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 injury to health or the environment including an unreasonable risk to a potentially exposed or

[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.

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 deny the exemption within 60 days. If EPA grants the exemption, it may impose appropriate restrictions on the activities described in the notice. See 40 CFR 725.250.

- Tier I Exemption - This exemption applies to certain microorganisms subject to physical containment and control technologies. EPA has developed specific criteria for the host microorganism, introduced genetic material, and containment technology to ensure that the microorganism will not present an unreasonable risk. See 40 CFR 725.400.

- Tier II Exemption - This exemption applies to the same microorganisms subject to a Tier I exemption without specified physical containment and control technologies. EPA may grant the exemption if it finds that the physical containment and control technologies described by the applicant will control releases of and exposure to the microorganism such that the microorganism 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 deny the exemption within 45 days. If EPA grants the exemption, it may impose appropriate restrictions on the activities described in the notice. See 40 CFR 725.428.

Finally, EPA recently promulgated a final rule under TSCA section 26(b) requiring that manufacturers and processors pay fees for PMNs, MCANs, certain PMN exemption applications and notices, and SNUNs submitted under TSCA sections 5(a) and (h) to help defray the cost of administering TSCA (83 FR 52694; October 17, 2018). The final rule, which took effect on October 18, 2018, established the following new fee amounts for all submissions received on or after October 1, 2018:

- $16,000 for single and consolidated PMN, SNUN and MCAN submitters;

- $2,800 for each PMN, SNUN, or MCAN submitted by a small business concern;

- $940 for each LVE, LoREX, TME, TERA, Tier II, or photographic film article exemption notice submitted by a small business concern;

- $4,700 for each LVE, LoREX, TME, TERA, Tier II, or photographic film article exemption notice submitted by all other respondents.

Under the new user fee rule, persons subject to TSCA fee requirements must complete fee payments electronically using the Department of Treasury's Pay.gov electronic collection payment services. The paperwork activities required by the fee rule are presented in another ICR approved under OMB Control No. 2070-0208 (EPA ICR No. 2569.02).

2(b) Use/Users of the Information

TSCA requires EPA to review submitters' section 5 notices and make an affirmative finding on the safety of new chemical substances or significant new uses of chemicals (identified by EPA in rulemaking) before they are manufactured for non-exempt commercial purposes. To make a reasoned evaluation of the potential risk to human health or the environment associated with new chemicals and significant new uses, EPA needs information on each chemical's structure and properties, manufacturing process, worker exposure, environmental release, production volume, potential industrial, commercial, and consumer use, and potential toxicity related to the substance. EPA needs sufficient information to enable Agency scientists to identify substances with analogous chemical structures and properties, with similar manufacturing processes and with similar uses. The Agency reviews available information to evaluate the toxicity of the chemical and estimate potential exposure to the substance to assess the potential risks to human health or the environment.

A chemical is considered to be a "new" chemical if it is not listed in the TSCA section 8(b) Inventory of chemicals manufactured or processed in the United States. The Inventory includes both public and confidential information. Chemicals appear in the public portion of the Inventory by name if the company manufacturing the chemical does not claim the name of the chemical to be confidential. Chemicals whose names are claimed confidential are identified in the public portion of the Inventory by an accession number and a generic name. The specific chemical name of a confidential chemical appears only in the confidential portion of the Inventory, which is not available to the public.

A company that demonstrates a bona fide intent to manufacture a chemical substance that does not appear by a specific name in the public portion of the Inventory may ask EPA whether the substance is included in the confidential portion of the Inventory (i.e., to determine whether the substance would be considered new and therefore subject to the TSCA section 5 notice requirements). Similarly, a person who demonstrates a bona fide intent to manufacture or process a chemical substance which is described by a generic chemical name in a SNUR, may ask whether their substance is subject to the requirements of the SNUR. EPA will respond to such an inquiry only if the Agency determines that the company has demonstrated a bona fide intent to manufacture or import the substance. Reporting provisions found at 40 CFR 720.25, 721.11 or 40 CFR 725.15 require additional information from a submitter so as to encourage the submission only of bona fide inquiries that reflect serious intent.

EPA requires submitters of PMNs and "bona fide notices" to provide a specific chemical identity for the substance for which a notice is made, based on a Chemical Abstracts (CA) Index name or a CA preferred name. This requirement reduces delays caused by incorrect or ambiguous chemical identity, expedites the Agency's ability to perform Inventory searches, and saves Agency resources spent on naming submitters' substances.

Since a company's initial intention to manufacture a substance or microorganism may change after making a PMN or MCAN submission, EPA requires companies to notify the Agency when manufacture (which includes import) begins by submitting a Notice of Commencement of Manufacture or Import (NOC) (see 40 CFR 720.102 and 725.190). Submitters specify in the NOC whether commencement occurred via domestic manufacture or importation and the address of the site(s) of first manufacture. This information is essential to the Agency as a compliance mechanism. The information requirements for NOC reporting also assist in identifying cases in which submitters have mistakenly reported the wrong case number in the NOC, or erroneously listed a substance that is very different from that which they intended to commence manufacture. In addition, the reporting requirements provide submitters an opportunity to update information that may no longer be correct or appropriate as reported in the notice. Finally, the NOC results in EPA adding that substance to the TSCA Inventory.

EPA requires the use of a specific reporting form (EPA Form No. 7710-56) for NOCs submitted for new chemicals in accordance with 40 CFR 720.102 (see Attachment I). Although submission of an NOC is also required for new microorganisms, a specific reporting form is not required to be used; however, the required contents of such an NOC are described in 40 CFR 725.190. The use of a standard form for new chemicals leads to greater efficiency by assisting EPA in readily identifying the type of notice, providing uniformity in recording responses in EPA databases, and providing manufacturers a format to assure that important information is not inadvertently omitted in their submissions. Before EPA required the use of a standard NOC form, a significant number of NOCs created difficulty because they were not recognized by the

Agency as a NOC or they contained confusing, missing or unnecessary information. These problems resulted in a waste of time and resources for both submitters and EPA personnel who must prepare or review these notices. The required use of a standard reporting form also reduces EPA processing time for NOCs.

On a monthly basis, EPA publishes for the public in the Federal Register information summarizing the content of each PMN and test market exemption application received, including the specific or generic name of the chemical substance and the proposed use(s), as required by TSCA section 5(d)(2). This monthly publication also includes a list of the PMNs for which EPA has received NOCs.

In order to be responsive to inquiries from Congress, the press and the public, EPA also periodically compiles certain information such as the number of notices submitted and their disposition.

The recordkeeping requirements for PMNs, MCANs, exemption applications, SNUNs and SNURs are necessary for EPA enforcement purposes. As part of its enforcement program, EPA conducts inspections to review the records of TSCA section 5 submitters to ensure that the information submitted in the notice was correct, that the submitter did not begin manufacture or processing before EPA made a determination, and that, for PMN chemicals or MCAN microorganisms, the notice of commencement was submitted when domestic manufacture or import began. The Agency also inspects manufacturers' or processors' chemical substances subject to SNURs to ensure that they are not doing so in violation of the SNUR. The recordkeeping requirements for exemptions are necessary for enforcement purposes as well. EPA conducts inspections to ensure that the information submitted in the aforementioned applications is true and that the person holding the exemption is complying with any restrictions EPA imposed when it granted the exemption.

Users of the information are EPA employees located primarily in the Office of Pollution Prevention and Toxics (OPPT), within the Office of Chemical Safety and Pollution Prevention (OCSPP), and in the Office of Enforcement and Compliance Assurance (OECA), and Core TSCA Regional Coordinator Inspectors. Staff of the New Chemicals Program within the various Divisions of OPPT use this information to review and evaluate the health and environmental effects of new chemicals and significant new uses of chemicals, and to recommend and implement regulatory actions if warranted. OCSPP employees in the Regional Offices and OECA employees in Headquarters and in the Regions use TSCA section 5 information for compliance monitoring and enforcement purposes.

3 NON-DUPLICATION, CONSULTATIONS AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

EPA is the only federal agency that regularly collects information on new *chemical substances* as defined under TSCA section 3. (In instances where chemical substances also have drug or cosmetic uses, the Food and Drug Administration would have jurisdiction over activities associated with those uses.) Therefore, the information submitters provide in a PMN or MCAN cannot be obtained elsewhere. However, information previously submitted to EPA need not be

resubmitted if the following conditions are met: the information was submitted with no claims of confidentiality and the PMN (or other TSCA section 5 notice) identifies the office or person to whom the information was submitted and the date of the submission.

3(b) Public Notice Required Prior to ICR Submission to OMB

In proposing to renew this ICR, EPA provided a 60-day public notice and comment period that ended on September 24, 2018 (83 FR 35629, July 25, 2018) (FRL-9978-03). EPA received two comments during the comment period, one from the American Chemistry Council and another from C. Silvon. Copies of the public comment(s) appear in Attachment K and Attachment L. EPA's responses to both public comments appear in Attachment M.

EPA published an additional notice in the Federal Register that provided an additional 30 days for public comment (83 FR 60845, November 27, 2018) (FRL-9986-96). EPA received one comment during the comment period from the TSCA New Chemicals Coalition (NCC). The TSCA NCC is a group of representatives from over 20 companies that have come together to identify new chemical notification issues under amended TSCA. In their comments, the TSCA NCC provided revised estimates of burdens for certain activities that had not been identified by EPA or that the TSCA NCC stated had been underestimated by EPA. The TSCA NCC encouraged EPA to consider utilizing these revised burden estimates. EPA has considered these revised estimates and has adopted them in this updated supporting statement. A copy of this public comment appears in Attachment O. EPA's responses to this public comment appear in Attachment P.

3(a) Consultations

Additionally, under 5 CFR 1320.8(d)(1), OMB requires agencies to consult with potential ICR respondents and information users about specific aspects of ICRs before submitting an ICR to OMB for review and approval. In accordance with this regulation, EPA submitted questions to several interested parties via e-mail. The individuals contacted were:

Mike Walls, Vice President
Regulatory and Technical Affairs
American Chemistry Council, Inc.

