

**Supporting Statement for a Request for OMB Review under
the Paperwork Reduction Act**

3 IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title and Number of the Information Collection

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

EPA ICR No.: 1188.09 OMB Control No.: 2070-0038

1(b) Short Characterization

Section 5 of the Toxic Substances Control Act (TSCA), 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, TSCA section 5(a)(1)(B) requires persons to submit a notice to EPA at least 90 days before they manufacture, import or process the substance for that use. Regulations implementing significant new uses appear at 40 CFR part 721 (see Attachment 2).

Once EPA receives a significant new use rule (SNUR) notice, EPA may take regulatory action under TSCA sections 5(e), 5(f), 6 or 7 to control the activities for which it has received a SNUR notice. If EPA does not take action, TSCA section 5(g) requires EPA to explain in the Federal Register its reasons for not taking action.

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). The 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 the Office of Pollution Prevention and Toxics (OPPT) with the authority to monitor and control significant new uses of existing chemical substances. The factors considered by the Administrator in determining a significant new use are:

- 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.

Once the Administrator makes such a designation, the Agency proposes a Significant New Use Rule (SNUR). If a final rule is promulgated, a person who intends to engage in a significant new use of a chemical covered by a SNUR must notify EPA of his/her intentions. This notification, made via the Significant New Use Notice (SNUN), must occur at least 90 days prior to commencing the new use of the identified substance. The required notice must be submitted on EPA's Premanufacture Notice (PMN) form (EPA Form 7710-25). The PMN form provides data on the identity and use of, and possible exposures to, the chemical substance. In addition, the PMN form provides test data plus descriptions of health and environmental effects data based on the manufacture, processing, use, distribution in commerce, and disposal of the chemical.

The Agency has 90 days to evaluate a SNUN once it has been received. This evaluation focuses on the health and environmental effects of the substance's significant new use. Should EPA find cause for concern, the Agency can take regulatory action as per TSCA sections 5(e) and 5(f).¹ Likewise, the Agency may extend the evaluation period by up to 90 days with good cause. If EPA takes no action at the end of the review period, the submitter can engage in the intended new use without any restrictions.

2(b) Practical Utility/Users of the Data

EPA uses this information to evaluate the health and environmental effects of the significant new use. During the evaluation period EPA can take further regulatory action pursuant to TSCA sections 5(e) and 5(f). Under TSCA section 5(e), the Administrator may issue an order to prohibit or limit the manufacture, import, processing, distribution in commerce, use, or disposal of such substance. TSCA section 5(f) allows the Administrator to, among other things, prohibit or limit the manufacture of the chemical substance, if the substance presents or will present an unreasonable risk of injury to health or the environment.

To date EPA has promulgated SNURs on 352 existing chemicals. Presented in Attachment 6 are selected case history abstracts for some of these substances. These abstracts highlight the needs of a particular office and the facts surrounding a substance. This information when applied to the Regulatory Selection Criteria has resulted in final SNURs.

4 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

¹ TSCA section 5(e) allows the Administrator to prohibit or limit the manufacture, import, processing, distribution in commerce, use, or disposal of the substance when the substance may present an unreasonable risk. TSCA section 5(f) allows the Administrator to use a TSCA section 6 regulation to prohibit or limit the manufacture of the substance when the substance will present an unreasonable risk.

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 produced, 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 August 18, 2008 (73 FR 34725, June 18, 2008). EPA received no comments during the comment period.

3(c) Consultations

In addition to the public notice and comment period required by the OMB regulations that implement the Paperwork Reduction Act (see section 3(b) of this Supporting Statement), the OMB regulations, 5 CFR 1320.8(d)(1), also require agencies to consult with potential ICR respondents and data users about specific aspects of an ICR before the agency submits the ICR to OMB for review and approval. EPA solicited comments from the following potential respondents and data users with respect to the renewal of this ICR:

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EPA received no responses to its solicitation for consultations. A copy of EPA's consultation e-mail to the above potential respondents is included below as Attachment 7 to this Supporting Statement.

