**Supporting Statement for a Request for OMB Review under**

**the Paperwork Reduction Act**

# **1. IDENTIFICATION OF THE INFORMATION COLLECTION**

**1(a) Title and Number of the Information Collection**

**Title: TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals**

**EPA ICR No.: 1188.13 OMB Control No.: 2070‑0038**

**Docket ID No.** EPA-HQ-OPPT-2015-0273

**1(b) Short Characterization**

Section 5 of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (15 U.S.C. 2604, see Attachment 1), authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use via issuance of a Significant New Use Rule (SNUR), TSCA section 5(a)(1)(B) requires persons to submit a notice to EPA at least 90 days before they manufacture (including import) or process the substance for that use. EPA must review the notice, make an affirmative determination on the safety of the significant new use of the existing chemical substance under TSCA section 5(a)(3), and, if appropriate, take action under TSCA section 5(e) or 5(f) to address any unreasonable risks that have been identified before the new use may occur. Regulations implementing significant new uses appear at 40 CFR part 721 (see Attachment 2).

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b), and regulations that interpret TSCA section 12(b) appear at 40 CFR part 707.

# **2. NEED FOR AND USE OF THE COLLECTION**

**2(a) Need/Authority for the Collection**

TSCA section 5(a)(2) provides EPA with the authority to designate by rule significant new uses of existing chemical substances for which notice to the Agency is required. This document covers information collection requirements relating to SNURs for existing chemical substances. SNURs for new chemical substances are covered under the renewal ICR for Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances (OMB Control No. 2070-0012). The Administrator must consider the following factors in determining a significant new use of an existing chemical substance:

1) The projected volume of manufacturing and processing of a chemical substance;

2) The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance;

3) The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance; and

4) The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

After proposal and finalization of a SNUR, a person who intends to manufacture (including import) or process a significant new use of a chemical substance covered by a SNUR must notify EPA of the intent via a Significant New Use Notice (SNUN) at least 90 days prior to commencing the new use. The required notice must be submitted electronically, via the Central Data Exchange (CDX), using the Agency’s e-PMN software. Within 90 days, EPA must either conclude, following review of a SNUN, that the activities are not likely to present an unreasonable risk to human health or the environment, or take appropriate action under TSCA section 5(e) or 5(f) to protect against any unreasonable risk to human health or the environment. 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 TSCA section 5(a)(3). If the Agency has not made a determination within 90 days, it may extend the evaluation period by up to 90 days with good cause.

If EPA makes a determination under TSCA section 5(a)(3) 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 (including import) or processing for the significant new use.

**2(b) Practical Utility/Users of the Data**

TSCA requires EPA to review submitters’ notices and make an affirmative finding on the safety of significant new uses of chemicals (identified by EPA in rulemaking) before they are manufactured (including imported) for non-exempt commercial purposes. To make a reasoned evaluation of the potential risk to human health or the environment associated with 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 data 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.

Users of these data 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. EPA staff use this information to review and evaluate the health and environmental effects of 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 data for compliance monitoring and enforcement purposes.

To date, EPA has promulgated SNURs on 591 existing chemicals.

**3. NON-DUPLICATION, CONSULTATIONS AND OTHER COLLECTION**

**CRITERIA**

**3(a) Non-Duplication**

EPA is the only federal agency that collects information on significant new uses of chemical substances. A notification of an intent to engage in a significant new use serves two functions: as a notice, and as a document that contains information about a chemical substance and potential exposures to that substance. The notification element is unique to SNURs and therefore not obtainable elsewhere. The chemical information aspect will also contain unique information. Only the person who intends to commence a significant new use of a chemical substance will know the potential for human and environmental exposures to that substance, the quantity intended to be manufactured (including imported) or processed, and the manner in which the person will engage in the significant new use.

A person submitting a significant new use notice is not required to develop test data. However, the person must submit data that are known to or reasonably ascertainable by that person. For published data the submitter need only provide a literature citation (40 CFR 720.50(d)(3)(ii)). For existing chemicals that are related to the chemical substance that is the subject of the SNUR (e.g., impurities, byproducts), neither the published data nor a literature citation need be submitted. Also, notices need not include information previously submitted to EPA (unless the previously submitted information was claimed confidential, in which case it must be resubmitted).

**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 November 2, 2015 (80 FR 53151, September 2, 2015). EPA received two comments, from the American Chemistry Council and the Society of Chemical Manufacturers and Affiliates (SOCMA), during the comment period. Copies of the comments are included as Attachment 4, and EPA’s response to the comments is found at Attachment 5.

**3(c) Consultations**

Additionally, under 5 CFR 1320.8(d)(1), OMB requires agencies to consult with potential ICR respondents and data 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 nine parties via e-mail (Attachment 6). The individuals contacted were:

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Jim Ford

American Petroleum Institute

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Brigid Klein

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William Carteaux

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Bill Allmond

Synthetic Organic Chemical Manufacturers Association

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EPA received two responses to its solicitation for consultations: one response from Christina Franz, representing the American Chemistry Council (ACC); and one response from Dan Newton, representing the Synthetic Organic Chemical Manufacturers Association (SOCMA). A copy of these ACC and SOCMA consultations responses are found in Attachment 7.

**3(d) Effects of Less Frequent Collection**

Whenever a person intends to engage in a significant new use, they must notify EPA. This is an explicit requirement of TSCA. TSCA section 5(a)(1)(B) states, “... no person may ... manufacture or process any chemical substance for a use which the Administrator has determined ... is a significant new use ... unless such person submits to the Administrator ... a notice ...” The consequence of less frequent collection of information (i.e., requiring only the first person who intends to engage in a significant new use to submit notice) is a violation of TSCA and would allow manufacturers (including importers) and processors to use a substance in a manner that EPA has determined may cause significant adverse exposures to the substance without prior notification to EPA.

**3(e) General Guidelines**

This information collection activity is necessary to implement the statutory requirements of TSCA section 5(a)(2) and is consistent with the requirements of 5 CFR 1320.6.

