Supporting Statement for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA)

EXECUTIVE SUMMARY

Identification of the Information Collection – Title and Numbers

Title: Updates to New Chemicals Regulations under the Toxic Substances Control Act; Proposed Rule (RIN 2070-AK65)

EPA ICR No.: 2749.01

OMB Control No.: 2070-NEW

Docket ID No.: EPA-HQ-OPPT-2022-0902

Abstract

This information collection request update addresses the reporting and recordkeeping requirements associated with the proposed rule to update the new chemicals procedural regulations at 40 CFR Parts 720, 721, 723, and 725 under the Toxic Substances Control Act (TSCA). The amendments included under this new chemicals procedural rule cover several goals, including in part to align the regulatory text with the amendments to TSCA's new chemical review provisions contained in the Frank R. Lautenberg Chemical Safety for the 21st Century Act, enacted on June 22, 2016 (15 U.S.C. 2604); increase the quality of information initially submitted in new chemicals notices, to reduce the need to update risk assessments if new information is received later in the process, and, ultimately, to reduce the length of time that new chemicals are under review for notices submitted under TSCA section 5(a)(1); and to update the regulations for low volume exemptions (LVEs) and low release and exposure exemptions (LoREXs) to make perfluoroalkyl and polyfluoroalkyl substances (PFAS) ineligible for these exemptions and to codify the ineligibility for these exemptions of certain persistent, bioaccumulative, and toxic (PBT) chemical substances as described in EPA's 1999 PBT policy.

With this ICR, EPA is updating the paperwork activities and related estimates for burden hours and costs that are currently approved under the following Information Collection Request (ICR):

1. "TSCA Section 5 Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances" (identified by EPA ICR No.1188.13 and OMB Control No. 2070-0038), which is currently approved through December 31, 2025.

The proposed new chemical procedural rule affects firms that intend to manufacture (including import) or process a chemical substance and are required to submit information to EPA under TSCA section 5. This includes firms reporting intended manufacture of a new chemical substance or intended manufacture or processing of a chemical substance for a significant new use to EPA using the Premanufacture Notice (PMN) form (EPA Form 7710-25) including PMNs, Significant New Use Notifications (SNUNs), LVEs, LoREXs, and Test-Marketing Exemptions (TMEs). The proposed new chemicals procedural rule is expected primarily to affect two types of firms:

- Manufacturers of PFAS who would have submitted an LVE or LoREX in the baseline but would need to submit a PMN under the proposed rule due to the proposed amendment to make PFAS ineligible for the exemptions.
- Firms submitting any TSCA section 5 notices through the PMN form (PMNs, SNUNs, LVEs, LoREXs, TMEs) that are expected to submit fewer amendments to their original submissions due to the amended procedural requirements of the proposed rule.

While this proposed rule includes additional amendments to the new chemicals regulations under TSCA, EPA expects that these additional amendments will not result in incremental burden or savings because they are largely already performed in the baseline.

This ICR update covers the information collection activities associated with new chemical notices under TSCA. The information for required notifications includes chemical identity, use and exposure information, test information and descriptions of other information related to the effects on health and the environment relating to the manufacture, processing, distribution in commerce, use and disposal of the new chemical or the significant new use of the existing chemical substance. EPA's new chemicals procedural rule is proposing to clarify the level of detail that a submitter is required to include in a PMN, SNUN, or exemption notice in order for the notice to be considered complete.

TSCA section 5 requires that any person who proposes to manufacture (which includes import) 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 action as appropriate. 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 opt to pursue that significant new use, in which case they must submit a notice and undergo a review. For such circumstances, TSCA section 5 requires a significant new use notice (SNUN) from any person who proposes to manufacture or process a chemical for a use that is determined by EPA to be a "significant new use."

TSCA section 5 requires EPA to make one of five possible determinations before the conclusion of its review of the submitted notices regarding risk to human health and 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, nothing relieves EPA of its obligation to make a determination. EPA requires that the submitter of a PMN or MCAN inform EPA when non-exempt commercial manufacture of the substance in question actually 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) appear at 40 CFR part 707 and the associated paperwork activities and burdens are approved under OMB Control No. 2070-0030, ICR entitled "Notification of Chemical Exports - TSCA Section 12(b)," identified by EPA ICR No. 0795.16.

