



EPA's PFAS LVE Stewardship Program

July 29, 2021

EPA Webinar



Overview

- PFAS Stewardship Program
 - Background and Goals
 - Implementation
- How to Determine if you Have an Eligible LVE
- How to Participate in the Program
 - CDX instructions
- Resources, Points of Contact, Other



Background

- EPA is renewing a program to work cooperatively with companies to voluntarily withdraw all previously granted LVEs for PFAS.
- The program builds upon a 2016 outreach effort that resulted in companies withdrawing more than half of the 82 long-chain PFAS LVEs targeted for withdrawal at the time.
- EPA intends to provide progress updates to highlight the PFAS LVE withdrawals, and recognition as appropriate on EPA's website, of those stakeholders that participate in the Program.



Program Goals

- In April 2021, EPA announced new policies on PFAS low volume exemptions to ensure that EPA can conduct an appropriately robust review of these new chemicals.
- The purpose of the PFAS LVE Stewardship Program is to encourage the voluntary withdrawal of previously granted PFAS LVEs.



Per- and Polyfluoroalkyl Substances

- Per- and polyfluoroalkyl substances (PFAS) are a group of man-made chemicals that includes PFOA, PFOS, GenX, and many other chemicals.
- Examples of where PFAS can be found include cleaners, textiles, leather, paper and paints, fire-fighting foams, and wire insulation.
- Certain PFAS can accumulate and stay in the human body for long periods of time.
- There is evidence that exposure to certain PFAS can lead to adverse health outcomes in humans.
- EPA has pursued a range of regulatory actions, policies, and voluntary efforts to address PFAS.



Low Volume Exemptions (LVEs)

- Certain categories of new low-volume chemical substances are exempt from full premanufacture notice (PMN) review under section 5 of the Toxic Substances Control Act (TSCA).
 - i.e., chemicals manufactured at 10,000 kg/year or less.
- LVE substances undergo a 30-day review.
- LVE substances are not added to the TSCA Chemical Substance Inventory.



What does it mean to withdraw your LVE?

- By withdrawing your LVE, you will be certifying that you will no longer manufacture and/or import the relevant chemical under this exemption.
- What about Existing Stocks?
 - Withdrawal of your LVE does not prohibit you or your customers from continuing to process, distribute in commerce, or use *existing stocks* of the chemical substance.
 - Consistent with the terms that were articulated in the LVE, after the LVE is withdrawn, any future processing/use of existing stocks remains subject to any use and exposure/release restrictions in the LVE notice under which those stocks were manufactured.
 - Your company also remains subject to the customer notification requirements in 40 CFR 723.50(k) for those existing stocks.



Recordkeeping and Existing Stocks

- 40 CFR 723.50(n) requires you to maintain certain records for a period of 5 years after their preparation.
- Recordkeeping requirements include records documenting compliance with any applicable requirements or restrictions related to processing, distribution, or use of existing stocks.



Eligible LVEs

- There are currently over 600 granted PFAS LVEs.
- Specifically, chemicals that structurally contain the unit $R-(CF_2)-C(F)(R')R''$ are considered PFAS for purposes of this program. Both the CF_2 and CF moieties are saturated carbons and none of the R groups (R , R' or R'') can be hydrogen.
- While the 2016 program targeted long-chain PFAS LVEs, under this 2021 expanded effort, EPA is soliciting voluntary withdrawals of the remaining long-chain PFAS as well as short-chain PFAS LVEs.



How to determine if you have an eligible LVE

- See the list of LVEs on our [website](#).
 - Note, LVEs for substances where confidential business information would be revealed by including them in the list have been omitted
- Check your email for an invitation via CDX
 - The invitation was sent through CDX to submitters whose LVE was received through CDX
 - The invitation is also posted on our website
- For some eligible LVEs, EPA either could not send the invitation through CDX to the submitter or did not publish the LVE on our website due to CBI claims. If you think you have an eligible LVE, contact us at PFASLVEstewardship@epa.gov



How To Participate

- If you are eligible for the program and wish to participate you should submit a voluntary withdrawal of your LVE.
- EPA will provide recognition of your participation in the Stewardship Program at the time you withdraw your LVE.



