



## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPPT-2018-0448; FRL-12439-01-OCSP]**

### **Vinyl Chloride; Draft Scope of the Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA or Agency) is announcing the availability of and seeking public comment on the draft scope of the risk evaluation to be conducted under the Toxic Substances Control Act (TSCA) for vinyl chloride (ethene, chloro-; CASRN 75-01-4). Under TSCA, the scope documents must include the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations that EPA expects to consider in conducting the risk evaluation for this chemical substance. The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, and without consideration of costs or non-risk factors.

**DATES:** Comments must be received on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0448, online at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:**

*For technical information:* Marcy Card, Existing Chemicals Risk Assessment Division (7403M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-1202; email address: VinylChloride.TSCA@epa.gov.

*For general information:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. Executive Summary**

#### *A. Does this action apply to me?*

This action is directed to the public in general and may be of particular interest to those involved in the manufacture (defined under TSCA section 3(9) to include import), processing, distribution, use, and disposal of vinyl chloride, related industry trade organizations, non-governmental organizations with an interest in human and environmental health, state and local governments, Tribal Nations, and/or those interested in the assessment of risks involving chemical substances and mixtures regulated under TSCA. As such, the Agency has not attempted to describe all the specific entities that this action might apply to. If you need help determining applicability, consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

#### *B. What is the Agency's authority for taking this action?*

The draft scope of the risk evaluation is issued pursuant to TSCA section 6(b)(4)(D), 15 U.S.C. 2605(b)(4)(D), and EPA's implementing regulations at 40 CFR 702.39(b).

#### *C. What action is the Agency taking?*

EPA is announcing the availability of and seeking public comment on the draft scope of the risk evaluation to be conducted under TSCA for vinyl chloride (ethene, chloro-; CASRN 75-01-4). Under TSCA, the scope documents must include the conditions of use, hazards,

exposures, and the potentially exposed or susceptible subpopulations that EPA expects to consider in conducting the risk evaluation for this chemical substance. The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, and without consideration of costs or non-risk factors.

*D. What should I consider as I prepare my comments?*

1. *Submitting CBI.* Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703, as applicable.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

## **II. Background**

*A. What is vinyl chloride?*

Vinyl chloride (ethene, chloro-), also known as chloroethylene, is a chlorinated ethene that does not occur naturally in the environment. Its primary use is as a reactant (monomer) in the production of polyvinyl chloride (PVC) in consumer, commercial, and industrial applications. Since 1986, the national aggregate production volume of vinyl chloride, as reported under the Chemical Data Reporting (CDR) rule, formerly known as the Inventory Update Rule (IUR) (40 CFR part 711), has been consistently over 1 billion pounds. In 2011, over 16 billion pounds were reported to CDR and since 2012 production volume has been reported between 10 billion and 20 billion pounds.

Due to its physical state as a gas at room temperature and pressure, vinyl chloride is expected to be primarily present in the atmosphere in vapor phase and is not expected to partition

to airborne particles. Exposure to vinyl chloride may result in a range of harmful health effects such as liver toxicity, neurotoxicity, immunotoxicity, and developmental toxicity. EPA previously determined that vinyl chloride is a “known human carcinogen.”

### *B. Draft Scope for the Risk Evaluation of Vinyl Chloride*

In December 2024, EPA announced its designation of vinyl chloride as a high priority substance for risk evaluation under TSCA (Ref. 1), which initiated the risk evaluation phase and started the 3 to 3.5 year statutory timeframe in which the risk evaluation is to be completed. The draft scope of the risk evaluation for this chemical substance (Ref. 2) includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations EPA expects to consider in the risk evaluation (15 U.S.C. 2605(b)(4)(D)). Development of the scope is the first step of a risk evaluation, and includes the following components (40 CFR 702.39(b)):

- The conditions of use, as determined by the Administrator, that EPA expects to consider in the risk evaluation;
- The potentially exposed populations, including any potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA under the conditions of use that EPA expects to evaluate;
- The ecological receptors that EPA expects to evaluate;
- The hazards to health and the environment that EPA expects to evaluate;
- A description of the reasonably available information and the science approaches that the Agency expects to use;
- A conceptual model that describes the actual or predicted relationships between the chemical substance, its associated conditions of use through predicted exposure scenarios, and the identified human and environmental receptors and human and ecological health hazards;
- An analysis plan that describes how EPA intends to assess hazards and exposures, and characterize risks; and
- A plan for peer review.

### III. Request for Comment

EPA seeks feedback on the approaches presented in the draft scope of the risk evaluation, use profile (Ref. 3), and draft chemistry and fate technical support document (Ref. 4), copies of which are available in the docket. EPA encourages commenters to provide information they believe might be missing or may further inform the risk evaluation. To the extent possible, the Agency asks commenters to please cite any public data related to or that supports the comments provided, and, to the extent permissible, describe any supporting data that is not publicly available.

### IV. Next Steps

EPA will consider comments received and prepare the final scope of the risk evaluation for vinyl chloride. EPA intends to publish a notice in the *Federal Register* announcing the availability of the final scope of the risk evaluation within six months of the designation of vinyl chloride as a high-priority substance for risk evaluation under TSCA (Ref. 1), i.e., by June 2025.

For more information about the TSCA risk evaluation process for existing chemicals, go to <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca>.

### V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability. *Federal Register*. 89 FR 102900, December 18, 2024 (FRL-11581-07-OCSP)

2. EPA. Vinyl Chloride; Draft Scope of the Risk Evaluation under the Toxic Substances

Control Act (TSCA). January 2025.

3. EPA. Use Report for Vinyl Chloride. January 2025.

4. EPA. Draft Chemistry and Fate Technical Support Document for Vinyl Chloride,  
January 2025.

**Authority:** 15 U.S.C. 2601 *et seq.*

Dated: January 10, 2025.

**Michal Freedhoff,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

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