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, 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.

3(f) Confidentiality

Information provided in a significant new use notice may receive confidential treatment. TSCA section 14 allows a manufacturer, 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.

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. A wrongful disclosure of CBI may result in either a fine or imprisonment.

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 a notice has been received, 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. Submitters are required to use the Premanufacture Notice (PMN) form (EPA Form 7710-25; see Attachment 3), which EPA developed to facilitate the information collection process for new chemical substances.

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 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).

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.

A SNUR is drafted only if it is an appropriate approach for a particular substance that has received approval prior to the development of the rule. The proposal then undergoes intra-agency review, OMB review and public comment. Once a decision has been made to promulgate an information collection rule, the next decision is to determine whether a TSCA section 8(a) rule or a TSCA section 5 SNUR is most appropriate. Attachment 5 identifies the selection criteria that are applied in determining whether a TSCA section 8(a) rule or SNUR is proposed.

5(b) Collection Methodology and Management

EPA has not been able to identify a more efficient, less expensive or more flexible means of obtaining the required data and remain within the constraints of TSCA. There is no new technology applicable to the collection of this information that would minimize the collection burden.

To aid persons subject to this information collection, 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 non-financial assistance to manufacturers, 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.

5(d) Collection Schedule

Whenever any person intends to engage in a significant new use of a chemical substance, they are required to submit a notice of their intentions to EPA not less than 90 days before beginning to manufacture, 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 largely consistent with the analysis presented in the supporting statement prepared for the previous ICR. A summary of the steps employed in this analysis is shown below:

- Step 1: The total number of SNURs promulgated and SNUNs to be submitted, on an annual basis and for the three year period during which this ICR will be in effect, was projected. The estimate is based on the Agency's experience with SNURs and submission of SNUNs from past experience as well as EPA's expectations for future actions. This step appears in section 4 of this analysis.
- Step 2: The average industry burden associated with recordkeeping, reporting, and customer notification was estimated. The reporting burden estimates used here are taken from an analysis performed in connection with OPPT's amendments to its PMN program. This step appears in section 5 of this analysis.
- Step 3: The unit costs for the different activities associated with section 5(a)(2) were estimated next (e.g., submitting a SNUN). The costs were derived by multiplying current estimates of unit labor costs by the burden estimates presented in Step 2. This step appears in section 6 of this analysis.

Step 4: Total industry costs and burden were computed by multiplying the average burden and cost per activity by the expected number of activities. This step appears in section 7 of this analysis.

Step 5: The final step estimates the cost to EPA and appears in section 8 of this analysis.

NUMBER OF SIGNIFICANT NEW USE NOTICES PROJECTED

During the years 2004-2007, EPA promulgated three existing chemical SNURs under TSCA section 5(a)(2). However, EPA expects this activity to increase over the next three-year period as EPA initiates work under its commitment under the Security and Prosperity Partnership (SPP) to complete risk characterizations and take necessary actions on over 6,750 chemicals by 2012. Therefore, EPA is estimating it will promulgate an average of five existing chemical SNURs per year under TSCA section 5(a)(2) during the time period covered by this ICR.

EPA may receive SNUNs as a result of SNURs 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. SNURs are also developed by EPA's existing chemical program under TSCA section 5(a)(2). It is the latter SNURs that are covered by this ICR, and therefore, only the SNUNs received based on those SNURs are estimated here.

EPA's experience is that in response to promulgation of well over 1,000 SNURs under both its new and existing chemicals programs, the Agency receives on average only 10 SNUNs per year. Of those SNUNs, only a fraction is the result of SNURs promulgated under section 5(a)(2). For this ICR, however, EPA is estimating 10 SNURs per year.

TABLE 1
ANTICIPATED NUMBER OF SNURs AND SNUNs

Year	Anticipated Number of SNURs	Anticipated Number of SNUNs
First Year	5	10
Second Year	5	10
Third Year	5	10
Three Year Totals	15	30

Given the uncertainty in projecting possible new uses for existing chemicals, it is not possible to determine if a large or small number of firms would be affected by any given SNUR, or whether any one firm might engage in more than one new use. Thus, this analysis makes the assumption that no firm submits more than one SNUN. The total number of firms engaging in new uses cannot be estimated.