Melissa Hockstad, President and CEO
American Cleaning Institute

Derek Swick, MPP
Senior Policy Advisor
Regulatory and Scientific Affairs
American Petroleum Institute

Tim A. Brown, Esq., Vice President and General Counsel
Consumer Specialty Products Association

Ann M. Begley, Secretary/Co-General Counsel
Enzyme Technical Association

Dan Naatz, Vice President of Government Relations
Independent Petroleum Association of America

Jim Cooper Vice President Petrochemicals
American Fuel and Petrochemical Manufacturers

William Carteaux, President
Society of the Plastics Industry, Inc.

Bill Allmond, Director
Government Relations
Society of Chemical Manufacturers and Affiliates Formerly the Synthetic Organic Chemical Manufacturers Association. (SOCMA)

EPA received no responses to its solicitation for consultations. A copy of EPA's consultation e-mail to the above potential respondents is included in Attachment N.

3(b) Effects of Less Frequent Collection

The frequency of the submission of information under TSCA section 5 is not under the Agency's control. Manufacturers of new chemical substances must submit a PMN, SNUN, or MCAN at least 90 days prior to anticipated manufacturing or distribution of the substance for non-exempt commercial use. Submissions of exemption applications must be submitted within 45 or 30 days prior to anticipated manufacturing or distribution of the substance for non-exempt commercial use. Information is provided to EPA on an as-needed basis, initiated by submitters. Subsequent reporting would only be required if EPA determined that a specific use of a substance not included in the notice under review constituted a significant new use. Less frequent collection would mean submitters not being required to provide notice to EPA at all, which is contrary to the statutory direction. Without the notice and included information, EPA would be unable to administer the TSCA new chemical review requirements and would be unable to carry out its statutory mandate to protect the public from unreasonable risks to health and the environment.

3(c) General Guidelines

This collection of information is consistent with all OMB guidelines under 5 CFR 1320.6 except with respect to the maintenance of records by respondents for more than three years. EPA believes a five-year recordkeeping requirement is needed to carry out an effective program. The five-year recordkeeping requirement is consistent with the five-year statute of limitations under 28 U.S.C. 2462 held applicable to all EPA enforcement actions, including administrative proceedings under TSCA. See 3M Company v. Carol Browner and EPA, 17 F.3d (DC Cir.1994). In addition, a five-year retention period comports with certain recordkeeping requirements imposed by the Occupational Safety and Health Administration (OSHA) and helps to keep these requirements consistent with one another, thereby avoiding different timing of reporting obligations. Therefore, the Agency requires respondents to retain records for more than three years.

3(d) Confidentiality

Much of the required premanufacture information may be considered by the submitter to be a trade secret, proprietary, or "confidential business information" (CBI). However, TSCA mandates that EPA require the submission of such information because it is essential for providing a basis to determine unreasonable risk. EPA cannot draw conclusions or make assumptions concerning toxicological effects and potential risks without examining physicochemical structure, methods of production, byproducts, potential uses, exposure information, etc. The Agency is required by TSCA section 5(d)(2) to publish a Federal Register notice that identifies the chemical substance, lists its uses or intended uses and describes test information. Congress included these provisions to allow active public participation in the review process.

The Agency's policies allow public involvement while preserving confidentiality. Amended TSCA section 14(a) prohibits disclosure of trade secret information publicly when the requirements of TSCA section 14(c) are met. Also, TSCA section 14(b) allows disclosure of health and safety studies, including underlying information, unless these studies disclose confidential process or mixture information. Under 40 CFR 720.85 and 720.87 (See also 40 CFR part 2), when the specific chemical identity or use information are claimed confidential, the Agency requires the submitter to provide generic descriptions for inclusion in Federal Register notices and the public file. Additionally, the submitter must provide a "sanitized" copy of all health and environmental effects information, with confidential information deleted, for placement in the public docket. Within the Agency, only personnel with the required clearance may handle TSCA CBI.

As amended by the Lautenberg Act, TSCA section 14(c)(3) requires that any CBI claims be substantiated concurrently with the submission of the information, except that CBI claims described in TSCA section 14(c)(2) are not subject to substantiation. Based on its experience, EPA expects that most information included in TSCA section 5 notices will be claimed CBI pursuant to TSCA section 14(c)(3). To implement this new requirement for substantiation, the Agency will generally allow a PMN submitter to substantiate or correct a previously submitted substantiation for a period of 30 days from the date the PMN submitter made a CBI claim. If properly substantiated, the Agency will continue to stringently prevent unauthorized disclosure of CBI. To do so, the EPA developed a system including procedures for both logging material in and out of the Confidential Business Information Center (CBIC) at EPA headquarters and for photocopying and transmitting CBI. These procedures apply to CBI submitted by manufacturers as well as CBI generated by EPA staff in the course of their review. Access to CBI is restricted to persons who need the information for their work. No one is allowed access to CBI without first undergoing instruction on procedures for handling CBI. Special procedures have been instituted to restrict access to computerized CBI and to ensure that such information is secure. These procedures are detailed in the "TSCA CBI Protection Manual," October 2003. EPA believes these procedures protect confidential business information while providing the public with as much information as possible.

Any information being sent via CDX is transmitted using secure technologies to protect CBI. The e-PMN software encrypts PMN submissions using a Federal Information Processing Standards (FIPS)-compliant encryption module. The encryption module employs a public key algorithm which converts readable text into encrypted text. This public key is downloaded from CDX to the e-PMN software, and the corresponding private key is sent to EPA's New Chemical

System (NCS). The encryption remains while the submission is transmitted via CDX to NCS. The file can be decrypted only with the NCS's private key when it has reached its final destination. The NCS is the only party that possesses the private key, which converts the encrypted text back into readable text.

The same thing will occur for all correspondence going back to the submitter. The NCS and e-PMN software are also provided with a set of public and private keys, so that correspondence containing any potential confidential business information will remain encrypted during transmission via CDX and can be opened only by the submitter within the e-PMN software.

3(e) Sensitive Questions

Information requirements under TSCA section 5 do not include questions of a sensitive nature.

4 THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

This information collection affects companies that manufacture or process chemical substances. These companies are typically found in NAICS major groups 325 (Chemical Manufacture) and 324 (Petroleum and Coal Products). The per-response reporting unit, or unit of analysis, is “notices.” A given notice typically submitted by a single firm may pertain to a single or multiple (related) chemical substances.

4(b) Information Requested

To assist in the evaluation, EPA encourages PMN submitters to contact an EPA specialist through a pre-submission or “pre-notice” consultation to ensure that the submitter understands EPA’s review process and information helpful to make a determination regarding the chemical. EPA also issued a guidance document, entitled “Points to Consider When Preparing TSCA New Chemical Notifications,” to inform and assist submitters planning to prepare PMNs, SNUNs, and exemption applications for Agency review.

(i) Data Items - Reporting Requirements

Premanufacture Notices - Premanufacture notices required by TSCA section 5 must include certain information to the extent known to or reasonably ascertainable by the submitter. This information is defined in TSCA sections 5(d)(1) and 8(a)(2) and 40 CFR 720.45. Specific information includes the following:

- Common or trade name, chemical identity and molecular structure of the chemical in question;
- Categories or proposed categories of use of the chemical;
- Estimate of the total amount of such chemical to be manufactured or processed, including the amount to be manufactured or processed for each use category;

- Description of the byproducts resulting from the manufacture, processing, use or disposal of the chemical;

- Estimate of the total number of individuals who will be exposed to the chemical in their places of employment, and the duration of such exposure; and

- Manner or method of the disposal of the chemical.

In addition, the submitter must provide any test data in the submitter's possession that indicate the health or environmental effects of the chemical, and a description of any other data known to the submitter concerning the health or environmental effects of the chemical. The specific information requirements are spelled out in 40 CFR part 720, on the PMN reporting form itself, and in the Instruction Manual for Reporting under the TSCA §5 New Chemicals Program (see Attachment H).

To facilitate the review of chemicals, EPA has developed a PMN reporting form (EPA Form 7710-25; see Attachment G). This form is required for reporting new chemicals under TSCA section 5(a)(1) and is also required for submitting Significant New Use Notices (SNUNs). By supplying the information specified in the form, submitters do not incur the burden of providing information unnecessary for EPA's review. Therefore, use of the form lessens the burden on companies by reducing uncertainty, minimizing the need for additional contact with EPA, and allowing companies to establish procedures for meeting reporting requirements.

EPA has limited the level of detail of information required in the PMN form to that necessary for EPA to conduct an initial review of a chemical. However, submitters may include additional or optional information in their notices that they believe EPA should consider in its review. For example, submitters may identify pollution prevention techniques being employed by the submitter that may be relevant to the Agency's risk assessment. EPA encourages submitters to provide information on the benefits of the new substance in comparison to existing chemical substances, information on the substitutes, and any additional information available to them on waste management techniques.

The existing PMN form is not appropriate for reporting of new microorganisms in MCANs since the form was designed with traditional chemical substances in mind. The submitter will be able to provide the information required by the regulations in a format of his or her own choosing. Submitters of MCANs are required to use the e-PMN software to generate a finalized "header" sheet, called EPA Form 6300-07, *TSCA Biotechnology Notice for Online Submissions*. The form simply requires contact information, the addition of any attachments, and a signature page.

The e-PMN form also includes a User Fee Payment Identity Number field to enable the Agency to match more easily a particular user fee with a particular notice submission. A User Fee Payment Identity Number is required and may be a wire transfer number, or a "Pay.gov" transaction number used to transmit the user fee. This information is presently in the submitter's possession.

Another information element on the PMN form is optional and consists simply of the e-mail addresses for the principals listed on the Submitter Identification section of the PMN form.

This information helps facilitate electronic communications with the proper point of contact from the submitting entity.

Exemption Applications - Applications for exemptions from premanufacture or microbial commercial activity notice requirements have additional information requirements, as follows:

- Test-Marketing Exemption (TME) (40 CFR 720.38)

  Since April 6, 2010, TME submitters have been required to use the e-PMN software to generate finalized submissions using either Form 7710-25 or a cover letter and attached information. The test-marking exemption rule states that applicants should provide the following information: (1) all existing health and environmental effects data on the chemical or a discussion of toxicity based on structure-activity relationships and relevant data on chemical analogues; (2) the maximum quantity of the chemical substance that the applicant will manufacture for test-marketing purposes; (3) the maximum number of persons who may be provided the chemical substance during test-marketing; (4) the maximum number of persons who may be exposed to the chemical substance as a result of test-marketing, including information regarding the duration and route of such exposure; and (5) a description of the test-marketing activity, including its length and how it can be distinguished from full-scale commercial production and research and development. The Agency retains the right to determine that an application contains insufficient information to make an evaluation. Any person who receives a test-marketing exemption must retain documentation of any information in the exemption application and documentation of their compliance with any restrictions imposed by EPA when it granted the application. This information must be retained for five years from the final date of manufacture or import under the exemption.

