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 \( R-(CF2)-C(F)(R')R'' \) are considered PFAS for purposes of this program. Both the CF2 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

  – 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
In CDX, click on the “Primary Authorized Official” link for the “CSPP: Submissions for Chemical Safety and Pesticide Programs” data flow.
Select “TSCA Section 5 Notices and Supports – ePMN” from the CISS screen drop-down list

Click “OK”
Within the reporting application, click on the “Forms” link or tab.
- Select the “Support” form type from the drop-down at the bottom of the screen
- Click “Start New Form”
• 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
• Follow the prompts to confirm your identity
• Follow the prompts to confirm your identity, certify form and complete your withdrawal submission
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?


• 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.