EPA developed e-PMN software for use in preparing and submitting TSCA section 5 notices such as SNUNs and support documents electronically to the Agency via CDX, and updated the e-PMN software in 2015 so that it operates more efficiently as a “cloud” software system rather than as a downloadable software system. EPA’s CDX is the point of entry on the Environmental Information Exchange Network (Exchange Network) for environmental data submissions to the Agency. CDX provides the capability for submitters to access their data through the use of web services. CDX enables EPA and participating program offices to work with stakeholders–including State, tribal, and local governments and regulated industries–to enable streamlined electronic submission of data via the Internet. For more information about CDX, go to <https://cdx.epa.gov/>. The use of CDX for submission of TSCA section 5 notices and support documents is consistent with the Government Paperwork Elimination Act (GPEA, Title XVII of Public Law 105-277) that requires Federal agencies to provide electronic submission, maintenance, or disclosure of information, when practicable as a substitute for paper.

**3(f) Confidentiality**

Information provided in a significant new use notice may receive confidential treatment. TSCA section 14 allows a manufacturer (including importer) or processor to designate submitted information as confidential business information (CBI). The Agency has developed a comprehensive system to prevent the unauthorized disclosure of CBI. This system includes procedures for logging CBI in and out of designated locked file cabinets, for photocopying and transmitting CBI, and for restricting confidential information only to personnel with CBI security clearance. No one is allowed access to CBI until they have received instructions for handling CBI.

EPA will ensure secure transmission of SNUN data submitted through CDX via the Transport Layer Security (TLS) protocol. TLS is a widely used approach for securing Internet transactions and is endorsed by the National Institute of Standards and Technology (NIST) for protecting data sent over the Internet. See NIST Special Publication 800–52 Revision 1, “Guidelines for the Selection, Configuration, and Use of Transport Layer Security (TLS) Implementations, (dated April 2014)” <http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-52r1.pdf>. In addition, e-PMN software enables the SNUN submitter to electronically sign, encrypt, and submit reports which EPA subsequently provides back to the submitter as an unaltered copy ofrecord. This assures the submitter that the Agency has received exactly what the submitter sent to EPA.

Additionally, special procedures also restrict access to computerized CBI. These security measures apply to CBI submitted by manufacturers as well as CBI generated by EPA staff in the course of their review.

**3(g) Sensitive Questions**

This section is not applicable. The information requested is not sensitive in nature.

**4. THE RESPONDENTS AND THE INFORMATION REQUESTED**

**4(a) Respondent NAICS Codes**

Respondents affected by this collection activity are mainly NAICS categories 325 - Chemicals and Allied Products Manufacturers and 32411- Petroleum Refining.

**4(b) Information Requested**

(i) Data items, including record keeping requirements

Information submitted under this collection must include, insofar as it is known to or reasonably ascertainable by the submitter, information described in TSCA section 8(a)(2) (i.e., chemical identity, use, and exposure data), as well as test data, and descriptions of other data related to the effects on health and the environment of the manufacture, processing, use, distribution in commerce, and disposal of the chemical substance (TSCA section 5(d)). After receipt of a notice, EPA has 90 days (extendable to 180 days) to evaluate the notice’s content.

(ii) Respondent Activities

Only those persons who intend to engage in a significant new use of a chemical substance must submit notice of their intentions to EPA. According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 720.50. SNUNs must be on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 721.25 and 720.40. E-PMN software is available electronically at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn>.

**5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION**

**METHODOLOGY, AND INFORMATION MANAGEMENT**

**5(a) Agency Activities**

A significant new use rule (SNUR) on an existing chemical substance is the product of a process that is designed to develop the appropriate information-gathering collection for a substance. This process has three major steps: Chemical Referral, Regulatory Selection, and Regulation Development.

Step 1. **Chemical Referral:** EPA offices that have identified information-gathering or follow-up monitoring needs for a particular existing chemical may refer the substance to OPPT. A systematic process has been developed for receiving and handling chemical referrals. Offices referring substances are asked to prepare concise summaries of relevant data. This information is used to select a regulatory approach and for rulemaking activities.

Step 2. **The Regulatory Selection Process - Referral and Review:** Once an office has detailed its need for information, an information collection approach is determined that best satisfies that office’s needs. The rulemaking options are: a TSCA section 8(a) reporting rule, a TSCA section 8(c) call-in, a TSCA section 8(d) health and safety data reporting rule, a TSCA section 5(a)(2) SNUR, or any combination of the above. It may also be determined that an alternative approach is more appropriate (e.g., use of existing data sources, no data-gathering at the present time, TSCA section 4 or 6 action, or referral to another office for information-gathering under a different statutory authority). See Attachment 3 for selection criteria.

Step 3. **Regulatory Development:** Prior to the development of a rule, the recommended rulemaking approach must be reviewed by the referring office and approved by the Office Director of OPPT. If the recommendation is approved, then the rulemaking process begins.

An existing chemical SNUR is developed and, if OMB determines that the proposed and/or final rule is a significant regulatory action under Executive Order 12866, the draft rule is submitted to OMB for interagency review under Executive Order 12866 prior to proposing or promulgating the rule in the *Federal Register.*

**5(b) Collection Methodology and Management**

Submitters are able to generate TSCA section 5 notices, including SNUNs, using the e-PMN software available at the EPA New Chemicals Program website (<https://cdx.epa.gov/ssl/pmn/download.asp>). The e-PMN software is available as a free internet download. The data being transmitted electronically via CDX is encrypted to protect CBI. CDX is the mechanism for submission of section 5 notices to the Agency. An electronic signature will be required for TSCA section 5 notices submitted to the Agency via CDX. Electronic signatures are granted as part of the CDX user-registration process.

Because companies will be registered with EPA to submit their data electronically to the Agency via CDX, the Agency in turn is able 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).

