SUPPORTING STATEMENT for an
INFORMATION COLLECTION REQUEST (ICR)
under the PAPERWORK REDUCTION ACT

1 IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

TITLE: Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances
EPA ICR No: 0574.18
OMB Control No.: 2070-0012
EPA Form Nos.: 7710-25 and 7710-56.
Docket ID No.: EPA-HQ-OPPT-0645

1(b) Short Characterization

This information collection request addresses the reporting and recordkeeping requirements associated with the new chemicals review and regulatory program administered by EPA under section 5 of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the "Lautenberg Act") (15 U.S.C. 2604, see Attachment A). TSCA section 5 requires that any person who proposes to manufacture (which includes import) a "new chemical" (i.e., a chemical not listed on the TSCA section 8(b) Inventory) must provide a premanufacture notice (PMN) or an exemption application to EPA at least 90 days prior to commencing manufacture of that chemical and that EPA review such notice and take action as appropriate. EPA considers certain genetically engineered microorganisms to be chemical substances for purposes of the notification requirements found in TSCA section 5; 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 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." Note that the scope of this ICR only includes reporting of estimates for respondent activities associated with SNURs in instances where a SNUN is submitted. For more information on new and existing chemical SNURs, see a recent EPA Economic Analysis for new chemical SNURs issued under 40 CFR 721 Subpart D expedited process[1] and the Supporting Statement for "TSCA section 5(a)(2) Significant New Use Rules for Existing Chemicals Information Collection Request."[2]

TSCA section 5 requires EPA to make determinations before the conclusion of its review of the submitted notices regarding whether the manufacture, processing, distribution in commerce, use and/or disposal of new chemical substances or significant new uses may present

[1] *Economic Analysis for the Significant New Use Rule on Certain Chemical Substances*, Docket No. EPA–HQ–OPPT–2015–0220.
[2] EPA ICR No. 1188.11; OMB Control No. 2070-0038.

unreasonable risk to health or the environment. EPA's determination on a chemical substance or new use will dictate how and to what extent the chemical's manufacture, use, processing or disposal may be restricted. If EPA fails to make a 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 (see Attachment I); EPA would then add the new chemical substance to the TSCA section 8(b) Inventory.

2 NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

TSCA section 5(a) (15 U.S.C. 2604(a)(1)(B)(i)), 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 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, use, distribution in commerce and 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 or processing of the chemical or 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 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"; final rule (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 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 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 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 sections 5(e) if the Agency determines (1) that the information available is insufficient to permit a reasoned evaluation of the health or environmental effects; (2) in the absence of sufficient information, the manufacture, processing, distribution, use, 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 disposal of the new chemical. 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 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, or distribution in commerce 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). Regulations providing details on EPA's SNUR authority were promulgated at 40 CFR part 721 and at 40 CFR part 725 subparts H-K. Promulgation of a significant new use rule (SNUR) can be an effective and efficient way to address reasonably foreseen conditions of use about which EPA has concerns, as part of the basis for EPA to conclude that the chemical is not likely to present an unreasonable risk of injury to health and the environment under the conditions of use under section 5(a)(3)(C). 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). The ability to issue a SNUR during or after the review period can enable EPA to focus its technical analysis on the intended conditions of use of a chemical and defer further analysis of reasonably foreseen conditions of use until such time as the submitter (or any other entity) actually intends to undertake them. This is consistent with EPA's long-standing use of SNURs to defer detailed analysis of activities associated with chemicals until such time as someone indicates the intention to undertake the activities by submitting a SNUN.

It can be more efficient for EPA to address concerns associated with reasonably foreseen conditions of use by issuing a SNUR that applies to all parties, including the submitter, rather than by issuing an order to the submitter addressing activities the submitter does not intend to undertake, and then taking an additional regulatory action to issue a SNUR.

TSCA section 5(e) or 5(f) Orders are only binding on the original PMN submitter for that substance. Consequently, after issuing a section 5 Order, EPA generally promulgates a SNUR that requires notice to EPA by any manufacturer or processor who wishes to manufacture or process the chemical in a way other than described in the terms and conditions contained in the Order. TSCA section 5(f)(4) requires EPA to either initiate a SNUR rulemaking or explain its reasons for not doing so following action under section 5(e) or 5(f).