6(a) Estimating Respondent Burden

A. 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 reporting 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) A company can request an equivalency determination. This option would be chosen if a manufacturer/importer had reason to believe that there may be alternative methods not considered by EPA that provide equivalent or superior protection from exposure or release of the subject chemical.
- 3) The company can comply with the SNUR, ensuring that all provisions of the SNUR are implemented in connection with 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, processors, and importers 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 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 of submitting a SNUN (option 1) and then discusses the other options.

B. Burden Estimates

TSCA section 5(a)(2) imposes two requirements on industry. First, manufacturers, processors, and importers 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, processors, and importers of chemicals covered

² Unless manufacturers, processors, and importers 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, processors, and importers must file a SNUN.

by SNURs will incur burden and costs to notify customers of the hazards posed by the covered chemical. Therefore, they must first determine if their chemical is on 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 if their chemical is subject to the rule. During the 2004-2007 timeframe, the majority of SNURs promulgated by the Agency under TSCA section 5(a) applied to new chemicals submitted to the Agency under the Premanufacture Notice Program. Only three SNURs applying to existing chemicals were promulgated during the same time period. The Agency typically notifies the manufacturer(s) of chemicals subject to a SNUR prior to its issuance. Therefore it is estimated that no more than 0.167 hours (10 minutes) of technical time per chemical is used to verify that a chemical is subject to the rule. This is equivalent to 6.8 hours (0.167 hours/chemical x 41 chemicals/SNUR) per SNUR.

Submitting a SNUN

In submitting a SNUN, individuals at different occupational levels must spend time on the required recordkeeping and reporting activities. In estimating the burden required to prepare a SNUN, the analysis uses the breakdown of activities and activity estimates as developed for the premanufacture notification (PMN) baseline model in the Agency's "Regulatory Impact Analysis of Amendments to Regulations for TSCA Section 5 Premanufacture Notifications" (OPPT, 1994). The PMN reporting cost estimates were used because SNUNs would be filed on the standard PMN form. Table 2 presents EPA's estimate of respondent reporting burden associated with the filing of a SNUN.³

When submitting an SNUN, manufacturers must maintain records associated with the SNUN for five years. In keeping with the conservative assumptions already employed, the high end of the range of reporting burden hours (i.e., 113.25 hours) will be used in subsequent cost calculations (see section 6 below). The recordkeeping associated with preparing and filing a SNUN is assumed to require five percent of the time spent on reporting. Thus, 5.67 record keeping hours ($[113.25 \text{ hours}] * [5 \text{ percent}]$) will be spent in preparation of a SNUN. The average industry burden per notice, then, is 118.92 hours (113.25 + 5.67).

The estimates shown in Table 2 are average burden levels. Thus, it is entirely possible that certain respondents may incur burden greater or lesser than the estimates noted above; nevertheless, EPA believes the upper bound of the range of average burden hours to be an appropriate estimate for the calculations performed in this analysis.

³ The burden estimates presented in Table 2 differ from the PMN Amendments analysis, which were based on a Chemical Manufacturers Association survey, only in that burden for researching synonyms and generic chemical names was not included in this analysis. This is because subject chemicals would be existing chemicals, and such information would already be known.

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 118.92 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.

The final alternative for a company considering a significant new use of a chemical which is the subject of 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

As noted above, unless manufacturers, processors, and importers 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, processors, and importers must file a SNUN. 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, processors, and importers 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 1 hour of a technical employee's time per manufacturer, processor, or importer per chemical.

