

better align with TSCA's objective of protecting health and the environment. For the PCE risk evaluation, this includes: (1) Making the risk determination in this instance based on the whole chemical substance instead of by individual conditions of use and (2) Emphasizing that EPA does not rely on the assumed use of PPE when making the risk determination.

B. What are the revisions?

EPA is now finalizing the revised risk determination for the December 2020 PCE Risk Evaluation (Ref. 2) pursuant to TSCA section 6(b). Under the revised determination (Ref. 1), EPA concludes that PCE, as evaluated in the risk evaluation as a whole, presents an unreasonable risk of injury to health when evaluated under its conditions of use. This revision replaces the previous unreasonable risk determinations made for PCE by individual conditions of use, supersedes the determinations (and withdraws the associated order) of no unreasonable risk for the conditions of use identified in the TSCA section 6(i)(1) no unreasonable risk order, and clarifies the lack of reliance on assumed use of PPE as part of the risk determination.

These revisions do not alter any of the underlying technical or scientific information that informs the risk characterization, and as such the hazard, exposure, and risk characterization sections are not changed, except to statements about PPE assumptions in section 2.4.1.4 (Consideration of Engineering Controls and PPE) and section 4.2.2.2 (Occupational Inhalation Exposure Summary and PPE Use Determinations by OES). The discussion of the issues in this *Notice* and in the accompanying final revision to the risk determination supersede any conflicting statements in the prior executive summary, section 2.4.1.4 and section 4.2.2.2 from the December 2020 PCE Risk Evaluation (Ref. 2), and the response to comments document (Ref. 11).

The revised unreasonable risk determination for PCE includes additional explanation of how the risk evaluation characterizes the applicable OSHA requirements, or industry or sector best practices, and also clarifies that no additional analysis was done, and the risk determination is based on the risk characterization (section 4) of the December 2020 PCE Risk Evaluation (Ref. 2).

C. Will the revised risk determination be peer reviewed?

The risk determination (section 5 of the December 2020 PCE Risk Evaluation

(Ref. 2)) was not part of the scope of the Science Advisory Committee on Chemicals (SACC) peer review of the PCE risk evaluation. Thus, consistent with that approach, EPA did not conduct peer review of the final revised unreasonable risk determination for the PCE risk evaluation because no technical or scientific changes were made to the hazard or exposure assessments or the risk characterization.

V. Order Withdrawing Previous Order Regarding Unreasonable Risk Determinations for Certain Conditions of Use

EPA is also issuing a new order to withdraw the TSCA section 6(i)(1) no unreasonable risk order issued in section 5.4.1 of the December 2020 PCE Risk Evaluation (Ref. 2). This final revised risk determination supersedes the condition of use-specific no unreasonable risk determinations in the December 2020 PCE Risk Evaluation (Ref. 2). The order contained in section 5.5 of the revised risk determination (Ref. 1) withdraws the TSCA section 6(i)(1) order contained in section 5.4.1 of the December 2020 PCE Risk Evaluation (Ref. 2). Consistent with the statutory requirements of section 6(a), the Agency will propose risk management action to address the unreasonable risk determined in the PCE risk evaluation.

VI. 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. Unreasonable Risk Determination for Perchloroethylene (PCE). *December 2022*.
2. EPA. Risk Evaluation for Perchloroethylene. December 2020. EPA Document #740-R1-8011. <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0502-0057>.
3. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. **Federal Register** (86 FR 7037, January 25, 2021).
4. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. **Federal Register** (86 FR 7009, January 25, 2021).
5. Executive Order 14008. Tackling the

Climate Crisis at Home and Abroad.

Federal Register (86 FR 7619, February 1, 2021).

6. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. **Federal Register** (86 FR 8845, February 10, 2021).
7. EPA. Press Release; EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 2021. <https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>.
8. EPA. Proposed Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. **Federal Register** (82 FR 7562, January 19, 2017) (FRL-9957-75).
9. EPA. Final Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. **Federal Register** (82 FR 33726, 33744, July 20, 2017).
10. EPA. Response to Public Comments to the Revised Unreasonable Risk Determination; Perchloroethylene (PCE). *December 2022*.
11. EPA. Summary of External Peer Review and Public Comments and Disposition for Perchloroethylene (PCE). December 2020. Available at: <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0502-0059>.
12. Occupational Safety and Health Administration (OSHA). Top 10 Most Frequently Cited Standards for Fiscal Year 2021 (Oct. 1, 2020, to Sept. 30, 2021). Accessed October 13, 2022. <https://www.osha.gov/top10citedstandards>.
13. OSHA. Permissible Exposure Limits—Annotated Tables. Accessed June 13, 2022. <https://www.osha.gov/annotated-pels>.

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

Dated: December 9, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2022-0116; FRL-9412-17-OCSPP]

Certain New Chemicals or Significant New Uses; Statements of Findings for August and September 2022

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Toxic Substances Control Act (TSCA) requires EPA to publish in the **Federal Register** a statement of its findings after its review of certain TSCA submissions when EPA makes a finding that a new chemical substance or

significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to premanufacture notices (PMNs), microbial commercial activity notices (MCANs), and significant new use notices (SNUNs) submitted to EPA under TSCA. This document presents statements of findings made by EPA on such submissions during the period from August 1 to September 30, 2022.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2022-0116, is available online at <https://www.regulations.gov> or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Additional instructions on 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 contact: Rebecca Edelstein, New Chemical Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-1667; email address: edelstein.rebecca@epa.gov.

For general information contact: 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 provides information that is directed to the public in general.

B. What action is the Agency taking?

This document lists the statements of findings made by EPA after review of submissions under TSCA section 5(a) that certain new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment. This document presents statements of findings made by EPA during the reporting period.

C. What is the Agency's authority for taking this action?

TSCA section 5(a)(3) requires EPA to review a submission under TSCA section 5(a) and make one of several specific findings pertaining to whether the substance may present unreasonable risk of injury to health or the environment. Among those potential findings is that the chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment per TSCA section 5(a)(3)(C).

TSCA section 5(g) requires EPA to publish in the **Federal Register** a statement of its findings after its review of a submission under TSCA section 5(a) when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to PMNs, MCANs, and SNUNs submitted to EPA under TSCA section 5.

Anyone who plans to manufacture (which includes import) a new chemical substance for a non-exempt commercial purpose and any manufacturer or processor wishing to engage in a use of a chemical substance designated by EPA as a significant new use must submit a notice to EPA at least 90 days before commencing manufacture of the new chemical substance or before engaging in the significant new use.

The submitter of a notice to EPA for which EPA has made a finding of "not likely to present an unreasonable risk of injury to health or the environment" may commence manufacture of the chemical substance or manufacture or processing for the significant new use notwithstanding any remaining portion of the applicable review period.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

II. Statements of Findings Under TSCA Section 5(a)(3)(C)

In this unit, EPA provides the following information (to the extent that such information is not claimed as Confidential Business Information (CBI)) on the PMNs, MCANs and SNUNs for which, during this period, EPA has made findings under TSCA section 5(a)(3)(C) that the new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment:

The following list provides the EPA case number assigned to the TSCA

section 5(a) submission and the chemical identity (generic name if the specific name is claimed as CBI).

- J-22-0014, J-22-0015, Modified yeast, chromosomally and stably modified to improve fermentation performance (Generic Name).

To access EPA's decision document describing the basis of the "not likely to present an unreasonable risk" finding made by EPA under TSCA section 5(a)(3)(C), look up the specific case number at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely>.

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

Dated: December 7, 2022.

Madison Le,

Director, New Chemicals Division, Office of Pollution Prevention and Toxics.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2022-0542; FRL-9985-02-OCSPP]

Pesticides; Removal of PFAS Chemicals From Approved Inert Ingredient List for Pesticide Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is removing twelve chemicals from the current list of inert ingredients approved for use in pesticide products because these inert ingredients have been identified as per- and polyfluoroalkyl substances (PFAS) and they are no longer used in any registered pesticide product.

DATES: This action is applicable December 14, 2022.

FOR FURTHER INFORMATION CONTACT: Dan Rosenblatt, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: RDfRNNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is