- Research and Development Exemption (R&D) (40 CFR 720.36)

  A manufacturer using this exemption must notify all persons in its employ, or to whom it distributes the chemical substance and who are involved in any way in the research, of any risk to health associated with the chemical substance.

- TSCA section 5(h)(4) Exemptions

  1. For the low volume exemption (LVE) (40 CFR 723.50), submitters are required to submit their exemption on the PMN form (generated using the e-PMN software) to ensure that the Agency has adequate information to make a determination that these substances will not present an unreasonable risk. Statements describing exposure and release controls, site, and use in an exemption application are legally binding and enforceable.

  2. For the low exposure/low release exemption (LoREX) (40 CFR 723.50), submitters are required to submit their exemption on the PMN form (generated using the e-PMN software). The LoREX exemption encourages the use of pollution prevention practices through the development of manufacturing, processing and use techniques that minimize exposure to workers, consumers, the general public and the environment. As with the low volume exemption, site, use, exposure and release controls identified in the notice are binding.

3. The polymer exemption rule (40 CFR 723.250) requires the submission of a post-manufacture report to EPA. A simple one-page annual report is required to be submitted to the Agency no later than January 31 of the year subsequent to initial manufacture under the terms of the exemption. The report must include company identity information including the name and telephone number of a technical contact and the number of exempt substances for which manufacture commenced during the preceding year. These reports are not subject to the electronic reporting requirements of the e-PMN rule.

4. Instant photographic film articles exemption notices (under 40 CFR 723.175) must, at a minimum, identify the manufacturer and the new chemical substance. Applicants must submit an exemption notice when manufacture begins and comply with certain requirements to limit exposure to the chemical. Applicants must retain certain records for 30 years from the final date of manufacture.

5. A TSCA experimental release application (TERA) (under 40 CFR 725.250) applies to research and development activities that result in intentional environmental releases of new microorganisms. Applicants are required to include adequate information in their exemption application so that the Agency can make a determination as to whether the microorganism will present an unreasonable risk. Submitters must follow the conditions described in the TERA as well as any conditions of EPA's TERA approval.

6. Tier I exemption (40 CFR 725.424) - This exemption applies to certain new microorganisms subject to physical containment and control technologies. EPA has developed specific criteria for the host microorganism, introduced genetic material, and containment technology to ensure that the microorganism will not present an unreasonable risk. Applicants must notify EPA 10 days before manufacture, certifying compliance with the exemption criteria and include the site of manufacture or import.

7. Tier II exemption (40 CFR 725.428) - This exemption applies to the same microorganisms subject to a Tier I exemption; however, the applicant must provide adequate information on its proposed physical containment and control technologies in order for EPA to evaluate the exemption. If EPA grants the exemption, it may impose appropriate restrictions on the activities described in the notice.

Submitters of biotechnology notices (i.e., MCANs, TERAs, Tier I exemptions, and Tier II exemptions) are required to use the e-PMN software to generate a finalized "header" sheet, called EPA Form 6300-07, *TSCA Biotechnology Notice for Online Submissions*. The form requires contact information, the addition of any attachments, and a signature page.

Notices of Commencement - Under 40 CFR 720.102 and 725.190, EPA requires companies to notify the Agency by submitting a Notice of Commencement (NOC) when non-exempt commercial manufacture (including importation) of a new chemical begins. Required reporting information includes the following:

- Specific chemical identity of the chemical, and a generic chemical name if the specific name is considered confidential;
- Premanufacture notice number assigned by EPA;
- Date that manufacture commenced;

- Address of the site where manufacture commenced;
- Name and address of the submitting company, the name of the authorized official signing the NOC, the name and telephone number of a technical contact person; and
- Clear indication of what information, if any, is to be considered confidential.

For traditional chemicals regulated under 40 CFR part 720, NOCs must be submitted to EPA using the NOC form (EPA Form 7710-56). Since the effective date of the e-PMN rule, submitters are required to use the e-PMN software to generate a finalized submission using Form 7710-56. The submitter must provide the NOC to EPA on, or no later than 30 calendar days after, the day manufacture (including importation) began. The existing NOC form is not appropriate for reporting of new microorganisms since the form was designed with traditional chemical substances in mind. Thus, under 40 CFR 725.190 the submitter may provide information in a format of his or her own choosing when reporting an NOC for a new microorganism.

Bona Fides - To determine whether a chemical substance is on the confidential portion of the TSCA Inventory, submitters of bona fide inquiries under 40 CFR 720.25 and 40 CFR 725.15 are required to provide the specific chemical identity of the substance in question, a signed statement that the submitter intends to manufacture that substance, a description of the research and development activity conducted on that substance, a description of the intended use of the substance, infrared spectrum data to identify the substance, the estimated date on which the company intends to submit a PMN, the address of the facility where manufacturing or processing will occur, and a description of the manufacturing process. A similar procedure is followed for companies wishing to obtain confidential information for a SNUR, including chemical identity, and terms of the SNUR (see 40 CFR 721.11).

To determine whether a microorganism is on the confidential portion of the TSCA Inventory, submitters of bona fide inquiries under 40 CFR 725.15 are required to provide the taxonomic designations, pertinent genotypic and phenotypic information, a signed statement that the submitter intends to manufacture that microorganism, a description of the research and development activity conducted on that substance, a description of the intended use of the substance, and an indication of whether a related microorganism was previously reviewed by EPA to the extent known by the submitter. Bona fides are also subject to the e-PMN rule electronic reporting requirements.

User Fees – There is a TSCA section 26(b) rule in place at 40 CFR part 700 that requires manufacturers and processors to pay fees for PMNs, MCANs, certain PMN exemption application notices, and SNUNs submitted under TSCA sections 5(a) and (h), and requires a limited amount of additional information to be submitted with the section 5 notice. This information includes certification that the firm is a “small business concern” (if applicable), a certification statement that the submitter remitted the appropriate fee, and the placement of corresponding identifying numbers both on the PMN form and the fee remittance. A final rule (and associated ICR) that established the TSCA-associated user fees was issued to implement the Lautenberg Act amendments to TSCA became effective October 18, 2018 (83 FR 52694).

(ii) Information Items - Recordkeeping Requirements

Under 40 CFR 720.78(a), TSCA section 5 notice submitters must keep the following information or data for five years from the date of commencement of manufacture or processing: documentation of information in the notice (e.g., sources of information provided in the notice); production volume for the first three years of production; the date of commencement, plus documentation of this information; and "other data" described in the notice, as required by 40 CFR 720.50(b).

Recordkeeping requirements under SNURs require persons who manufacture or process a substance subject to significant new use reporting to maintain records indicating their compliance with certain methods of manufacture or processing. Recordkeeping requirements apply to SNURs for which compliance can be monitored by recordkeeping or SNUR notice (SNUN) submission under TSCA section 5(a)(2). For example, upon occasion EPA may determine that a specific set of exposure controls will adequately mitigate risks to workers by a specific chemical substance. In such cases, EPA may determine, by rule, that the failure to utilize such controls constitutes a significant new use. However, those persons employing the controls identified in the SNUR are not required to report to EPA. In order to demonstrate to EPA inspectors that they are properly employing worker exposure controls (to avoid SNUR notification requirements), manufacturers or processors will likely maintain some record of their compliance. In instances such as those described above, EPA would require that records be kept documenting the establishment and implementation of procedures to ensure that the exposure controls were in place. These records aid inspectors in EPA's compliance monitoring program during their visits to plants where substances subject to SNUR requirements are manufactured or processed. EPA does not consider recordkeeping that indicates compliance with a SNUR to be burdensome. Information contained in these records is not submitted to EPA. Therefore, the costs of keeping such records should be minimal.

There are also recordkeeping requirements for persons subject to section 5 orders (most often consent orders) containing exposure controls. Depending on the facts of each case, submitters must keep records in connection with the use of the exposure controls including one or more of the following: (1) documentation of manufacture volumes of the PMN substance, with associated dates of manufacture; (2) documentation of the names and addresses of all persons outside the site of manufacture to whom the submitter directly sells or transfers the substance, with associated dates of transfer; (3) documentation of the establishment and implementation of personal protective equipment program; (4) documentation of chemical protective clothing imperviousness testing; (5) documentation of the hazard communication program; (6) copies of labels; (7) copies of material safety data sheets; (8) documentation of compliance with industrial, commercial and consumer use limitations; and (9) documentation of compliance with disposal and release to water limitations.

(iii) Respondent Activities

In responding to the reporting and recordkeeping requirements outlined in this document, respondents will engage in the following activities:

- Read regulatory requirements and provisions;
- Determine which provisions are applicable to their activities;
- Gather information necessary to meet the requirements;

- Substantiate any claims of confidential business information;
- Register with CDX;
- Use the e-PMN software;
- Submit information to EPA, as necessary;
- Comply with any restrictions EPA may impose upon completion of review of their submission; and
- Maintain any necessary records.

5 THE INFORMATION COLLECTED—AGENCY ACTIVITIES, COLLECTION METHODOLOGY AND INFORMATION MANAGEMENT

5(a) Agency Activities

From the Agency's perspective, the organizing reporting unit is "notices." A given notice typically submitted by a single firm may pertain to a single or multiple (related) chemical substances, but to the Agency involves similar burden according to notice.

In connection with administering the TSCA section 5 new chemical review and regulatory program, EPA performs the following activities:

- Conducts pre-notice meetings with respondents when requested;
- Reviews and makes determinations on PMN/MCAN/SNUN submissions;
- Analyzes submissions for confidentiality and provides appropriate protection for confidential information;
- Files and stores submissions to Agency data systems;

Proposes and implements regulatory action as appropriate

- Acknowledges receipt of submissions and notifies respondents of any submission deficiencies;
- Provides technical assistance to notice submitters pre- and post-submission; and
- Conducts site and record inspections and performs related compliance monitoring functions.