**TABLE 2
UNIT REPORTING BURDEN ESTIMATES ASSOCIATED WITH FILING A SNUN,
BY LABOR CATEGORY**

Activity	Clerical Hours	Technical Hours	Managerial Hours	Total Hours
General information/ instructions	2 - 2.5	1.5 - 2	3 - 4	6.5 - 8.5
Chemical identity	1.5 - 2	3 - 6	1	5.5 - 9
Trade name ID		.25		.25
Byproducts/impurities identification		1		1
Production and marketing data	1.5		2 - 3	3.5 - 4.5
Production volume		1		1
Category of use		3		3
Hazard information		3 - 4		3 - 4
Human exposure and environmental release	2.5 - 3.5		6 - 7	8.5-10.5
Site information		14 - 16		14 - 16
Occupational exposure		13 - 14		13 - 14
Environmental release/ disposal		9 - 10		9 - 10
Sites controlled by others	2	10 - 12	2 - 2.5	14 - 16.5
List of attachments	2	6 - 8	1 - 1.5	9 - 11.5
Certification			.5	.5
Data submissions	.5	1.5 - 2	.5	2.5 - 3
Totals	12 - 14	66.25 - 79.25	16 - 20	94.25 - 113.25

Source: OPPT, 1994.

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.

A. Wages

The basic methodology for estimating the industry wage rates used in this analysis is presented in Appendix A. Wage data used to develop the basic industry wage rates are derived from the U.S. Department of Labor, Bureau of Labor Statistics (BLS) for all goods-producing private industries. The annual salary estimates were adjusted to final-quarter (December) 2003 dollars using the BLS Employment Cost Index (ECI) for white-collar occupations for all private industries.

An overhead rate of 17 percent was applied to all wages based on information provided by the chemical industry and chemical industry trade associations. Benefit rates were applied to wages as follows: managerial, 47.7 percent; technical, 49.7 percent; and secretarial, 50.5 percent. Thus, total load factors are 64.7 percent for managerial labor, 66.7 percent for technical labor, and 67.5 percent for secretarial labor. The estimated hourly wage rates are presented in Table 3. Details on the calculation of the wage rates can be found in Appendix A.

TABLE 3
HOURLY WAGE AND LOAD RATES FOR INDUSTRY

Labor Category	Wage Rate
Managerial	\$68.18
Technical	\$55.44
Clerical	\$27.47

Note: Details on the calculation of these wages can be found in Appendix A.

B. Summary of Unit Costs

Labor Costs

Chemical Verification

The Agency estimates that chemical verification will require 6.8 hours per SNUR. The total estimated cost per SNUR is estimated to be \$377 (6.8 hours per SNUR x \$55.44).

Costs for Submitting a SNUN

Using these labor wage rates and the burden estimates presented above, EPA estimates that the labor cost associated with filing a SNUN ranges from \$5,094 to \$6,143. In addition, SNUN filers must pay a \$2,500 user fee to EPA. Thus, the total cost of filing a SNUN ranges from \$7,594 to \$8,643.

**TABLE 4
UNIT REPORTING BURDEN ESTIMATES ASSOCIATED WITH FILING A SNUN,
BY LABOR CATEGORY**

	Hours	Wage Rate	Total Cost
Clerical	12-14	\$27.47	\$330-\$385
Technical	66.25-79.25	\$55.44	\$3,673-\$4,394
Managerial	16-20	\$68.18	\$1,091-\$1,364
Totals	94.25-113.25	-	\$5,094-\$6,143

Costs for Record keeping

Record keeping requires 5.67 hours per SNUN. Assuming that the record keeping is performed by clerical staff, the costs for record keeping are \$156 [5.67 hours * \$27.47 (clerical labor)]

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 range from between \$7,594 and \$8,643. 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.

Customer Notification

EPA assumes that the customer notification requirement will be handled by technical labor. Section 5 of this analysis assumed that one hour of labor per chemical would be required to perform the notification, thus the unit cost of notification is estimated to be \$55.44 (i.e., the

hourly wage for technical labor). EPA estimates that each SNUR will cover approximately 20 chemicals. Furthermore, EPA assumes that there are two manufacturers, processors, or importers per chemical.⁴ Therefore, the burden per SNUR is estimated to be 40 hours per SNUR ([20 chemicals per SNUR]*[1 hour per manufacturer, processor, or importer]*[2 manufacturers, processors, or importers per chemical]), and the cost per SNUR is equal to \$2,218 [(\$55.44 per hour)*(40 hours per SNUR)].