How to Participate, cont'd

- If a company wishes to participate in the Stewardship Program but continue manufacturing the substance, they may wait to withdraw the LVE until they submit a PMN for the same substance and EPA issues a determination.
- The PMN review will give the Agency sufficient time to assess the PFAS in order to ensure that potential risks or data gaps are identified, and appropriate restrictions are in place to protect human health and the environment, as necessary.



How to Participate, cont'd

- If you are eligible for the program and wish to participate you must use CDX to submit your withdrawal.
- Currently, there is no end date to the program.
 - You may withdraw your eligible PFAS LVE at any time, although EPA encourages participation as soon as practical for your company.
 - After the withdrawal is submitted, participants will receive an acknowledgement letter from EPA.



Program Participation and Goals

- Your company can only be recognized as a participant in the Stewardship Program when you withdraw your LVE.
- Both options meet our stewardship program goal to ensure that potential risks or data gaps are identified, and appropriate restrictions are in place to protect human health and the environment, as necessary.
- Additionally, the contemporary EPA risk assessment using the most up-to-date methods and knowledge will provide valuable market knowledge and could increase consumer confidence.



PFAS Low Volume Exemption Stewardship Program Webpage

- Please visit <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/pfas-low-volume-exemption>
 - Program participation
 - How to withdraw your LVE
 - What it means to withdraw your LVE
 - Additional information
 - Links to: Basic information on PFAS including potential health effects, EPA actions to address PFAS



Instructions for submitting LVE withdrawal


CDX Central Data Exchange

 [Contact Us](#)

Logged in as HHOFFMANTEST ([Log out](#))

[MyCDX](#) [Inbox](#) [My Profile](#) [Role Sponsorship](#) [Submission History](#) [Payment History](#)

Services

Status	Program Service Name	Role
	CSPP: Submissions for Chemical Safety and Pesticide Programs	Primary Authorized Official

CDX Service Availability

[See the status for all program services](#)

News and Updates

No news/updates.

[Add Program Service](#)

[Manage Your Program Services](#)



- In CDX, click on the “Primary Authorized Official” link for the “CSPP: Submissions for Chemical Safety and Pesticide Programs” data flow

CHEMICAL INFORMATION SUBMISSION SYSTEM

Welcome to the EPA's Chemical
drop-down menu.



TSCA Mercury Electronic Reporting - MER
 TSCA Risk Evaluation Rule
 TSCA Section 12(b)
 TSCA Section 4
TSCA Section 5 Notices and Supports - ePMN
 TSCA Section 8(a) - Nanoscale Materials
 TSCA Section 8(b) - Notice of Activity
 TSCA Section 8(d) - Health & Safety Data Reporting
 TSCA Section 8(e) - Notice

Please select an application from the

- Select “TSCA Section 5 Notices and Supports – ePMN” from the CISS screen drop-down list
- Click “OK”

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.

- Within the reporting application, click on the “Forms” link or tab

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

- 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 (✖) icon.
- All columns may be sorted by clicking the column header.

Page 1 of 1

6 items found.

Items Per Page: 25

Alias	Type	Subtype	Case Number	Status	Modify Date	Submission Date	Action
Support-20210602-13:14:08 EST	Support	Withdrawal Request	L-90-0001	Submitted	06/02/2021	06/02/2021	Download
test case with 6 chems	Polymer Exemption			In Progress	10/20/2016		Delete
Support-20210602-13:40:25 EST	Support	Withdrawal Request	L-90-0002	Submitted	06/02/2021	06/02/2021	Download
Support-20210629-11:31:05 EST	Support	Withdrawal Request	L-21-0001	In Progress	06/29/2021		Delete
Support-20210602-09:19:15 EST	Support	Withdrawal Request	L-91-0012	In Progress	06/02/2021		Delete
Support-20210629-11:41:27 EST	Support			In Progress	06/29/2021		Delete