5(b) Collection Methodology and Management

With the exception of the post-manufacture report required under the polymer exemption rule and instant photographic film articles exemption notices, all section 5 notices must be generated and submitted electronically via CDX. The CDX stored data and data being transmitted electronically via CDX are encrypted to protect CBI. The e-PMN software is browser-based and works with Windows, Macs, Linux, and UNIX-based computers, using XML for more efficient data transmittal to Agency data systems that once was performed manually. Currently the Agency requires all section 5 notices and NOCs to be submitted electronically via CDX.

An electronic signature is required for TSCA section 5 notices submitted to the Agency via CDX. Electronic signatures are granted as part of the CDX user-registration process.

All e-PMN software users need to perform the "finalization" before submitting to EPA. During the "finalization" step, the e-PMN software checks that all legally required information is included and provides warnings where necessary. When no errors are found, the company is

allowed to send the submission to EPA's backend server. The CBI and non-CBI attachments are transmitted in one of EPA's approved formats in order for the Agency to open the files.

The electronic submission software is changing the way that companies now interact with the Agency with many of its submissions. Electronic communication reduces the reporting burden on industry because it will reduce both the cost and the time required to enter, review, edit and transmit data to the Agency. The electronic submission software improves data quality by facilitating data correction and validation by highlighting fields with omitted data prior to submission. The protection of encrypted TSCA CBI data and the generation of an electronic Copy of Record that is returned to the submitter are other critical advantages of submitting data electronically through CDX.

All information sent via CDX is transmitted securely to protect CBI. Furthermore, if anything in the submission has been claimed CBI, a sanitized copy of the notice must be provided by the submitter. The e-PMN software facilitates the creation of this sanitized non-CBI version, eliminating the need for the submitter to do this manually. It allows multiple Authorized Officials and their designated users access to the documents online. There are also download options from CDX registration to facilitate automatic re-entering of the same information into a new form, such as contact information and site information.

The Agency also benefits from receiving electronic submissions. Data systems that were populated manually are now populated electronically, reducing the potential for human error that exists when data are entered by hand.

Because companies register with EPA to submit their data electronically to the Agency via CDX, the Agency in turn will be able in the future to communicate electronically with submitters via CDX. Some examples of routine communications from EPA that could go through CDX include the Acknowledgment Letter (acknowledging receipt of a submission), and the Incomplete Letter (stating why a submission has been declared incomplete). Usually, these communications are sent through the mail. An electronic means of communication provides significant time and resource savings for both parties.

Additionally, to aid persons subject to this information collection, OPPT has set up a TSCA Hotline that provides information regarding TSCA regulatory requirements. When TSCA Hotline staff members are unable to answer questions regarding TSCA section 5, the questions are referred to OPPT staff for appropriate resolution.

5(c) Small Entity Flexibility

The reporting and recordkeeping requirements associated with TSCA section 5 are applicable to all affected entities, regardless of size of business. However, EPA provides specialized assistance to respondents, particularly to small entities. TSCA section 26(d) established the TSCA Assistance Office, now known as the Environmental Assistance Division (EAD), to provide technical and other non-financial assistance to manufacturers and processors of chemical substances. This office has established a TSCA Hotline to assist small businesses complying with TSCA rules. It provides material such as copies of Federal Register notices, advisories, and other information on request. In addition, currently "small business concerns" submit a reduced fee for notices and exemptions where such fees apply. Under the 2018 user fee rule, for PMNs, SNUNs, and MCANs, small business concerns submit a fee of $2,800 (rather

than $16,000) and for LVE, LoREX, TME, TERA, Tier II, and photographic film article exemptions, a fee of $940 (rather than $4,700).

Moreover, EPA has taken certain steps to minimize the reporting burden associated with complying with this collection for all respondents. For example, the information technology used by EPA includes bibliographic databases that reference scientific literature and databases containing previously-submitted chemical information. These databases allow EPA to exempt submitters from needlessly providing already-published data or resubmitting previously submitted information (unless the previously submitted information was claimed confidential).

Also, as discussed above, EPA has issued several TSCA section 5 exemption rules that reduce PMN reporting requirements thereby providing relief to submitters from the burden of responding to the full PMN/MCAN requirements.

Finally, EPA provides the services of pre-submission communications coordinators and other personnel to assist persons in a comprehensive manner for purposes of notice preparation prior to submission. For instance, for new chemical substances a PMN submitter may, upon consultation with the pre-submission communication coordinator, prepare one “consolidated notice” for up to six chemical substances if they are similar in physicochemical structure and use and share common test data or other information. Pre-submission communication coordinators respond to other pre-submission inquiries that may pertain to the full scope of the TSCA section 5 regulations.

5(d) Collection Schedule

This collection of information occurs on an occasional, as-needed basis, and is initiated by the submitters.

6 ESTIMATING THE BURDEN AND COST OF THE COLLECTION

This analysis covers submissions of PMNs, SNUNs, MCANs, and associated exemption applications: TME, R&D, LVE/LoREX, instant photographic film articles, TERAs, and Tier I and II exemption applications. It also covers submission of NOCs and Bona Fide notifications, and the burden associated with implementation of TSCA section 5(e) and 5(f) consent order restrictions. Since the last renewal of this ICR, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, amending TSCA, was signed into law. Manufacturers (including importers) must complete the activities outlined in section 4 of this document. Burden and cost calculations are based on the assumption that EPA will receive approximately **1,686** TSCA section 5 notices each year, based on the average annual number of notices submitted to EPA between Fiscal Year FY 2015 and FY 2017 (except for polymers, which are based on FY 2016 and FY 2017 data) and adjusted for a decrease in the number of PMNs, SNUNs, and MCANs expected to be submitted by Industry as a result of higher fees (83 FR 52694, October 17, 2018; see Table 2 for average number of annual responses). The fees for LVE, LoREX, TME, TERA, Tier II, and photographic film articles similarly increased, but EPA does not anticipate a decrease in these submissions (due to an anticipated shift away from PMNs toward these exemptions).

6(a) Estimating Respondent Burden

The burden to respondents includes: (1) reporting burden for submission of PMNs,

SNUNs, MCANs, exemption notices, and implementation of TSCA section 5(e) and 5(f) consent order restrictions such as the use of exposure controls and/or performing toxicity testing; (2) marking any information as confidential and substantiating any claims of confidentiality in a separate statement; (3) recordkeeping burden associated with notice submissions, consent orders, exposure controls and toxicity testing; and (4) burden associated with CDX registration activities.

(i) Burden Associated with Reporting

The total respondent reporting and third-party notification burden associated with this information collection is estimated to total **192,156** hours. This burden estimate is calculated by multiplying the number of each type of notice that EPA expects to receive by the corresponding hours of reporting burden and summing across the notice types (see Table 2).

Number of Notices. The number of notices expected to be submitted annually for each of the submission types is found in Table 2. Expected numbers are mostly based on the average number of submissions EPA received between FY 2015 and FY 2017 rounded up to the nearest whole number. The number of post manufacture reports claiming the polymer exemptions are expected to be submitted for approximately 119 chemicals each year, based on FY 2016-FY 2017 data. For R&D exemptions, firms are not required to submit any data to EPA to meet the exemption requirements; however, they must meet certain procedural requirements. EPA maintains the estimate from the previous ICR and assumes that approximately 200 chemicals will meet the requirements for the R&D exemption each year. Additionally, EPA has not received any Instant Photographic Film Articles notifications in many years, but maintains a count of 1 notification per year for analytical purposes. Lastly, the number of PMNs, SNUNs, and MCANs is then reduced by 20 percent from FY 2015 – FY 2017 levels due to the anticipated impact of increased fees in the October 17, 2018 fees rule (83 FR 52694).

The number of and basis for each type of notice is presented in Table 1.

Table 1. Average Annual Responses

Type of Notice	Average Annual Responses	Basis[1]	Fees Rule Reduction[2]
PMN	409	FY 2015-FY 2017	Yes
SNUN	7	FY 2015-FY 2017	Yes
MCAN	24	FY 2015-FY 2017	Yes
Exemptions:			
TME	15	FY 2015-FY 2017	No
LVE/LoREX	414	FY 2015-FY 2017	No
TERA	2	FY 2015-FY 2017	No
Tier I	1	FY 2015-FY 2017	No
Tier II	4	FY 2015-FY 2017	No
Polymer	119	FY 2016-FY 2017	No
Research & Development	200	EPA's best professional judgement	No
Instant Photographic Film Articles	1	EPA's best professional judgement	No
Bona Fide	181	FY 2015-FY 2017	No
Section 5(e)/5(f) Order Test	66	FY 2015-FY 2017	No
Non-Testing Section 5(e)/5(f) Order	45	FY 2015-FY 2017	No

Table 1. Average Annual Responses

Type of Notice	Average Annual Responses	Basis[1]	Fees Rule Reduction[2]
NOC	198	FY 2015-FY 2017	No
Total	**1,686**		

[1] Where data are drawn from a range of fiscal years, EPA's estimate is the average number of submissions EPA received in this timeframe and rounded to the nearest whole number. The number of R&D and instant photographic film article exemptions is based on EPA's best professional judgment (BPJ) and industry data.

[2] The estimated average number of PMNs, SNUNs, and MCANs are expected to decrease due to increased fees in the final rule on Fees for the Administration of the Toxic Substances Control Act (2018) (83 FR 52694).

Burden hours.

Burden hours for each type of notice were estimated in previous analyses, beginning with EPA's 1994 Regulatory Impact Analysis of Amendments to Regulations for TSCA section 5 Premanufacture Notifications and 2009 Economic Analysis of the e-PMN final rule.

This ICR also reflects burden changes stemming from the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended TSCA on June 22, 2016. The revised statutory requirements include a requirement for substantiation of CBI claims at the time the claim is made and is being implemented though a separate action, initiated in 2017 (82 FR 6522, January 19, 2017). EPA is providing questions to help submitters develop their CBI substantiations at the time of the claim. Based on the number of substantive questions and data elements applicable to post-market submissions, and in keeping with the burden estimates developed in EPA's 2018 Information Collection Request for Chemical Data Reporting, EPA estimates that CBI substantiation will be associated with an additional 16.245 burden hours for each notice (see able 3).