Table 1. Summary Total Burden and Costs

Notice	Average Annual Number of Notices	Total Change in Burden (hours)	Total Change in Cost (2021$)
PMN	271	-3,642	($303,617)
SNUN	9	-97	($8,103)
LVE/LoREX (non-PFAS)	265	-2,321	($193,512)
LVE/LoREX (PFAS)	12	1,533	$550,352
TME	3	0	$0
Respondent Total	**560**	**-4,528**	**$45,120**
Agency Total	**560**		**($923,280)**

SUPPORTING STATEMENT

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

TSCA section 5(a) (15 U.S.C. 2604(a)(1)(B)(i)) (Attachment 1), requires manufacturers (which includes importers) of new chemical substances to submit to the Administrator of EPA a premanufacture notice (PMN) of intent to manufacture a new chemical substance at least 90 days before manufacture begins. TSCA section 5(a)(1) also requires notification from any person who proposes to manufacture or process a chemical substance for a use that EPA has by rule determined to be a significant new use. The notice must include, insofar as known to or reasonably ascertainable by the submitter, information described in TSCA section 8(a)(2) (e.g., chemical identity, use and exposure information), plus test information and descriptions of other information related to the effects on health and the environment of the manufacture, processing, distribution in commerce, use, and/or disposal of the new chemical substance. TSCA requires EPA to conduct a review of the notice, make one of five possible determinations on the notice, and take such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)) before manufacturing of the new chemical substance or manufacturing or processing of the chemical substance for a significant new use can commence. EPA reviews the information provided in the notice and other relevant information available to EPA to evaluate the health and environmental effects of the new chemical substance or significant new use and make the required determination.

TSCA section 5, as interpreted in EPA's "Microbial Products of Biotechnology; Final Regulation under the Toxic Substances Control Act" (62 FR 17910, April 11, 1997), authorizes EPA to regulate "new" genetically engineered microorganisms. According to the 1997 final rule, "new" microorganisms are those that, through deliberate human intervention, contain genetic material from dissimilar source organisms. Specifically, "intergeneric microorganisms" are those formed by either the deliberate combination of genetic material from organisms classified in different taxonomic genera or constructed with synthetic genes that are not identical in DNA that would be derived from the same genus as the recipient microorganism. Manufacturers of these new microorganisms must submit to EPA a microbial commercial activity notice (MCAN) at least 90 days before manufacture begins. These microorganisms are subject to the same determinations and potential regulatory controls as new chemical substances.

TSCA section 5(d)(1)(B) (15 U.S.C. § 2604(d)(1)(B)) requires premanufacture notices to include all health or environmental effects information in the submitter's possession or control and TSCA section 5(d)(1)(C) (15 U.S.C. § 2604(d)(1)(C)) requires PMN submitters to provide a description of other information on environmental or health effects that are known to or reasonably ascertainable by the submitter. These requirements are described in 40 CFR 720.50.

TSCA section 5(e) authorizes EPA to prohibit or limit the manufacture, processing, distribution in commerce, use and/or disposal of a new chemical substance or

significant new use pending development of information sufficient to allow EPA to perform a reasoned evaluation of the health and environmental effects of the substance. EPA must issue an order under TSCA section 5(e) if the Agency determines under section 5(a)(3)(B) that either: (1) the information available is insufficient to permit a reasoned evaluation of the health or environmental effects of the chemical substance; (2) in the absence of sufficient information, the manufacture, processing, distribution, use, and/or disposal may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use; or (3) the substance is or will be produced in substantial quantities and may be released to the environment in substantial quantities or there may be significant or substantial human exposure to the chemical. EPA's actions often involve negotiation of a TSCA section 5(e) Consent Order to prohibit or limit activities associated with manufacture, processing, distribution in commerce, use and/or disposal of the new chemical substance. TSCA section 5(e) Consent Orders can typically include requirements for exposure or release mitigation, testing, labeling and hazard communication, and recordkeeping.

Similarly, if EPA determines under section 5(a)(3)(A) that a new chemical substance or significant new use presents an unreasonable risk of injury to health or environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use, the Agency must regulate the chemical under section 5(f) by either (1) issuing a proposed rule under section 6(a); or (2) issuing an order to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the substance. EPA's action can involve negotiation of a TSCA section 5(f) Consent Order with the PMN submitter.

Significant New Use Rules (SNURs) are authorized under TSCA section 5(a)(2) and EPA is required to consider whether to promulgate SNURs following issuance of section 5(e) or 5(f) orders pursuant to section 5(f)(4). EPA's SNUR regulations were promulgated at 40 CFR part 721 and at 40 CFR part 725 (Attachment 2). A SNUR requires that any manufacturer or processor – including the PMN submitter – who intends to undertake the activities subject to the SNUR must submit to EPA a significant new use notice (SNUN). EPA must either conclude, following review of a SNUN, that the activities are not likely to present an unreasonable risk, or take appropriate action under section 5(e) or 5(f) to protect against any unreasonable risk. The review would factor in the conditions of use of the chemical specifically associated with the significant new use and, as appropriate, any other conditions of use relevant to the evaluation of the significant new use under section 5(a)(3). TSCA section 5(e) or 5(f) Orders are only binding on the original PMN submitter for that substance. Consequently, after issuing a