SNUN submitters are required to use the e-PMN software to generate section 5 notices and support documents. The e-PMN software includes many useful features for section 5 notice preparers. One feature is a built-in validation mechanism which will alert users that information, required by regulation, is missing or potentially incorrect. This should help reduce the number of incomplete section 5 notices, saving submitter and EPA processing resources and time. Also, the new e-PMN software allows for the creation of a sanitized non-CBI version from the complete section 5 notices submission containing CBI. It also allows submitters to share a draft notice within their company during the creation of a section 5 notice and to save a copy of the final file for future reference. The software allows the submitter to create a profile with his/her contact information, which saves the submitter time in reentering that information on subsequent notices.

In addition to support provided with the e-PMN software, OPPT has set up a TSCA Hotline that provides information regarding TSCA section 5(a)(2) reporting as well as other regulatory information. When Hotline staff are unable to answer questions regarding TSCA section 5(a)(2), the questions are referred to the OPPT Chemical Control Division (CCD) staff for resolution.

**5(c) Small Entity Flexibility**

All business, regardless of size, must comply with the requirements of TSCA section 5. However, OPPT has taken a number of steps intended to minimize the burden placed on small business. For instance, TSCA section 26(d) established an Assistance Office to provide technical and other nonfinancial assistance to manufacturers (including importers) and processors of chemical substances and mixtures. This office has established a toll-free hotline, performs on-site field visits and consultations, and has hired a contractor to assist small businesses, free of charge, in complying with TSCA requirements. Small businesses also pay a lower fee for SNUN submissions.

**5(d) Collection Schedule**

Whenever any person intends to engage in a significant new use of an existing chemical substance, they are required to submit a notice of their intentions to EPA not less than 90 days before beginning to manufacture (including import) or process the substance for the intended use.

**6**. **ESTIMATING THE BURDEN AND COST OF THE COLLECTION**

This section presents estimates of the cost and burden associated with the recordkeeping and reporting requirements for significant new use rules for existing chemicals under TSCA section 5(a)(2). The methodology used to estimate the recordkeeping costs, reporting costs, and burden for this ICR renewal is largely based on previous experience with SNURs, and is consistent with the analysis presented in the supporting statement prepared for the previous ICR. This ICR is updated from the previous ICR to account for the changes in burden resulting from updated assumptions and corrections to prior analyses.

To comply with the regulation, manufacturers (including importers) must complete the activities listed in Table 1. Table 1 also provides a cross-walk of the related Information Collection that corresponds to each activity.

**Table 1: Cross-walk between Industry Activities and Related Information Collections (ICs)**

| **Activity** | **Description** | **Related IC(s)** |
| --- | --- | --- |
| Chemical verification | When a SNUR is published, companies must review the rule to verify whether a chemical they manufacture (including import) is subject to the rule. | Chemical Verification |
| Rule familiarization | Site staff must familiarize themselves with the requirements of the rule. This entails reading the rule, understanding the various reporting and administrative requirements, and determining the manner in which the reporting requirements will be met. | Rule Familiarization |
| CDX registration, electronic signature agreement, and Pay.gov account set up | Before submitting a SNUN, all respondents must register with CDX. In addition, respondents must complete an Electronic Signature Agreement form, which is signed, dated, and either submitted electronically or mailed back to EPA, and register for a Pay.gov account. | CDX Registration Activities |
| Preparation of reports (form completion and form submission) | Site staff must collect all information required for a SNUN and submit an electronic SNUN form. Firms must also keep records supporting their submissions. | Prepare and Submit Report, and Maintain Records |

**6(a) Estimating Respondent Burden**

Number of Significant New Use Notices Projected

During the years 2012 through May 2015, EPA proposed five and finalized five existing chemical SNURs under TSCA section 5(a)(2). EPA expects to promulgate six existing chemical SNURs between 2018 and 2020, for an average of two existing chemical SNURs per year. Therefore, EPA is estimating an average of two existing chemical SNURs per year under TSCA section 5(a)(2) during the period covered by this ICR[[1]](#footnote-1).

EPA may receive SNUNs as a result of SNURs. SNUNs cover SNURs that are issued for both the new chemical and existing chemical programs. EPA reviewed the number of SNUNs received between 2012 and 2015 and determined that only one of the 35 SNUNs received resulted from promulgation of an existing chemical SNUR. Therefore, this ICR conservatively estimates an average of one SNUN received per year as a result of existing chemical SNURs, with a single firm impacted per SNUN submitted.

**Table 2: Anticipated Number of SNURs and SNUNs**

|  |  |  |
| --- | --- | --- |
| **Year** | **Anticipated Number of SNURs** | **Anticipated Number of SNUNS** |
| First Year | 2 | 1 |
| Second Year | 2 | 1 |
| Third Year | 2 | 1 |
| **Three Year Totals** | **6** | **3** |

1. Alternative Responses

The burden associated with a SNUR could involve a number of possible industry responses. That is, when a SNUR is promulgated, a firm seeking to engage in a new use for a subject chemical has five options regarding possible courses of action that may generate burden:

1) The company could submit a SNUN. This option would be chosen by any company not intending to abide by the provisions of the SNUR.

2) In the event that a significant new use is described as the failure to establish and implement programs for providing for the use of specific measures to control worker exposure to or release of substances, a company can request an equivalency determination. This option would be chosen if a manufacturer (including importer) had reason to believe that there may be alternative methods not considered by EPA that provide equivalent or superior protection from worker exposure or environmental release of the subject chemical.

3) The company can comply with the SNUR, ensuring that all provisions of the SNUR are implemented regarding the planned use of the subject chemical.

4) The company can request review of the SNUR for possible modification or revocation.

5) The company may simply decide to forgo the new use, avoiding regulatory compliance activities altogether.

Additionally, under current regulations at 40 CFR 721.5(a)(2), all manufacturers (including importers) and processors of chemicals subject to SNURs are subject to certain requirements regardless of whether they engage in a significant new use unless certain information can be demonstrated[[2]](#footnote-2). However, without prior knowledge of chemicals which would be the subject of future SNURs, estimating the number of potentially affected entities subject to 40 CFR 721.5(a)(2) is not possible.

The following section estimates the cost and burden of submitting a SNUN (option 1) and then discusses the other options qualitatively.