EPA also issued an information document entitled "*Points to Consider When Preparing TSCA New Chemical Notifications*" to inform and assist submitters planning to prepare PMNs, SNUNs, and exemption applications for Agency review. EPA estimates that it will take submitters 1.4 hours of managerial and technical burden per notice to read through and familiarize themselves with the document (see able 3). This burden applies to PMN, SNUN, MCAN, TME, LVE/LoREX, TERA, and Tier I/Tier II notices. EPA also estimates an additional burden of 10 managerial and technical hours per notice for submitters planning to prepare PMNs.

This ICR also considers the time and resources expended by submitters of PMNs to undertake pre-notification consultations as well as post-notification communications with EPA. EPA estimates an additional burden of 5 managerial hours and 10 technical hours per PMN for pre-notification consultation. The 10 technical hours is used for review of prenotice submissions across all relevant branches in OPPT and then in consultation with the PMN submitter. The 5 managerial hours consists of facilitating and assigning appropriate professionals to address issues raised in the prenotice materials. This additional burden is only incurred by some submitters, so this ICR estimates that this burden applies only to 20 percent of PMNs submitted. Similarly, for PMNs in particular, EPA estimates that submitters expend time in engaging in post-notification communications with EPA, consisting of an estimated 97.5 managerial and technical hours (see able 3).

These changes and the reporting burden estimates associated with them have been incorporated into this ICR supporting statement.

The burden hours for each type of notice are described below and summarized in Table 2.

- *PMNs*: The base hours for respondent reporting burden for a full electronic PMN submission are expected to average 109.33 respondent burden hours. Additionally, EPA estimates an average of 141.17 additional hours per PMN submission, as discussed further in section 6(a)(1) below. This yields a total of 250.498 hours per PMN.

- *SNUNs, LVEs and LoREXs:* The hours for respondent reporting burden for SNUNs, LVEs, and LoREX are expected to average 109.33 respondent burden hours per notice. The derivation of the burden hours for these types of notices (exclusive of the burden hours for CBI substantiation) is detailed in Section (1) of this document.

- *MCANs:* The respondent burden for an MCAN is estimated to average of 305.85 hours.

- *TMEs:* The respondent burden for submission of a TME is estimated to average 103.85 hours.

- *TERAs:* The respondent burden for a TERA is estimated to average 524.85 hours.

- *Tier I or Tier IIs*: The respondent burden for a Tier I or Tier II exemption is estimated to average 127.85 hours.

- *Polymer Exemptions:* The respondent burden for submission of a polymer exemption post-manufacture annual report is estimated to average 18.50 hours.

- *R&D Exemptions:* The respondent burden to meet the procedural requirements for an R&D exemption is estimated to average 18.75 hours.

- *Instant Photographic Film Article:* The minimum amount of information that is required to be contained in an exemption notification for instant photographic film articles is the identity of the manufacturer and the new chemical substance. The burden associated with preparing and submitting this type of exemption notification is 16.75 hours.

- *Bona Fides:* The respondent burden for submission of a bona fide notice is estimated to average 32.75 hours.

- *TSCA section 5(e) and 5(f) Consent Orders:* The respondent burden for consent orders ranges from 41.25 to 167.75 hours per submission, depending on whether or not testing data are submitted. For TSCA section 5(e) consent orders where testing data are submitted, EPA assumes testing is contracted out to a laboratory and burden associated with testing requirements represents the time that personnel from the submitting firm would spend overseeing the testing.

- *NOCs:* The respondent burden for submission of a NOC is estimated to be 16.85 hours.

Table 2. Reporting Burden

Type of Notice	Average Annual Responses	Average Reporting Hours per Response	Average Annual Burden
PMN[1,2]	409	250.498	102,454
SNUN[1,2]	7	109.328	765
MCAN[1,2]	24	305.845	7,340
Exemptions:			
TME[1]	15	103.845	1,558
LVE/LoREX[1]	414	109.328	45,262
TERA[1]	2	524.845	1,050
Tier I[1]	1	127.845	128
Tier II[1]	4	127.845	511
Polymer[3]	119	18.495	2,201
Research & Development[4]	200	18.745	3,749
Instant Photographic Film Articles[4]	1	16.745	16.7
Bona Fide[1]	181	32.745	5,927
Section 5(e) Orders with Triggered Testing[1]	66	167.745	11,071
Section 5(e) Orders with Pended Testing/ 5(f) Orders with No Testing[1]	45	41.245	1,856
NOC[1]	198	16.845	3,335
Total	**1,686**		**187,224**

[1] Based on the average number of submissions EPA received between FY 2015 and FY 2017, rounded to the nearest whole number.

[2] The estimated average number of PMNs, SNUNs, and MCANs are expected to decrease as indicated in in the final rule *Fees for the Administration of the Toxic Substances Control Act* (2018) (83 Fed.Reg. 52694).

[3] Based on the average number of submissions EPA received between FY 2016 and FY 2017, rounded up to the nearest whole number.

[4] Based on EPA professional judgment and industry data.

(1) Development of Burden Estimate Associated with PMNs

The unit submission costs for TSCA section 5 PMNs has been developed over the course of several rulemakings, discussed here in some detail. The PMN burden is also used as the basis for estimating the burden for other notices (PMN, SNUN, TME, and LVE/LoREX), because each of these notices requires the submission of a complete PMN form.

The burden estimate began with EPA's (1994) Regulatory Impact Analysis of Amendments to Regulations for TSCA section 5 Premanufacture Notifications and EPA's (2009) Economic Analysis of the Premanufacture Notification Electronic Reporting (e-PMN) final rule.

The PMN submission time estimates are derived from two documents, which we refer to using the following terms:

1. "**The 1994 RIA**": Regulatory Impact Analysis of Amendments to Regulations for TSCA Section 5 Premanufacture Notifications.

2. "**The 2009 EA**": The Economic Analysis of the e-PMN final rule.

The 1994 RIA was the first to estimate the PMN submission time, and gives a range of low/high estimates for each element of the PMN form.[4] When these estimates are summed for the entire PMN form, they result in a range of 12 to 14 Clerical hours, 67 to 80 technical hours, and 16 to 20 managerial hours, for a total of 95 to114 total hours per PMN (see able 3).

The 2009 e-PMN rule EA used the PMN submission time estimates given in the 1994 RIA, with three key modifications. First, it used the average of the ranges presented in the 1994 RIA instead of ranges. Second, it eliminated the average of 13 clerical hours due to the PMN form being submitted electronically rather than in paper form. Third, the e-PMN final rule added two data fields, and the 2009 e-PMN EA adds burden to reflect these new items. These include 10 minutes of additional technical time for the User Fee Payment Identification Number field and 1 minute of additional technical time for the email address field, for a total of 11 new minutes (or 0.183 hours). Taken together, these three changes result in a total of 0 Clerical hours, 73.683 technical hours, and 18 managerial hours, for a total of 91.683 hours per PMN (see able 3).

As noted in Section (i) above, the 2016 TSCA amendments also added burden for CBI substantiation. Based on the number of substantive questions and data elements applicable to post-market submissions, and in keeping with the burden estimates developed in EPA's 2017 Information Collection Request for Chemical Data Reporting, EPA estimates that CBI substantiation will be associated with a total of 16.245 additional burden hours. For Chem ID-based substantiation, this includes 9.625 hours and 4.750 managerial hours. For Non-Chem ID-based substantiation, this includes 1.550 technical hours and 0.320 managerial Hours (see able 3).

Based on consideration of comments received from the TSCA NCC relevant to burden costs, this ICR now estimates an additional notice preparation burden of 25.67 technical hours and five managerial hours per PMN, for a total of 30.67 hours per PMN (see able 3).

EPA's document entitled "Points to Consider When Preparing TSCA New Chemical Notifications" was released as part of an emergency amendment to ICR 0574.17 and OMB control number 2070-0012 (83 FR 27768, June 14, 2018) to inform and assist submitters planning to prepare PMNs, SNUNs, and exemption applications for Agency review. EPA estimates that it will take submitters 1.4 hours of managerial and technical burden per notice to read through and familiarize themselves with the document. One-third of this total burden is allocated to technical labor and two-thirds to managerial labor. For PMNs in particular, EPA also estimates that familiarization with the "Points to Consider" document will require an additional 9 hours of technical burden and 1 hour of managerial burden per notice, for a total of 11.4 hours per PMN (see able 3).

EPA also estimates that 20 percent of PMNs will require time for pre-notification consultation, consisting of 10 hours of technical time and 5 hours of managerial time, or 15 hours total. Converting this number to an overall average applicable to *all* PMNs, the expected burden for the average PMN is 2 hours of technical time, 1 hours of managerial time, and 3 hours total (see able 3).[5]

[4] These estimates are shown in Table III-3 of the 1994 RIA.
[5] This estimate is calculated as an expected value: 20% × 15 hours + 80% × 0 hours = 5 hours.

Finally, EPA estimates that PMN submitters will spend time engaging in post-notification communications with EPA, consisting of 90 hours of technical time and 7.5 hours of managerial time, for a total of 97.5 hours (see able 3).