Export options: [CSV](#) | [Excel](#) | [XML](#) | [PDF](#)

Select the form type and then click **Start New Form**

Form Type:

- Premanufacture Notice (PMN)
- Support**
- Notice of Commencement (NOC)
- Biotechnology
- Bona Fide
- Alternative Control Measures (ACM)
- Polymer Exemption
- Pre-Notice Communication

- Select the “Support” form type from the drop-down at the bottom of the screen
- Click “Start New Form”



The form alias is an optional field that changes the form name on the **Forms Screen**. Its purpose is to make it easier to distinguish between multiple forms. If an alias is not selected, the field will default to the date it was created. The form alias may be changed at any time.

Form Alias:

**Please do not include any CBI information in the form alias.

I. Original Notice Submission Information

Case Number:

TS Number:

IV. Type of Support

Check if requested by EPA/Contractor: ☐

V. Description or Explanation of Support

CBI: ☐

File Name	Description	Subtype	Pages	CBI	Actions
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- When the support document screen opens, enter the case number associated with the LVE in the “Case Number” field under “I. Original Notice Submissions Information”
- Select “Withdrawal Request” from the dropdown under “IV. Type of Support”
- Within field “V. Description or Explanation of Support” please add text or an attachment describing your activity
- After selecting the file type follow the prompts to complete the submission



Support

Primary Authorized Official

Support-20170731-12:13:21 EDT

General Form Information

Original Submitter Information

Submitting Official Information

CBI Substantiation

Instructions for Substantiating CBI Claims

Support (Support-20170731-12:13:21 EDT) > Original Submitter Information



ORIGINAL SUBMITTER INFORMATION

Please enter the information of the Authorized Official who submitted the original PMN/Biotecth/Bona Fide form for which you are filing a Support document.

Click here to copy your information from CDX Registration:

Copy CDX Registration

Check here to claim this information as CBI:

☐

First Name:

Last Name:

Position:

Company Name:

Phone Number:

(Do not enter any dashes (-) in Phone Number field above.)

Phone Extension:

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country:

United States

Previous

Next



- Follow the prompts to confirm your identity

Support

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20170731-12:13:21 EDT

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Substantiation

Instructions for
Substantiating CBI Claims

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: ☒

First Name: Jane

Middle Initial:

Last Name: Doe

Job Title: Not Applicable

Company Name: TESTORG

Phone Number:

Email Address:

Mailing Address 1: TEST

Mailing Address 2:

City: TEST

State: AL

Postal Code: 12345

Country: US

Previous

Next



- Follow the prompts to confirm your identity, certify form and complete your withdrawal submission



Validate



Save



Preview



Submit



Other

- On June 28th EPA issued a proposed rule under TSCA 8(a)(7) authority titled, “TSCA Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances” (86 FR 33926)
 - The rule proposes that certain persons that manufacture (including import) or have manufactured these chemical substances in any year since January 1, 2011, would be subject to the rule.
 - Participation in the PFAS LVE stewardship program would not exempt you from the requirements of this rule as proposed.



Questions?

- See the program page at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/pfas-low-volume-exemption> and announcement at <https://www.epa.gov/chemicals-under-tsca/epa-launches-stewardship-program-reduce-pfas-marketplace>.
- For questions about the PFAS Low Volume Exemption Stewardship Program, please email us at PFASLVEstewardship@epa.gov.
- For questions about CDX:
 - Contact the CDX help desk at 888-890-1995 | (970) 494-5500 for International callers.
- If you need to create a CDX account, a CDX registration guide can be found at https://cdx.epa.gov/content/FAQ/CSPP/CDX_CSPP%20Registration%20User%20Guide%20v3.02.pdf.