1. Burden Estimates

TSCA section 5(a)(2) imposes two requirements on industry. First, manufacturers (including importers) and processors of chemicals must choose among the options mentioned above. This section presents estimates of submitting SNUNs (i.e., the first option) and then briefly discusses the other four options. Second, manufacturers (including importers) and processors of chemicals covered by SNURs will incur burden and costs associated with notifying customers of the hazards posed by the covered chemical. Therefore, they must first determine if their chemical is subject to the SNUR and then must determine how to notify their customers.

Chemical Verification

When a SNUR is published, companies must review the rule to verify whether their chemical substance is subject to the rule. EPA distinguishes between SNURs that regulate a specific chemical and SNURs that regulate a chemical formula, understood as a set of distinct chemicals that share a common chemical structure. EPA expects to promulgate six existing chemical SNURs during the three-year period covered by this ICR, covering an average of 4.33 chemicals and 0.83 chemical formulas per SNUR. The Agency typically notifies the manufacturer(s) of a chemical or a chemical formula subject to a SNUR prior to its issuance, reducing the time required for manufacturers to review the rule and verify that their chemical is subject to the SNUR. EPA estimates that an average of 0.17 hours (10 minutes) of technical labor time per chemical is used to verify that a chemical is subject to a SNUR and 0.50 hours (30 minutes) to verify that a chemical formula is subject to a SNUR. This is equivalent to 1.14 hours ([0.17 hours/chemical x 4.33 chemicals/SNUR] + [0.50 hours/chemical x 0.83 chemical formulas/SNUR] = 1.14 hours).

### Rule Familiarization

Staff at firms who are subject to the SNUR must become familiar with the SNUR and its various requirements. In EPA’s best professional judgment, rule familiarization is estimated to be equivalent to the burden for companies to become familiar with the Premanufacture Notification Electronic Reporting Rule, which requires the mandatory electronic reporting of SNUNs and other TSCA section 5 notices: 0.55 hours of technical labor and 0.27 hours of managerial labor, as described in the *Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule* (EPA, 2009a).

Table 3: Rule Familiarization Burden for SNUR Submitters

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Activity** | **Clerical Hours** | **Technical Hours** | **Managerial Hours** | **Total Hours** |
|
| Rule familiarization | 0.00 | 0.55 | 0.27 | **0.82** |
| **Note:** Some burden estimate totals may not calculate due to rounding of unit burden estimates | | | | |

### CDX Registration, CDX Electronic Signature, and Pay.gov Account Setup

First-time submitters of any section 5 notice (including Premanufacture Notices (PMNs), Significant New Use Notices (SNUNs), Test Market Exemption (TME) applications, Low Volume Exemption (LVE) notices, Low Exposure/Low Release (LoREX) exemption notices, Biotechnology Notices for genetically modified microorganisms, Notices of Commencement of Manufacture or Import (NOCs), and support documents to section 5 notices) are required to register their company and key users with the CDX reporting tool, deliver a CDX electronic signature to EPA, and establish and use a Pay.gov E-payment account. These activities are only required of first-time submitters of any section 5 notice. It is not known how many submitters of SNUNs from existing chemical SNURs will be first-time submitters of any section 5 notices; therefore, EPA conservatively assumes that all submitters will incur these costs. These activities are estimated to require the following burden, based on the estimates presented in the *Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule* (EPA, 2009a):

* + *CDX registration:* EPA estimates that companies will spend approximately 0.18 hours per employee to register with CDX, and that an average of four technical staff members and one manager will need to register for each company, totaling approximately 0.92 hours of burden per company.
  + *CDX electronic signature:* EPA estimates that companies will spend 0.25 hours preparing, submitting, and filing an electronic signature agreement (Authentication of Identity) form to EPA per employee. This burden will apply to four technical staff members and one manager per company, totaling 1.25 hours of burden per company. In addition, EPA estimates that a manager will spend an additional 0.50 hours accessing, preparing, and submitting verification forms (Verification of Authorization) for all authorized submitters to EPA. The total burden incurred by companies submitting and then verifying electronic signature agreements is 1.75 hours. Note that this burden does not include any additional time required to contact EPA’s CDX help desk to notify a change of submitter status, should one occur.
  + *Payment via Pay.gov account:* EPA estimates that one manager per company will spend approximately 0.13 hours setting up a Pay.gov ID account, logging into the system, finding the appropriate form, and filling it out. This burden does not include the time required to click ‘submit’ on the form and wait for payment processing.

Table 4: CDX Registration, CDX Electronic Signature, and Pay.gov Account Setup Burden for First-Time Submitters

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Activity** | **Clerical Hours** | **Technical Hours** | **Managerial Hours** | **Total Hours** |
|
| CDX registration | 0.00 | 0.73 | 0.18 | **0.92** |
| CDX electronic signature | 0.00 | 1.00 | 0.75 | **1.75** |
| E-payment (Pay.gov ID) | 0.00 | 0.00 | 0.13 | **0.13** |
| **Total** | 0.00 | **1.73** | **1.07** | **2.80** |
| **Note:** Some burden estimate totals may not calculate due to rounding of unit burden estimates | | | | |

Submitting a SNUN

When submitting a SNUN, individuals at different occupational levels must spend time on the required recordkeeping and reporting activities. SNUN submitters are required to gather and submit information regarding the data elements identified in the applicable SNUN reporting form. The methodology and calculations assume that the employee responsible for collecting, filling out, and submitting the requested information has a reasonable level of familiarity with the company and knowledge of operations at the site. It is assumed that, for most entities, these tasks are similar to other employee duties that require familiarity with EPA, state, and other federal agency requests for chemical information and do not require additional familiarization or training beyond the basic rule familiarization described above.