Table 3. Reference PMN Submission Labor Time Estimates (Hours per Response)

Activity Description	1994 RIA Averages				2009 EA				2016 TSCA CBI Substantiation				Additional Notice Preparation			
	Clerical	Tech.	Manager	Total	Clerical	Tech.	Manager	Total	Clerical	Tech.	Manager	Total	Clerical	Tech.	Manager	Total
	Average				Total				Total				Total			
Costs Based on 1994 RIA																
General Instructions	2.250	1.750	3.500	7.500	0.000	1.750	3.500	5.250	0.000	1.750	3.500	5.250	0.000	1.750	3.500	5.250
Certification			0.500	0.500			0.500	0.500			0.500	0.500			0.500	0.500
I. General Information																
A. Submitter Information																
B. Chemical Identity Info	1.750	4.500	1.000	7.250	0.000	4.500	1.000	5.500	0.000	4.500	1.000	5.500	0.000	4.500	1.000	5.500
1. Impurities		0.500		0.500		0.500		0.500		0.500		0.500		0.500		0.500
2. Synonyms		0.250		0.250		0.250		0.250		0.250		0.250		0.250		0.250
3. Trade Identification		0.250		0.250		0.250		0.250		0.250		0.250		0.250		0.250
4. Generic Chemical Name		0.500		0.500		0.500		0.500		0.500		0.500		0.500		0.500
5. Byproducts		0.500		0.500		0.500		0.500		0.500		0.500		0.500		0.500
C. Production, Import, and Use Information	1.500		2.500	4.000	0.000		2.500	2.500	0.000		2.500	2.500	0.000		2.500	2.500
1. Production		1.000		1.000		1.000		1.000		1.000		1.000		1.000		1.000
2. Use Information		3.000		3.000		3.000		3.000		3.000		3.000		3.000		3.000
3. Hazard Information		3.500		3.500		3.500		3.500		3.500		3.500		3.500		3.500
II. Human Exposure	3.000		6.500	9.500	0.000		6.500	6.500	0.000		6.500	6.500	0.000		6.500	6.500
A. Ind. Sites Controlled by the Submitter																
1. Operation Description																
a. Identity		1.000		1.000		1.000		1.000		1.000		1.000		1.000		1.000
b. Type of Operation		1.000		1.000		1.000		1.000		1.000		1.000		1.000		1.000
c. Amount and Duration		2.000		2.000		2.000		2.000		2.000		2.000		2.000		2.000
d. Process Description		11.000		11.000		11.000		11.000		11.000		11.000		11.000		11.000
2. Occupational Exposure		13.500		13.500		13.500		13.500		13.500		13.500		13.500		13.500
3. Environmental Release and Disposal		9.500		9.500		9.500		9.500		9.500		9.500		9.500		9.500
B. Industrial Sites Controlled by Others	2.000	11.000	2.250	15.250	0.000	11.000	2.250	13.250	0.000	11.000	2.250	13.250	0.000	11.000	2.250	13.250
1. Operation Description																
2. Worker Exposure and Environmental Release																
III. List of Attachments	2.000	7.000	1.250	10.250	0.000	7.000	1.250	8.250	0.000	7.000	1.250	8.250	0.000	7.000	1.250	8.250
Physical and Chemical Properties Worksheet	0.500	1.750	0.500	2.750	0.000	1.750	0.500	2.250	0.000	1.750	0.500	2.250	0.000	1.750	0.500	2.250
New Form Fields in 2009 EA																
User Fee Payment Number	N/A	N/A	N/A		0.000	0.167	0.000	0.167	0.000	0.167	0.000	0.167	0.000	0.167	0.000	0.167
Email address	N/A	N/A	N/A		0.000	0.017	0.000	0.017	0.000	0.017	0.000	0.017	0.000	0.017	0.000	0.017
2016 TSCA CBI Substantiation																
6. Chem ID CBI Substantiation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.000	9.625	4.750	14.375	0.000	9.625	4.750	14.375

Table 3. Reference PMN Submission Labor Time Estimates (Hours per Response)

Activity Description	1994 RIA Averages				2009 EA				2016 TSCA CBI Substantiation				Additional Notice Preparation			
	Clerical	Tech.	Manager	Total	Clerical	Tech.	Manager	Total	Clerical	Tech.	Manager	Total	Clerical	Tech.	Manager	Total
	Average				Total				Total				Total			
Questions																
III. Non-Chem ID CBI Substantiation Questions	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.000	1.550	0.320	1.870	0.000	1.550	0.320	1.870
Additional Notice Preparation																
Additional Notice Preparation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.000	25.670	5.000	30.670
***"Points to Consider"* Document**																
"Points to Consider" Document	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pre-Notification Consultation																
Pre-Notification Consultation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Post-Notification Communication																
Post-Notification Communication	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total	**13.000**	**73.500**	**18.000**	**104.500**	**0.000**	**73.683**	**18.000**	**91.683**	**0.000**	**84.858**	**23.070**	**107.928**	**0.000**	**110.528**	**28.070**	**138.598**

able 3. Reference PMN Submission Labor Time Estimates (Hours per Response), Continued

Activity Description	*"Points to Consider"* Document				Pre-Notification Consultation				Post-Notification Communication			
	Clerical	Tech.	Manager	Total	Clerical	Tech.	Manager	Total	Clerical	Tech.	Manager	Total
	Total				Total				Total			
Costs Based on 1994 RIA												
General Instructions	0.000	1.750	3.500	5.250	0.000	1.750	3.500	5.250	0.000	1.750	3.500	5.250
Certification			0.500	0.500			0.500	0.500			0.500	0.500
I. General Information												
A. Submitter Information												
B. Chemical Identity Info	0.000	4.500	1.000	5.500	0.000	4.500	1.000	5.500	0.000	4.500	1.000	5.500
1. Impurities		0.500		0.500		0.500		0.500		0.500		0.500
2. Synonyms		0.250		0.250		0.250		0.250		0.250		0.250
3. Trade Identification		0.250		0.250		0.250		0.250		0.250		0.250
4. Generic Chemical Name		0.500		0.500		0.500		0.500		0.500		0.500
5. Byproducts		0.500		0.500		0.500		0.500		0.500		0.500
C. Production, Import, and Use Information	0.000		2.500	2.500	0.000		2.500	2.500	0.000		2.500	2.500
1. Production		1.000		1.000		1.000		1.000		1.000		1.000
2. Use Information		3.000		3.000		3.000		3.000		3.000		3.000
3. Hazard Information		3.500		3.500		3.500		3.500		3.500		3.500
II. Human Exposure	0.000		6.500	6.500	0.000		6.500	6.500	0.000		6.500	6.500
A. Ind. Sites Controlled by the Submitter												
1. Operation Description												
a. Identity		1.000		1.000		1.000		1.000		1.000		1.000
b. Type of Operation		1.000		1.000		1.000		1.000		1.000		1.000
c. Amount and Duration		2.000		2.000		2.000		2.000		2.000		2.000
d. Process Description		11.000		11.000		11.000		11.000		11.000		11.000
2. Occupational Exposure		13.500		13.500		13.500		13.500		13.500		13.500
3. Environmental Release and Disposal		9.500		9.500		9.500		9.500		9.500		9.500
B. Industrial Sites Controlled by Others	0.000	11.000	2.250	13.250	0.000	11.000	2.250	13.250	0.000	11.000	2.250	13.250
1. Operation Description												
2. Worker Exposure and Environmental Release												
III. List of Attachments	0.000	7.000	1.250	8.250	0.000	7.000	1.250	8.250	0.000	7.000	1.250	8.250
Physical and Chemical Properties Worksheet	0.000	1.750	0.500	2.250	0.000	1.750	0.500	2.250	0.000	1.750	0.500	2.250
New Form Fields in 2009 EA												
User Fee Payment Number	0.000	0.167	0.000	0.167	0.000	0.167	0.000	0.167	0.000	0.167	0.000	0.167
Email address	0.000	0.017	0.000	0.017	0.000	0.017	0.000	0.017	0.000	0.017	0.000	0.017
2016 TSCA CBI Substantiation												
6. Chem ID CBI Substantiation Questions	0.000	9.625	4.750	14.375	0.000	9.625	4.750	14.375	0.000	9.625	4.750	14.375
III. Non-Chem ID CBI Substantiation Questions	0.000	1.550	0.320	1.870	0.000	1.550	0.320	1.870	0.000	1.550	0.320	1.870
Additional Notice Preparation												

able 3. Reference PMN Submission Labor Time Estimates (Hours per Response), Continued

Activity Description	*"Points to Consider"* Document				Pre-Notification Consultation				Post-Notification Communication			
	Clerical	Tech.	Manager	Total	Clerical	Tech.	Manager	Total	Clerical	Tech.	Manager	Total
	Total				Total				Total			
Additional Notice Preparation	0.000	25.670	5.000	30.670	0.000	25.670	5.000	30.670	0.000	25.670	5.000	30.670
***"Points to Consider"* Document**												
"Points to Consider" Document	0.000	9.470	1.930	11.400	0.000	9.470	1.930	11.400	0.000	9.470	1.930	11.400
Pre-Notification Consultation[1]												
Pre-Notification Consultation[1]	N/A	N/A	N/A	N/A	0.000	2.000	1.000	3.000	0.000	10.000	5.000	15.000
Post-Notification Communication												
Post-Notification Communication	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.000	90.000	7.500	97.500
Total	**0.000**	**119.998**	**30.000**	**149.998**	**0.000**	**121.998**	**31.000**	**152.998**	**0.000**	**211.998**	**38.500**	**250.498**

[1] This additional burden is only incurred by some submitters, so this ICR estimates that this burden applies only to 20 percent of PMNs submitted.

(ii) Burden Associated with Recordkeeping

The total respondent recordkeeping burden associated with this information collection is an estimated **3,049 hours** (Table 4). This burden estimate is calculated by multiplying the estimated recordkeeping burden associated with each type of submission, by the estimated number of submissions for each notice and summing across notice types. All recordkeeping burden estimates are taken from the *Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule* (EPA, 2009). It should be noted that there is no recordkeeping burden associated with submitting a full electronic PMN SNUN, LVE, or LoREX submission because the burden estimate of 91.683 hours per form already includes the burden associated with recordkeeping.[6]

Once a respondent presents information in an initial TSCA section 5 submission, the burden for maintaining or updating these records is minimal. The recordkeeping burden for several TSCA section 5 submissions have decreased due to the implementation of the e-PMN rule, which was finalized in 2010. EPA assumes an aggregate annualized recordkeeping burden of one hour for each PMN, SNUN, MCAN, exemption submission, or biotech submission under this new rule. This estimate is based on the recordkeeping burden associated with essential technical requirements, such as records that demonstrate that the first commercial batch of a chemical manufactured for commercial purposes under the exemption met certain eligibility criteria. The recordkeeping burden estimate for section 5(e) testing is17.5 hours. For section 5(e) and 5(f) non-testing the burden estimate is 25 hours.

The overall respondent recordkeeping burden is displayed below in Table 4.

[6] As stated in the 1994 *Regulatory Impact Analysis of Amendments to Regulations for TSCA section 5 Premanufacture Notifications*, the burden estimates for PMN submissions include the time "maintaining a file of the submission" (p. III-13). Because SNUNs, LVE, and LoREX are assumed to have the same burden as PMN submissions, the recordkeeping burden is also included in the reporting burden for these submissions.