**TABLE 5
SUMMARY OF UNIT COSTS**

Unit Cost	Estimated Cost
Chemical Verification	\$377 per SNUR
Submitting a SNUN	Between \$7,594 and \$8,643 per SNUN*
SNUN Record Keeping	\$156 per SNUN
Notifying Customers	\$2,218 per SNUR

* Includes \$2,500 user fee per SNUN.

Summary

Table 4 summarizes the unit costs estimated in this section. Reviewing a SNUR to verify that a chemical is included is estimated to cost \$377 per SNUR. Submitting a SNUN is estimated to cost between \$7,594 and \$8,643 per SNUN and notifying customers is estimated to cost \$2,218 per SNUR. As noted above, the upper bound cost for filing a SNUN (\$8,643) will be used in subsequent calculations.

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 three categories: chemical verification, submitting SNUNs and notifying customers.

A. Verifying Chemicals

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. As noted above, this analysis assumes that EPA will promulgate five SNURs per year. Total burden and costs for chemical verification are presented in Tables 6 and 7.

⁴ The assumption that there are two manufacturers, processors, or importers per chemical follows from previous ICRs for these requirements.

**TABLE 6
TOTAL INDUSTRY BURDEN ASSOCIATED WITH CHEMICAL VERIFICATION**

Activity	Hours Per SNUR	SNURs per Year	Total hours
Chemical Verification	6.8	5	34

**TABLE 7
TOTAL INDUSTRY COSTS ASSOCIATED WITH CHEMICAL VERIFICATION**

SNURs Per Year	Cost Per SNUR	Total Annual Cost	Three Year Cost
5	\$377	\$1,885	\$5,655

Note: Estimates may contain some rounding error caused by rounding dollar values to the nearest whole dollar.

B. Submitting SNUNs

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 and SNUNs. As noted above, this analysis assumes that EPA will promulgate five SNURs and receive ten SNUNs per year.

Table 8 presents the total burden of submitting SNUNs. Section 5 of this analysis estimated that the reporting requirements for submitting SNUNs would impose 113.25 hours for each SNUN. An additional 5.67 hours are assumed to be required to satisfy recordkeeping requirements. Thus, a total of 118.92 hours are required for each SNUN.⁵ From section 4 of this analysis, EPA estimates that it will receive ten SNUNs per year. Thus, the total burden imposed on industry is estimated to be 1,189.2 hours annually, or 3,567.6 hours over a three year period.

**TABLE 8
TOTAL INDUSTRY BURDEN ASSOCIATED WITH SUBMITTING SNUNs**

Activity	Hours Per SNUN	SNUNs per Year	Total hours
Reporting	113.25	10	1,132.5
Recordkeeping	5.67	10	56.7
Total Annual Burden	118.92	10	1,189.2
Three Year Burden	-	-	3,567.6

The total cost of submitting SNUNs is presented in Table 9. Section 6 of this analysis estimated that submitting SNUNs will cost affected parties \$8,643 per SNUN. Assuming 10 SNUNs per year (see section 4) implies a total annual cost of \$86,430 ([10 SNUNs]*[\$86,430 per SNUN]) and a three year cost of \$259,290 ([86,430 per year]*[3 years]).

⁵ In deriving the totals for this analysis, EPA uses the upper bound estimates for the number of hours and the cost of submitting SNUNs.

TABLE 9
TOTAL INDUSTRY COSTS ASSOCIATED WITH SUBMITTING SNUNs

SNUNs Per Year	Cost Per SNUN	Total Annual Cost	Three Year Cost
10	\$8,643	\$86,430	\$259,290

Note: Estimates may contain some rounding error caused by rounding dollar values to the nearest whole dollar.