Estimates of the burden of completing a SNUN form are based on the burden of completing a PMN submission, since the data requirements are the same and the same form is used for both. EPA has harmonized estimates of the reporting and recordkeeping burden related to the submission of both new and existing chemical SNUNs. The reporting and recordkeeping burden for Existing Chemical SNUNs is estimated to be 91.68 hours and is based on the 1994 *Regulatory Impact Analysis of Amendments (RIA) to Regulations for TSCA Section 5 Premanufacture Notifications* (EPA, 1994) and has been adjusted to reflect burden reductions resulting from the 2009 final PMN Electronic Reporting (ePMN) Rule that requires the electronic submission of all TSCA section 5 notices. Electronic submission of SNUN forms is expected to remove all clerical burden and reduce the recordkeeping burden associated with preparing and submitting a SNUN (EPA, 2009a). In addition, electronic submission is expected to generate an additional 0.18 hours of technical burden associated with the completion of the User Fee Payment Identification Number and email address data elements on the electronic SNUN form**.**

Alternative Options

Should a company choose to request an equivalency determination (i.e., the second option), or review for modification/revocation (i.e., the fourth option), EPA estimates that a data collection and preparation effort similar to that of a SNUN would be required, and thus the burden is estimated to range up to 91.68 hours for these alternatives, the same as for submitting a SNUN.

In complying with a SNUR, a company would incur costs to ensure all provisions of the SNUR were implemented at the subject facility (i.e., the third option). Since the nature of such provisions will vary depending on the significant new uses identified in each respective SNUR, estimating burden at this time is not possible. In addition to costs of implementation, firms choosing this option will have minor costs associated with keeping records that document compliance with SNUR conditions for avoiding a Significant New Use. Such recordkeeping requirements may involve copying and filing relevant records, including those related to: category of use and marketing, and production volume. Records would typically be required to be maintained for five years from the date of their creation. Previous existing chemical SNUR ICRs have estimated recordkeeping requirements to be five percent of the reporting burden for a certain activity (EPA, 2009b). Per-activity burden is taken from the midpoint estimated burden of each section of the SNUN form (EPA, 1994). The recordkeeping burden per significant new use is estimated to range from 0.01 hours (0.25 \* 0.05) for keeping records of trade names and chemical synonyms to 0.76 hours (15.25 \* 0.05) for keeping records of sites controlled by others. The total recordkeeping burden per firm will depend on the significant new use(s) identified.

The final alternative for a company considering a significant new use of a chemical that is subject to a SNUR is to forgo the new use (i.e., the fifth option). In carrying out such a response, the company would incur no direct regulatory burden or costs.

Customer Notification

Manufacturers (including importers) and processors of chemical substances subject to SNURs must notify recipients of such chemicals of the SNUR or verify that knowledge of the SNUR has been otherwise acquired by recipients, or that the recipients are unable to engage in significant new uses. Since it is not expected that all such entities will have complete knowledge of all uses of any products subject to a SNUR, and because filing a SNUN could require significantly more burden, it is assumed that manufacturers (including importers) and processors will most often choose to notify their customers of SNUR regulatory activities. As this notification may be accomplished by simply annotating an MSDS, EPA estimates the associated burden to be about one hour of a technical employee's time per manufacturer or processor per chemical and three hours per manufacturer or processor per chemical formula. EPA estimates that each SNUR will cover approximately 4.33 chemicals and 0.83 chemical formulas. Furthermore, EPA assumes that there are two manufacturers (including importers) or processors per chemical.[[3]](#footnote-3) Therefore, the burden per SNUR is estimated to be 13.67 hours per SNUR ([1.00 hours/chemical x 4.33 chemicals/SNUR x 2.00 manufacturers] + [3.00 hours/chemical x 0.83 chemical formulas/SNUR x 2.00 manufacturers] = 13.67 hours).

Summary of Unit Burdens

The following table summarizes the burden associated with the activities required under a SNUR, under compliance option 1.

**Table 5: Summary of Unit Burdens**

|  |  |
| --- | --- |
| **Collection Activity** | **Estimated Burden Hours** |
| Chemical verification (per SNUR) | 1.14 |
| Rule Familiarization (per company) | 0.82 |
| CDX registration, electronic signature, and Pay.gov account set-up (per company) | 2.80 |
| SNUN preparation (per report) | 91.68 |
| Notifying customers (per SNUR) | 13.67 |

**6(b) Estimating Respondent Costs**

The unit costs of filing a SNUN are estimated by monetizing the labor time spent preparing the SNUN and then adding any fixed costs associated with filing a SNUN. This section derives these unit costs.

(i) Wages

EPA multiplied burden estimates by standard wage rates for managerial, technical, and clerical levels developed from information published by the Bureau of Labor Statistics (BLS) and a method outlined in the document *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* (EPA, 2002b). Wage data for the three occupational categories were gathered for manufacturing industries from *Employer Costs for Employee Compensation Supplementary Tables: December 2006 – December 2017 (U.S. Bureau of Labor Statistics, 2018).*

The cost of fringe benefits, such as health insurance and vacation, is taken for each labor category from the same ECEC series. Following the methodology outlined in EPA 2002b, fringe benefits are calculated as a percentage of total wages for each category. EPA added 17 percent to the wages in each category to account for overhead, based on information provided by the chemical industry and chemical industry trade associations in the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002a). The wages for each of the three categories were then multiplied by benefits and overhead factors to estimate loaded, annual salaries in year 2017 dollars. Table 6 contains the loaded wage rates for the managerial, technical and clerical occupational categories.

Table 6: Derivation of Loaded Wage Rates for the Private Manufacturing Sector in 2017$

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Wage1** | **Fringe Benefits1** | **Fringes as % of Wage** | **Overhead % of Wage2** | **Fringe + Overhead Factor** | **Loaded Wages** |
| **(a)** | **(b)** | **(c) = (b)/(a)** | **(d)** | **(e)=(1)+(c)+(d)** | **(f) = (a) x (e)** |
| **Clerical** | $20.49 | $11.02 | 54% | 17% | 1.71 | **$34.99** |
| **Technical** | $45.82 | $24.33 | 53% | 17% | 1.70 | **$77.94** |
| **Managerial** | $46.59 | $22.16 | 48% | 17% | 1.65 | **$76.67** |
| 1 *Employer Costs for Employee Compensation Supplementary Tables: December 2006 – December 2017 (U.S. Bureau of Labor Statistics, 2018).*  2 An overhead rate of 17 percent was estimated based on industry data gathered for the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002a). | | | | | | |

(ii) Summary of Unit Costs

Costs for Chemical Verification

The Agency estimates that chemical verification will require 0.19 technical hours per SNUR. The total estimated cost per SNUR is estimated to be $88.77 (1.14 hours per SNUR x $77.94).