Table 4. Respondent Recordkeeping Burden

Type of Notice	Average Annual Responses	Hours for Recordkeeping[1]	Average Annual Burden
PMN	409	0	0
SNUN	7	0	0
MCAN	24	1	24
Exemptions:			
TME	15	1	15
LVE/LoREX	414	0	0
TERA	2	1	2
Tier I	1	1	1
Tier II	4	1	4
Polymer	119	3.5	416.5
Research & Development	200	0.5	100
Instant Photographic Film Articles	1	0.25	0.25
Bona Fide	181	1	181
Section 5(e) Orders with Triggered Testing[1]	66	17.5	1155
Section 5(e) Orders with Pended Testing/ 5(f) Orders with No Testing[1]	45	25	1125
NOC	198	0.125	24.75
Total	**1,686**		**3,049**

[1] Average recordkeeping hours per response

(iii) Burden Associated with CDX Registration

As part of EPA's electronic reporting requirements, submitters of TSCA section 5 notices are required to register and submit information electronically with EPA's Central Data Exchange (CDX) system. EPA estimates that companies submitting TSCA section 5 notices for the first time would incur a one-time burden to complete CDX registration activities, obtain a CDX electronic signature, and set up a Pay.gov ID account. The total burden associated with CDX registration is approximately 2.80 hours per company. EPA assumes each company will register five employees, resulting in a per-employee burden of 0.66 hours. This per-employee burden includes 0.18 hours for CDX registration, 0.35 hours for submitting and then verifying electronic signature agreements, and 0.13 hours for setting up a Pay.gov account. In FY 2015 through FY 2017, there were an average of 2,855 new registrants, of which an average of 2,214 TSCA-Authorized Officials (AO) and 641 TSCA-Support Registrants (SR) were approved via CDX for all TSCA section 5 activities. Multiplying the annual burden by the average number of new registrants results in a total annual burden of **1,884.3** hours (Table 5).

Table 5. Burden Associated New CDX Registration Activities

CDX Registration Burden (Hours)	CDX E-Signature Burden (Hours)	E-Payment (Pay.gov ID account) (Hours)	Total Burden for CDX Registration Activities (Hours)	Annual Number of New CDX Registrants	Total Annual Burden for CDX Registration (Hours)
0.18	0.35	0.13	0.66	2,855	**1,884.30**

6(b) Estimating Total Burden

Table 6 below contains the total annual respondent burden for all submissions and activities covered under this ICR. The total annual burden is estimated to be approximately **192,156 hours** (187,224 reporting hours + 3,049 recordkeeping hours + 1,884 CDX registration hours). For this ICR, EPA estimated the total number of potential respondents at 234. This estimate is based on the number of unique entities that submitted a response of any kind during FY 2017 or the first complete year following the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended TSCA on June 22, 2016. EPA estimates the average number of responses per respondent as the total number of annual responses (minus any CDX registration activity) divided by the total number of respondents, which yields approximately 7.21 responses per respondent (1,686 annual responses ÷ 234 annual respondents).

Table 6. Total Annual Respondent Burden Calculation

Type of Notice	Average Annual Responses	Managerial Hours	Technical Hours	Clerical Hours	Total Labor Hours	Total Burden
PMN	409	38.5	211.998	0	250.498	**102,454**
SNUN	7	24	85.328	0	109.328	**765**
MCAN	24	71	235.345	0.5	306.845	**7,364**
Exemptions:						
TME	15	23	81.345	0.5	104.845	**1,573**
LVE/LoREX	414	24	85.328	0	109.328	**45,262**
TERA	2	135	390.345	0.5	525.845	**1,052**
Tier I	1	29	99.345	0.5	128.845	**129**
Tier II	4	29	99.345	0.5	128.845	**515**
Polymer	119	6.32	13.425	2.25	21.995	**2,617**
R&D	200	5.07	13.925	0.25	19.245	**3,849**
Film Articles	1	5.07	11.925	0	16.995	**17.00**
Bona Fide	181	11.07	22.675	0	33.745	**6,108**
Section 5(e) Orders with Triggered Testing[1]	66	43.87	132.625	8.75	185.245	**12,226**
Section 5(e) Orders with Pended Testing/ 5(f) Orders with No Testing[1]	45	24.57	29.175	12.5	66.245	**2,981**
NOC	198	5.07	11.8375	0.0625	16.97	**3,360**
New CDX Registration[1]	2,855	0.132	0.528	0	0.66	**1,884**
Total						**192,156**

[1] Based on the 2009 Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule, EPA assumes that 20 percent of CDX registrants will be managerial employees and 80 percent will be technical employees. Therefore, the per employee registrations burden is split between managerial and technical hours using a 20/80 ratio.

6(c) Estimating Respondent Cost

Respondents to TSCA section 5 reporting requirements experience costs associated with (1) reporting, (2) recordkeeping, and (3) compliance with exposure controls and testing requirements included in TSCA section 5(e) and 5(f) orders, when EPA takes regulatory action. The respondent costs associated with this information collection are estimated to total **$49,979,150** (able 7).

Respondent costs for all submissions consist of three components: (1) labor costs, calculated by multiplying the estimated burden hours associated with each submission type by the appropriate labor rate; (2) delay costs, estimated as the cost of the delayed receipt of profits by chemical manufactures as a result of the submission review process, and (3) explicit costs, such as user fees or lab testing fees.

In order to estimate total respondent cost associated with TSCA section 5 submissions, an average cost per notice was first calculated for each type of notice. The cost for each notice type was calculated by summing each of the associated cost components, and then multiplying by the expected number of notice submissions. The total industry cost was calculated by summing the costs across notice types. able 7 outlines the average cost calculations for the various types of notice submissions and presents the total respondent cost estimate.

Wages for managerial, professional/technical, clerical and production labor were taken from the Bureau of Labor Statistics (BLS) *Employer Costs for Employee Compensation* (ECEC) data, for December 2017, for manufacturing industries. The cost of fringe benefits such as paid leave and insurance, specific to each labor category, are taken from the same ECEC series. Fringe benefits as a percent of wages are calculated separately for each labor category. For example, for December 2016, the average wage rate for professional/technical labor was $45.82, the average fringe benefit was $24.33. Fringe benefits as a percent of wages were $24.33/$45.82 or approximately 53.1 percent.

An additional loading factor of 17 percent is applied to wages to account for overhead. This approach is used for consistency with Office of Pollution Prevention and Toxics economic analyses for two major rulemakings: *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* (2002), and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (2002). This overhead loading factor is added to the benefits loading factor, and the total is then applied to the base wage to derive the fully loaded wage. For example, the December 2016 fully loaded wage for professional/technical labor is $45.82 × (1+0.53099 + 0.17) = $77.94.

As noted above, delay costs reflect the cost of the delayed receipt of profits by chemical manufactures as a result of the submission review process. Industry delay costs used to calculate the average cost per submission were computed using the midpoint of the low and high delay cost estimates (1993 dollars) as presented in the “Regulatory Impact Analysis of Amendments to Regulations for TSCA section 5 Premanufacture Notifications” (1994), and inflated to 2016 dollars using the Bureau of Labor Statistics’ Producer Price Index data for the Chemical Manufacturing industry.

The EPA fees (explicit costs) used to calculate the average cost per submission were taken from the 2018 fees rule: *Fees for the Administration of the Toxic Substances Control Act* (83 Fed.Reg. 82694). This rule increased fees for PMNs, SNUNs, and MCANs from $2,500 to $16,000 and fees for LVE, LoREX, TME, TERA, Tier II, and photographic film articles from $0 to $4,700. Laboratory testing costs were inflated to 2016 dollars using the Bureau of Labor Statistics (BLS) Employment Cost Index (ECI) series for private industry workers in all industries and occupations.

Table 7. Total Respondent Cost Calculation

Type of Notice	Average Annual Responses	Total Burden (Reporting + Recordkeeping) and Wage Rate by Labor Category						Labor Costs[1]	Delay Costs[2]	Fees[3]	Avg. Cost Per Notice[4]	Total Respondent Cost[6]
		Managerial		Technical		Clerical						
		Hours	Wage ($)	Hours	Wage ($)	Hours	Wage ($)					
PMN	409	38.5	$76.67	211.998	$77.94	0	$34.99	$19,475	$31,680	$16,000	$67,155	$27,466,449
SNUN	7	24	$76.67	85.328	$77.94	0	$34.99	$8,491	$31,680	$16,000	$56,171	$393,196
MCAN	24	71	$76.67	235.345	$77.94	0.5	$34.99	$23,804	$31,680	$16,000	$71,484	$1,715,618
Exemptions:												
TME	23	$76.67	81.345	$77.94	0.5	$34.99	$8,121	-	$4,700	$12,821	$192,313	23
LVE/LoREX	24	$76.67	85.328	$77.94	0	$34.99	$8,491	$15,946	$4,700	$29,137	$12,062,596	24
TERA	135	$76.67	390.345	$77.94	0.5	$34.99	$40,791	-	$4,700	$45,491	$90,982	135
Tier I	29	$76.67	99.345	$77.94	0.5	$34.99	$9,984	-	-	$9,984	$9,984	29
Tier II	29	$76.67	99.345	$77.94	0.5	$34.99	$9,984	-	$4,700	$14,684	$58,735	29
Polymer	6.32	$76.67	13.425	$77.94	2.25	$34.99	$1,610	-	-	$1,610	$191,546	6.32
R&D	5.07	$76.67	13.925	$77.94	0.25	$34.99	$1,483	-	-	$1,483	$296,555	5.07
Film Articles	5.07	$76.67	11.925	$77.94	0	$34.99	$1,318	-	$4,700	$6,018	$6,018	5.07
Bona Fide	11.07	$76.67	22.675	$77.94	0	$34.99	$2,616	-	-	$2,616	$473,499	11.07
Section 5(e) Orders with Triggered Testing[1]	43.87	$76.67	132.625	$77.94	8.75	$34.99	$14,006	-	$150,319[5]	$164,326	$10,845,488	43.87
Section 5(e) Orders with Potentially Useful Information/ 5(f) Orders with No Testing[1]	24.57	$76.67	29.175	$77.94	12.5	$34.99	$4,595	-	-	$4,595	$206,779	24.57
NOC	5.07	$76.67	11.8375	$77.94	0.0625	$34.99	$1,314	-	-	$1,314	$260,076	5.07
New CDX Registration	0.132	$76.67	0.528	$77.94	0	$34.99	$51	-	-	$51	$146,383	0.132
Total												**$54,416,216**

[1] Labor costs are calculated by multiplying burden hours by the wage rate for each labor category and summing across labor categories.