If EPA makes a determination under TSCA section 5(a)(3)(C) that a chemical substance or significant new use is not likely to 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 or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, then the submitter may commence manufacture of the chemical substance or manufacture or processing for the significant new use, notwithstanding the remainder of the review period. In addition, the Administrator shall make public a statement of the "not likely" finding in the Federal Register, in accordance with TSCA section 5(g). The same reporting requirements that apply to PMNs also apply to SNUNs, and EPA has the same authorities under TSCA section 5(e) and 5(f) to evaluate and regulate the SNUR chemical during the notice review period.

As noted in section 1b of this ICR supporting statement, the scope of this ICR renewal does not include estimates for respondent activities associated with SNURs, except for conditions specific to a SNUN submission. For more information on new and existing chemical SNURs, see a recent Economic Analysis for new chemical SNURs issued under 40 CFR 721 Subpart D expedited process (Docket No. EPA-HQ-OPPT-2017-0166) and the Supporting Statement for "TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals" Information Collection Request (OMB Control No. 2070-0038).[3]

EPA may also grant certain exemptions from the PMN, SNUN, and MCAN requirements of TSCA section 5, including the following. These exemption rules reduce reporting requirements, thereby providing relief to submitters from the burdens of the full PMN reporting requirements.

(i) Test-Marketing Exemption (TME)

Under TSCA section 5(h)(1), persons may apply for an exemption from the requirements of TSCA section 5 for test-marketing purposes. EPA may grant the exemption if it finds that the test-marketing activities described by the applicant will not present an unreasonable risk of

[3] EPA implements SNURs in two different ways, depending on the manner by which the chemical was listed on the TSCA Inventory. New chemicals are chemicals that are submitted to EPA via TSCA section 5(a)(1), and that subsequently get added by EPA to the TSCA Inventory upon notification to EPA of commencement of manufacturing or import. SNURs for new chemicals are generally published by EPA either during or soon following EPA's review of the new chemical submission to EPA. Existing chemicals are chemicals that are already listed on the TSCA Inventory, and, therefore, "existing chemical SNURs" are generally written to require notice for significant new uses for chemicals that are already (or were and are no longer) in commerce.

injury to health or the environment including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific conditions of use identified in the application. The applicant must provide the information necessary to make this finding and EPA must grant or deny the exemption within 45 days. If EPA grants the exemption, it may impose appropriate restrictions on the test-marketing activities. See 40 CFR 720.38 and 725.370.

(ii) Research and Development Exemption (R&D)

TSCA section 5(h)(3) exempts from PMN reporting small quantities of chemical substances manufactured only for research and development purposes. Persons using this exemption must have their research overseen by a technically qualified individual and must notify any person involved in the research of any risk. See 40 CFR 720.36. Small quantities of genetically modified microorganisms manufactured solely for research and development purposes are also exempt when additional criteria are met as described in 40 CFR 725.235, activities conducted inside a structure, and 40 CFR 725.238 and 239, activities conducted outside a structure.

(iii) TSCA Section 5(h)(4) Exemptions

TSCA section 5(h)(4) authorizes EPA to exempt any person from the provisions of TSCA section 5 if EPA determines, upon application and by rule, that the chemical substance will not present an unreasonable risk of injury to health or the environment when manufactured, processed, distributed, used or disposed of under the exemption. To date EPA has promulgated four rules under this section for traditional chemical substance exemptions and three rules for exemptions specific to microbial products of biotechnology:

- Low Volume Exemption (LVE) - This exemption applies to substances manufactured in quantities of 10,000 kilograms or less per year; submitters may request that EPA evaluate their exemption at a lower production volume level, to which the submitter would be legally bound. See 40 CFR 723.50.

- Low Release/Low Exposure (LoREX) - This exemption applies to certain chemical substances that meet strict human exposure and environmental release criteria to ensure that these substances will not present an unreasonable risk. See 40 CFR 723.50.

- Polymer Exemption - This exemption applies to polymers that comply with certain chemical characterizations and that therefore will not present an unreasonable risk of injury to health or the environment. See 40 CFR 723.250.

- Instant Photographic Film Articles Exemption - This exemption applies to chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles. See 40 CFR 723.175.

- TSCA Experimental Release Application (TERA) - This exemption applies to research and development activities that result in intentional environmental releases of intergeneric microorganisms. EPA may grant the exemption if it finds that the activities described by the applicant will not present an unreasonable risk of injury to health or the environment. The applicant must provide the information necessary to make this finding and EPA must grant or