### Costs for Rule Familiarization

EPA estimates rule familiarization costs will require 0.82 hours per firm and total cost per firm is expected to be $63.31.

Costs for CDX Registration, CDX Electronic Signature, and Pay.gov Account Setup

First-time submitters of any TSCA section 5 notice are required to register their company and key users with the CDX reporting tool, deliver a CDX electronic signature to EPA, and establish and use a Pay.gov E-payment account. EPA estimates that companies will spend approximately $71.21 on CDX registration, $135 on completing the Electronic Signature Agreements, $2.79 mailing electronic signature agreements, and $10.22 setting up a Pay.gov account. Therefore, the total expected costs associated with CDX registration, completing and mailing an electronic signature agreement and setting up a Pay.gov account is approximately $220.

Table 7: CDX Registration, CDX Electronic Signature, and Pay.gov Account Setup Cost for First-Time Submitters

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Activity** | **Clerical Labor ($34.99/hour)** | **Technical Labor ($77.94/hour)** | **Managerial Labor ($76.67/hour)** | **Total Labor Cost**  **(2017$)** |
|
| CDX registration | $0.00 | $57.16 | $14.06 | **$71.21** |
| CDX electronic signature | $0.00 | $77.94 | $57.50 | **$135** |
| Mailing cost |  | | | **$2.79** |
| E-payment (Pay.gov ID) | $0.00 | $0.00 | $10.22 | **$10.22** |
| **Total** | **$0.00** | **$135.10** | **$81.78** | **$220** |

Costs for Submitting a SNUN

Using these labor wage rates and midpoint burden estimates presented above, EPA estimates that the labor cost associated with filing a SNUN is $7,123. In addition, SNUN filers must pay a $16,000 user fee to EPA. Thus, the total cost of filing a SNUN is approximately $23,123.

**Table 8: Unit Reporting Cost Estimates, Associated with Filing a SNUN by Labor Category**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Activity** | **Clerical Labor ($34.99/hour)** | **Technical Labor ($77.94/hour)** | **Managerial Labor ($76.67/hour)** | **Total Labor Cost**  **(2017$)** |
|
| SNUN preparation | $0.00 | $5,743 | $1,380 | **$7,123** |
| User fee |  | | | **$16,000** |
| **Total** | **$0.00** | **$5,743** | **$1,380** | **$23,123** |

Alternative Responses

As noted in section 4, five alternative responses to any particular SNUR could be chosen by firms planning to engage in significant new uses of subject chemicals. Although EPA has not projected or quantified how frequently these alternatives might be selected, the unit costs associated with each option are discussed briefly below.

The estimated burden of requesting an equivalency determination (the second option) or review for modification/revocation (the fourth option) was judged to be similar to filing the SNUN; thus, total costs including the EPA user fee were estimated to be $23,123. However, the firm may incur additional costs in developing the data necessary to justify the alternative. This option will be preferable to compliance with the SNUR if the total cost of obtaining EPA approval of a request is less than the costs of SNUR compliance.

Firms choosing to comply with a SNUR (the third option), will incur costs to ensure all provisions of the SNUR were implemented at the subject facility and to implement recordkeeping. The costs of implementing provisions at a facility were not quantified for this ICR. Recordkeeping is expected to range from 0.01 hours to 0.76 hours for each significant new use. All recordkeeping activities are expected to be conducted by clerical staff; therefore, recordkeeping costs range from $0.35 to $26.59 per significant new use. The total recordkeeping burden per firm will depend on the significant new use(s) identified.

Customer Notification

EPA assumes that the customer notification requirement will be handled by technical labor. Section 5 of this analysis assumes a total burden of 13.67 hours of technical labor, supposing that there are two manufacturers (including importers) or processors per chemical[[4]](#footnote-4). Given the loaded wage of technical laborers is $77.94, the cost per SNUR is $1,065 [($77.94 per hour)\*(13.67 hours per SNUR)].

Summary

Table 9 summarizes the unit costs estimated in this section. Reviewing a SNUR to verify that a chemical is included is estimated to cost $88.77 per SNUR and notifying customers is $1,065 per SNUR. The cost of completing and submitting a SNUN is approximately $23,123. EPA estimates the costs associated with rule familiarization to be $63.31 per company, and CDX registration activities to be $220 per company.

**Table 9: Summary of Unit Costs**

|  |  |
| --- | --- |
| **Collection Activity** | **Estimated Cost** |
| Chemical verification (per SNUR) | $88.77 |
|
| Rule familiarization (per company) | $63.31 |
| CDX registration, electronic signature, and Pay.gov account set-up (per company) | $220 |
| SNUN preparation\* | $23,123 |
| Notifying customers (per SNUR) | $1,065 |
|

\* Includes $16,000 user fee per SNUN.

1. Total Burden and Costs to Industry

This section provides estimates of the total burden and costs imposed by the TSCA section 5(a) requirements. These estimates can be divided into five categories: chemical verification, rule familiarization, completing and submitting SNUNs, CDX registration activities, and notifying customers.

The total cost and burden imposed on industry by TSCA section 5(a)(2) requirements can be calculated by multiplying the unit burden and cost estimates by the expected number of SNURs, SNUNs, and firms. As noted above, this analysis assumes that EPA will promulgate 2 SNURs and receive 1 SNUN per year. Table 10 presents the annual burden and cost to industry. EPA estimates the total annual industry burden of existing chemical SNUR action is 138 hours and $26,752.