[2] Delay costs calculated using the average of low and high estimates from "Regulatory Impact Analysis of Amendments to Regulations for TSCA section 5 Premanufacture Notifications" September 9, 1994 (RIA, 1994), updated to 2016$, using Bureau of Labor Statistics Producer Price Index data for the chemical manufacturing industry. MCANs are assumed to have the same delay costs as PMNs.

[3] User fees charged by EPA, except where noted.

[4] Average cost per notice is the sum of labor costs, delay costs and fees.

[5] This figure is for a representative testing regimen consisting of 835.3110 (ready biodegradability), 850.1010, 850.1075, 850.5400 (aquatic base set), and OECD 407 (28-day repeated dose), based on an analysis of average costs for 277 testing cases and inflated to 2016$ using the Bureau of Labor Statistics (BLS) Employment Cost Index (ECI) series for all workers in private industry (Series ID CIS20100000000000I (B)).

[6] While companies incur costs for control equipment, such costs are outside the scope of this ICR

6(d) Estimating Agency Cost

The Agency costs associated with this information collection are estimated to total **$28,287,555** (Table 8). Costs to the government include: (1) review of the chemical substance or significant new use under the conditions of use (circumstances under which the chemical is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of), (2) making a final determination on the chemical substance under TSCA section 5(a)(3), and (3) as appropriate, taking regulatory action under TSCA sections 5(e), 5(f) or 5(g).

The provisions of TSCA, as amended, result in additional TSCA section 5 Agency costs that arise primarily from the requirement to review the intended, known or reasonably foreseen activities associated with the chemical, from the requirement to make an affirmative risk determination, and from development of significant new use rules (SNURs) and orders that result from our analysis and findings under TSCA, as amended. Therefore, the Agency used the cost estimates from prior experience and prior versions of this ICR as a starting point and then added estimates for the costs of these additional responsibilities to calculate the Agency's program costs associated with TSCA section 5 as part of the final rule: *Fees for the Administration of the Toxic Substances Control Act* (83 Fed. Reg. 52694) (2018).

Agency cost estimates include the costs of processing, reviewing, and making determinations, and the Agency's costs of taking any regulatory action, such as with a SNUR or a consent order. Costs of reviewing any data that is submitted to the Agency as a result of an order is also included. Agency cost estimates for administering TSCA section 5 also include the costs associated with processing and retaining records related to NOCs. NOC costs also include the cost of registering the chemical with the Chemical Abstracts Service (CAS). These estimates of average cost per notice are based on projected FTE and extramural support needed for these actions divided by the number of notices the Agency assumes will be received each year once fees are in place. Total Agency cost estimates are then calculated as average cost per notice multiplied by the average number of notices estimated in section 6(b) of this ICR.

Table 8. Total Agency Cost Calculation

Type of Notice	Average Annual Responses	Avg. Cost Per Notice[1]	Total Agency Cost[2]
PMN[3]	409	$41,000	**$16,769,000**
SNUN[3]	7	$41,000	**$287,000**
MCAN[3]	24	$41,000	**$984,000**
Exemption:			
TME	15	$5,622	**$84,330**
LVE/LoREX	414	$5,622	**$2,327,508**
TERA	2	$5,622	**$11,244**
Tier I	1	$5,622	**$5,622**
Tier II	4	$5,622	**$22,488**
Polymer	119	$5,622	**$669,018**
R&D	200	$5,622	**$1,124,400**
Film Articles	1	$5,622	**$5,622**
Bona Fide[4]	181	-	**-**
Section 5(e) Orders with Triggered Testing[4]	66	-	**-**
Section 5(e) Orders with Potentially Useful Information/ 5(f) Orders with No Testing[4]	45	-	**-**
NOC	198	$5,805	**$1,149,390**
New CDX Registration[4]	2,855	-	**-**
Risk Management[5]	-	-	**$4,847,933**
Total			**$28,287,555**

[1] Values derived from TSCA User Fees Technical Support Document (2018).

[2] Total Agency Cost per type of notice calculated as average cost per notice multiplied by average number of annual responses per type of notice.

[3] Average of annual responses of PMN/SNUN/MCAN based on historical activity and are expected to decline because fees were increased by the final rule titled *Fees for the Administration of the Toxic Substances Control Act* (2018) (83 Fed.Reg. 52694).

[4] Agency costs associated with review of Bona Fide notices, 5(e) orders, 5(f) orders, and new CDX registrations is included in the average cost per notice for PMNs, SNUNs, MCANs, Exemptions and NOCs, as well as in the total Agency cost associated with Risk Management activities.

[5] Includes costs associated with taking regulatory actions under TSCA sections 5(e), 5(f), or 5(g), as well as reviewing data submitted from consent orders.

6(e) Reasons for Change in Burden

This renewal reflects an increase in the total estimated respondent burden of 73,601 hours (from 118,555 hours to 192,156 hours) from that currently in the OMB inventory. This increase is driven by several changes.

First, the mix of the estimated number of each type of notice changed, based on the most recent EPA data available. While the net effect of these changes was that the number of notices decreased by 440, increases in the types of notices with a high associated unit burden (such as Section 5(e)/5(f) Order Test and Non-Testing Section 5(e)/5(f) Order) led to a net increase in burden.

Similarly, the estimated number of annual CDX registrants also increased (from 392 submissions to 2,855 submissions), reflecting the most recent EPA data available. This change results in increased burden of 1,626 hours.

This ICR also integrates corrections to rounding errors and recordkeeping unit burden estimates for PMNs, SNUNs, LVEs, and LoREXs.

This ICR removes 276 hours of rule familiarization attributed to the change request submitted for the 2015 amendment to the ePMN rule.

This ICR also adds 12,544 hours to the estimated PMN burden for additional notice preparation, 4,090 for additional familiarization with the *"Points to Consider"* document, 1,227 hours for pre-notification consultation, and 39,878 hours for post-notification communication.

Table 9. Summary of the Change in Burden

Burden Change	
Starting Burden	118,555
Change due to Adjustments	46,212
Change in the annual number of notices	-11,097
Change in the annual number of CDX registrants	1,626
Change due to correcting rounding error in previous ICRs	-547
Change resulting from corrections to recordkeeping burden estimates for PMNs, SNUNs, LVEs, and LoREXs	-1,235
Elimination of "rule familiarization" IC from previous change request	-276
Additional notice preparation	12,544
Additional "Points to Consider" burden	4,090
Program changes	27,389
Adding CBI Substantiation due to 2016 TSCA amendments	*27,389*
Pre-notification consultation	*1,227*
Post-notification communication	*39,878*
Total	**192,156**

Note: Totals may not be exact due to rounding

6(f) Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0012, is estimated to range between **16.97 hours and 525.85 hours per**

response (for NOCs and TERAs, respectively), depending upon the type of response. Burden is defined in 5 CFR 1320.3(b). 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. The OMB control number for this information collection appears above. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPPT-2017-0645, which is available for online viewing at *www.regulations.gov*, or in-person viewing at the Office of Pollution Prevention and Toxics Docket in the EPA Docket Center (EPA/DC). The EPA/DC Public Reading Room is located in the West William Jefferson Clinton Bldg., Room 3334, 1301 Constitution Ave., N.W., Washington, DC. The EPA/DC 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 EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280.

You may submit comments regarding the Agency's need for this information, the accuracy of the provided burden estimates, including the estimates involving the "*Points to Consider*" document and any suggested methods for minimizing respondent burden, including the use of automated collection techniques. Submit your comments, referencing Docket ID No. EPA-HQ- OPPT-2017-0645 and OMB Control No. 2070-0012, to both EPA and OMB as follows:

• To EPA online using http://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.

• To OMB via email to oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the 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. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

7 ATTACHMENTS TO THIS SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number EPA-HQ-OPPT-2017-0645. These attachments are available for online viewing at www.regulations.gov or otherwise accessed as described in section 6(f) of the supporting statement.

Attachment A: **15 U.S.C. Chapter 53, Section 2604 - Toxic Substances Control Act, as amended by Frank R. Lautenberg Chemical Safety for the 21st**

Century Act. Also available online at the U.S. House of Representatives' U.S. Code website

Attachment B: **40 CFR part 700 - General**. Also available online at the National Archives and Records Administration's Electronic CFR website

Attachment C: **40 CFR part 720 - Premanufacture Notification**. Also available online at the National Archives and Records Administration's Electronic CFR website

Attachment D: **40 CFR part 721 (excluding subpart E) - Significant New Uses of Chemical Substances**. Also available online at the National Archives and Records Administration's Electronic CFR website

Attachment E: **40 CFR part 723 - Premanufacture Notification Exemptions**. Also available online at the National Archives and Records Administration's Electronic CFR website

Attachment F: **40 CFR part 725 - Reporting Requirements and Review Processes for Microorganisms**. Also available online at the National Archives and Records Administration's Electronic CFR website

Attachment G: **EPA Form 7710-25 - Premanufacture Notice.** Also available online at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/sample-premanufacturehttps://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/sample-premanufacture-notification

Attachment H: **Instruction Manual for Reporting under the TSCA Section §5 New Chemicals Program**. Also available online at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/instruction-manual-reporting-under

Attachment I: **EPA Form 7710-56 - Notice of Commencement of Manufacture or Import.** Also available online at https://www.epa.gov/sites/production/files/2015-10/documents/noc_print_form070709.pdf Also see: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa#tab-1

Attachment J: **Points to Consider When Preparing TSCA New Chemical Notifications.** Also available online at: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/points-consider-when-preparing-tsca

Attachment K: **Comment from Christina Silvon.** Also available online at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0645-

0012

Attachment L: **Comment from American Chemistry Council.** Also available online at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0645-0013

Attachment M: **Response to Comments Memorandum**

Attachment N: **Consultation Email to Potential Respondents**

Attachment O: **Comment Letter from TSCA New Chemicals Coalition (NCC)**

Attachment P: **Response to Comment Letter from NCC**