm the

User Management

Resources

RESOURCES

Section 5 Notices and Supports User Guide

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

User Guide

Helpful Web Links

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

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

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

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

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

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

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

CDX Homepage

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

> Click the link provided below to access additional information related to Substance Registry Services Substance Registry Services (SRS)

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

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

CAS Inventory Expert Services