**Table 10: Estimated Annual Respondent Burden and Cost**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Information Collection Activity** | **Total Burden per Activity (hours)** | **Total Cost per Activity**  **(2017$)** | **Total Number of Units Annually** | **Total Annual Burden (hours)** | **Total Annual Cost (2017$)** |
| Rule familiarization (per firm) | 0.82 | $63.31 | 4.67 Firms | 3.81 | $296 |
| Preparation, submission, and recordkeeping for SNUN (per report) | 91.68 | $23,123 | 1 SNUN | 91.68 | $23,123 |
| CDX registration, electronic signature, Pay.gov set-up (per firm) | 2.80 | $220 | 4.67 Firms | 13.08 | $1,026 |
| Chemical verification (per SNUR) | 1.14 | $88.77 | 2 SNURs | 2.28 | $178 |
| Notifying customers (per SNUR) | 13.67 | $1,065 | 2 SNURs | 27.33 | $2,130 |
| **Total Industry Burden and Cost** | | | | **138** | **$26,752** |

Some burden estimate totals may not calculate due to rounding of unit burden estimates

Table 11 presents the total burden and cost to industry over the three-year ICR period. EPA estimates the total annual industry burden of existing chemical SNUR action to be 415 hours and $80,257.

**Table 11: Estimated Total Respondent Burden and Cost, Three Year Totals**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Information Collection Activity** | **Total Burden per Activity (hours)** | **Total Cost per Activity**  **(2017$)** | **Total Number of Units** | **Total Burden (hours)** | **Total Cost (2017$)** |
| Rule familiarization (per firm) | 0.82 | $63 | 14.01 Firms | 11.44 | $887 |
| Preparation, submission, and recordkeeping for SNUN (per report) | 91.68 | $23,123 | 3 SNUNs | 275.05 | $69,369 |
| CDX registration, electronic signature, Pay.gov set-up (per firm) | 2.80 | $220 | 14.01 Firms | 39.23 | $3,078 |
| Chemical verification (per SNUR) | 1.14 | $89 | 6 SNURs | 6.83 | $533 |
| Notifying customers (per SNUR) | 13.67 | $1,065 | 6 SNURs | 82.00 | $6,391 |
| **Total Industry Burden and Cost** | | | | **415** | **$80,257** |

Some burden estimate totals may not calculate due to rounding of unit burden estimates

Table 12 presents the annual burden by collection activity. Chemical verification is expected to have a total burden of 2.28 hours annually. Notifying consumers is expected to have a total burden of 127.65 hours annually. Companies are expected to incur a total burden of 3.81 hours for rule familiarization, 13.08 hours for CDX registration activities and a total of 89.91 hours for SNUN completion, each year.

**Table 12: Annual Information Collection Tally for ICR Reporting Period**

| **Information Collection** | **No. of**  **Respondents** | **No. of Responses / Respondent** | **Responses Subtotal** | **Annual Burden Hours per Response** | **Annual Burden Hours per Activity** |
| --- | --- | --- | --- | --- | --- |
| ***Per Firm Activities*** | | | | | |
| Rule familiarization | 4.67 | 1 | 4.67 | 0.82 | **3.81** |
| CDX registration activities | 4.67 | 1 | 4.67 | 2.80 | **13.08** |
| * *CDX registration* | 4.67 | *1* | 4.67 | *0.92* | **4.28** |
| * *ESA* | 4.67 | *1* | 4.67 | *1.75* | **8.17** |
| * *Pay.gov account* | 4.67 | *1* | 4.67 | *0.13* | **0.62** |
| Preparation, submission, and recordkeeping for SNUN | 4.67 | 0.21 | 0.98 | 91.68 | **89.91** |
| ***Per SNUR Activities*** | | | | | |
| Chemical verification | 2 | 1 | 2 | 1.14 | **2.28** |
| Notifying customers (per SNUR) | 4.67 | 2 | 9.34 | 13.67 | **127.65** |
| ***Total*** | | | | | **249.80** |

Some burden estimate subtotals may not calculate due to rounding of unit burden estimates

Table 13 presents the total burden hours for the ICR period, organized by information collection. Chemical verification is expected to result in a total burden of 6.83 hours over the three-year ICR period. Notifying consumers is expected to result in a total burden of 382.94 hours over the three-year ICR period. Companies are expected to incur at total of 11.44 hours in burden for rule familiarization, 39.23 hours for CDX registration activities and a total of 269.74 hours for SNUN completion, submission and recordkeeping over the three-year ICR period.

**Table 13: Total Information Collection Tally for ICR Reporting Period**

| **Information Collection** | **No. of**  **Respondents** | **No. of Responses / Respondent** | **Responses Subtotal** | | **Total Burden Hours per Response** | | **Total Burden Hours Subtotal** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Per Firm Activities*** | | | | | | | | |
| Rule familiarization | 14.01 | 1 | | 14.01 | | 0.82 | | **11.44** |
| CDX registration activities | 14.01 | 1 | | 14.01 | | 2.80 | | **39.23** |
| * *CDX registration* | 14.01 | *1* | | 14.01 | | 0.92 | | **12.84** |
| * *ESA* | 14.01 | *1* | | 14.01 | | 1.75 | | **24.52** |
| * *Pay.gov account* | 14.01 | *1* | | 14.01 | | 0.13 | | **1.87** |
| Preparation, submission, and recordkeeping for SNUN | 14.01 | 0.21 | | 2.94 | | 91.68 | | **269.74** |
| ***Per SNUR Activities*** | | | | | | | | |
| Chemical verification | 6 | 1 | | 6 | | 1.14 | | **6.83** |
| Notifying customers (per SNUR) | 14.01 | 2 | | 28.02 | | 13.67 | | **382.94** |
| ***Total*** | | | | | | | | **749.41** |

Some burden estimate subtotals may not calculate due to rounding of unit burden estimates

