



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2021-0660; FRL-13157-01-OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; TSCA Section 5 Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), TSCA Section 5 Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances (EPA ICR Number 1188.16, OMB Control Number 2070-0038) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through December 31, 2025. Public comments were previously requested via the *Federal Register* on May 9, 2025 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OPPT-2021-0728, to EPA online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information

whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Office of Program Support (Mail Code 7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: 202-566-1204; email address: sleasman.katherine@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR which is currently approved through December 31, 2025. 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.

Public comments were previously requested via the *Federal Register* on May 9, 2025, during a 60-day comment period (90 FR 19713). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Abstract: TSCA section 5 requires manufactures (which includes import) of a "new chemical substance" (*i.e.*, a chemical not listed on the TSCA section 8(b) Inventory) must provide a premanufacture notice (PMN) to EPA at least 90 days prior to commencing manufacture of that chemical and that EPA review such notice and take appropriate action. Under TSCA, the term "chemical substance" includes microorganisms; the 90-day notice for microorganisms is a Microbial Commercial Activity Notice (MCAN).

Under TSCA section 5, EPA is authorized to determine that a use of a chemical substance is a significant new use and promulgate a significant new use rule (SNUR). In certain instances, persons may pursue a significant new use, thus they must submit a notice and undergo a review. TSCA section 5 requires a significant new use notice (SNUN) from any person who proposes to manufacture or process a chemical for a use EPA determined to be a “significant new use.”

TSCA section 5 requires EPA to make one of five possible determinations before concluding its review of submitted notices about risk to human health & the environment from the manufacture, processing, distribution in commerce, use and/or disposal of new chemical substances or significant new uses. EPA's determination on a new chemical substance or new use will dictate how and to what extent the chemical's manufacture, processing, distribution, use, and/or disposal may be restricted. If EPA fails to make a timely determination, fees may be refunded; however, EPA's obligation to make a determination remains. EPA requires the submitter of a PMN or MCAN inform EPA when non-exempt commercial manufacture of the substance in question begins by submitting a Notice of Commencement; EPA would then add the new chemical substance to the TSCA section 8(b) Inventory.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b), and regulations that interpret TSCA section 12(b) at 40 CFR part 707; and the associated paperwork activities and burdens approved under OMB Control No. 2070-0030 (EPA ICR No. 0795.16), “Notification of Chemical Exports—TSCA Section 12(b)”.

Existing chemicals are chemicals already listed on the TSCA Inventory; and therefore “existing chemical SNURs” are often written to require notice for significant new uses of chemicals already in commerce.

Form number(s): 7710-23, 7710-25, 7710-56, 6300-7.

Respondents/affected entities: Potentially affected entities include processors; e.g., entities identified by the North American Industrial Classification System (NAICS) codes 325,

Chemicals and Allied Products Manufacturers, and 324, Petroleum Refining.

Respondent's obligation to respond: Mandatory (CFR 720, 721, 723 & 725)

Estimated number of respondents: 4,234 (total)

Frequency of response: On occasion.

Total estimated burden: 128,367 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$45,183,758 (per year), which includes \$0 annualized capital or operation & maintenance costs.

Changes in the estimates: There is no change in the burden hours in the total estimated respondent burden compared with the ICR currently approved by OMB.

Courtney Kerwin,

Deputy Director, Data & Enterprise Programs Division.

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