**6(c) Estimating Agency Burden and Cost**

1. SNUN Processing

EPA’s cost to review and process SNUN submissions is assumed to be represented by its costs for a larger category of similar TSCA section 5 notices that includes SNUNs. On September 27, 2018, EPA finalized a fees rule under the Toxic Substances Control Act (TSCA), as amended in 2016 by the Frank R. Lautenberg Act Chemical Safety for the 21st Century Act. The final rule establishes new fees for actions under TSCA sections 4, 5, and 6 (83 FR 8212) to defray a portion of TSCA implementation costs. In developing the fees, EPA estimated its total annual costs for processing, reviewing, and making determinations under TSCA section 5 between fiscal years 2019 and 2021. EPA estimated its direct and indirect costs for reviewing PMNs, SNUNs, and Microbial Commercial Activity Notices (MCANs) to be $18,934,659 per year during this period, and assumed that an average of 462 PMNs, SNUNs, and MCANs will be submitted per year.[[5]](#footnote-5) This yields an average Agency cost of approximately $41,000 apiece for reviewing and processing PMNs, SNUNs, and MCANs.[[6]](#footnote-6) Thus, processing and reviewing any SNUNs submitted due to this SNUR is also expected to cost EPA approximately $41,000.

**6(d) Reasons for Change in Burden**

There is a decrease of approximately 598 hours (from 736 hours to approximately 138 hours) in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB (Request for a Non-Substantive Change to an Existing Approved Information Collection submitted September 2012). This change results from adjustment changes that updated the estimated average number of SNURs promulgated annually, the estimated average number of SNUNs submitted annually (from 7 SNUNs to 1 SNUN per year), the estimated number of affected sites (from 4.24 to 4.67 per year), from recalculating the average number of chemicals per SNUR to account for SNURs based on distinct chemicals and those based on chemical formulas (7 chemicals to 4.33 chemicals and 0.83 chemical formulas, respectively), and correcting rounding errors in the burden estimate for completing a SNUN (92.2 hours to 91.68 hours) and for rule familiarization (0.83 hours to 0.82 hours).

**Table 14: Estimate of Changes in Annual Burden Hours from Previous ICR by Activity**

|  |  |
| --- | --- |
|  | **Annual Burden Hours** |
| Current OMB Inventory | 736 |
| Change in Burden due to Adjustments | -598 |
| *Updated estimated average number of SNURs promulgated annually* | *-72* |
| *Updated estimated average number of SNUNs submitted annually* | *-553* |
| *Updated estimated number of affected sites* | *2* |
| *Updated estimated average number of chemicals and chemical formulas* | *25* |
| *Updated estimated burden estimate for completing a SNUN* | *-0.5* |
| *Updated estimated burden estimate for rule familiarization* | *-0.1* |
| Change in Burden due to Program Changes | 0.0 |
| ***Total Change in Burden*** | ***-598*** |
| **Total Burden** | **138** |

**6(e) Burden Statement**

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0038, is estimated to average approximately 30 hours per 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 current and valid OMB control number. 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-2015-0273, which is available for online viewing at www.regulations.gov, or in person viewing at the Pollution Prevention and Toxics Docket in the EPA Docket Center (EPA/DC). The EPA/DC Public Reading Room is located in the EPA West Building, Room 3334, 1301 Constitution Ave., NW., 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 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-2015-0273 and OMB Control No. 2070-0038, 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, and
* To OMB via email to oira\_submission@omb.eop.gov. Address comments to *OMB Desk Officer for EPA*.

**REFERENCES**

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EPA, 2009b. U.S. EPA, Office of Pollution Prevention and Toxics *ICR No. 118.09.* *[Information Collection Request for] TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals (Renewal). Supporting Statement for a Request for OMB Review under the Paperwork Reduction Act*, February 6, 2009.

**ATTACHMENTS TO THE SUPPORTING STATEMENT**

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number **EPA-HQ-OPPT-2015-0273**. These attachments are available for online viewing at [www.regulations.gov](http://www.regulations.gov_) or otherwise accessed as described in section 6(f) of the supporting statement.

Attachment 1: Toxic Substances Control Act Section 5 - 15 U.S.C. 2604

Attachment 2: 40 CFR Part 721 (Subpart A through Subpart D) *-* Significant New Uses of Chemical Substances

Attachment 3: Selection Criteria -- TSCA section 8(a) Rule vs. SNUR

Attachment 4: Public Comments Received

Attachment 5: EPA’s Response to Public Comments

Attachment 6: Consultations Message Sent by EPA to Potential Respondents

Attachment 7: Consultations Responses from ACC and SOCMA

1. EPA develops SNURs for a number of reasons, some based on findings from its *new* chemicals program in order to bind manufacturers and processors of chemicals reviewed under its Premanufacture Notice (PMN) review process to certain requirements (OMB Control No. 2070-0012). However, this ICR covers only SNURs that are developed by EPA’s *existing* chemical program under TSCA section 5(a)(2) and, therefore, only the SNUNs received based on those SNURs are estimated here. [↑](#footnote-ref-1)
2. Unless manufacturers (including importers) and processors of chemicals subject to SNURs have either notified recipients of such chemicals and all significant new uses, verified that knowledge of the SNUR has been otherwise acquired by recipients, or verified that recipients are unable to engage in significant new uses, manufacturers (including importers) and processors must file a SNUN. [↑](#footnote-ref-2)
3. The assumption that there are two manufacturers (including importers) or processors per chemical follows from previous ICRs for these requirements. [↑](#footnote-ref-3)
4. The assumption that there are two manufacturers (including importers) or processors per chemical follows from previous ICRs for these requirements. [↑](#footnote-ref-4)
5. Table 9 - Annual Section 5 PMN/SNUN/MCAN Cost Estimates. *EO 12866 Documentation; Draft Submitted to OMB – Technical Background Document (RIN 2070-AK27; Final Rule*. EPA-HQ-OPPT-2016-0401-0020. <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0401-0020>. [↑](#footnote-ref-5)
6. This $41,000 review cost is lower than the overall average cost of $55,200 for TSCA section 5 activities that EPA calculated for the 2018 TSCA Fees rule because the $55,200 value includes costs for activities (such as issuing SNURs following a PMN review, and reviewing Notices of Commencement) that are not relevant to SNUNs. [↑](#footnote-ref-6)