C. Customer Notification

Table 10 presents estimates of the customer notification burden and costs. EPA estimates that burden for customer notification is 40 hours per SNUR. EPA estimates that 5 SNURs will be promulgated per year. The annual burden associated with customer notification is estimated to be 200 hours (40 hours/SNUR * 5 SNURs/year). The three year burden is estimated to be 600 hours.

The cost of customer notification is estimated by multiplying the burden hours by the unit cost of notification. Section 6 assumed that notification would be accomplished using technical labor, valued at \$55.44 per hour. Thus, the total annual cost of customer notification is \$11,088 and the three year cost is \$33,264.

**TABLE 10
ESTIMATED BURDEN AND COST FOR CUSTOMER NOTIFICATION**

Cost element	Value/Estimate
Burden	
Chemicals per SNUR [a]	20
Hours per manufacturers/processors/importers [b]	1.0
Manufacturers/processors/importers per chemical [c]	2
SNURs per year [d]	5
Total annual burden [e] = [a]*[b]*[c]*[d]	200
Three year burden [f] = 3*[e]	600
Cost	
Cost per hour [g]	\$55.44
Total annual cost [h] = [e]*[g]	\$11,088
Three year cost [j] = 3*[h]	\$33,246

C. Summary of Industry Costs

The total estimated industry burden and cost associated with SNURs is equal to the total of chemical verification burden and cost (34 hours / \$1,885 annually), reporting and record keeping burden and cost (1,189 hours / \$86,430 annually) plus the total customer notification burden and cost (200 hours / \$11,088 annually) which is equal to 1,423 hours annually with an associated estimated cost of \$99,403 annually. Over a three-year period, the burden is estimated to be 4,269 hours and costs are estimated to be \$298,209.

6(c) Estimating Agency Burden and Cost

EPA will incur costs associated with the promulgation of SNURs and the processing of SNURs. The previous ICR estimated that the cost for issuing a SNUR can be as high as \$35,082 in 2003 dollars. The Office of Personnel Management reports that federal salaries increased by 11.57 percent (Washington, D.C. salary including locality adjustment) from 2003 to 2007 (Office of Personnel Management, 2008).⁶ The annual salary for EPA staff used for calculations of Agency costs is an average of the OPM year 2007 annual salaries for GS-12 Steps 1 and 10 for Washington, DC -- \$66,767 and \$86,801, respectively, or \$76,784. Multiplying by an assumed

⁶ This percentage increase is composed of four annual increases: a 4.42 percent increase in 2004, a 3.71 percent increase in 2005, a 3.44 percent increase in 2006, and a 3.44 percent increase in 2007. (Office of Personnel Management, 2008).

loading factor of 1.6 to reflect fringe benefits and overhead (Office of Policy Planning and Evaluation, 1992), the loaded annual salary of EPA staff was calculated to be \$122,854. Dividing the wage by a 12 person-months/year results in \$10,238/person-month. Consistent with the previous ICR, it is estimated that it will take 3.94 person-months of EPA staff time to develop a final SNUR. Therefore, the wage per person-month (\$10,238) multiplied by a 3.94 person-months/SNUR yields an EPA cost per SNUR of \$40,338.⁷

EPA's costs to review and process SNUNs are assumed to be the same as EPA costs to review PMNs. These costs are estimated at \$4,778 per case. The Agency actions required, full-time equivalent (FTE) staff needs, and extramural costs such as for contractor support are derived in Appendix B from EPA's analysis of the Agency costs of processing PMN submissions (RIB, 1994), with updates to 2007 dollars.

Using the estimates of annual SNUR promulgation and SNUR notice submissions presented above, EPA's estimated costs are presented in Table 11. Promulgating SNURs and processing SNUNs are estimated to cost the Agency \$126,261 annually and \$378,783 for three years. The Agency may also incur a cost for modifying a SNUR if submitted data indicate a need for such an action. Costs to perform such a modification have not been estimated.

**TABLE 11
AGENCY COSTS**

Activity	Number Per Year	Cost Per Action	Annual Cost	Three Year Cost
SNURs	5	\$40,338	\$201,690	\$605,070
SNUNs	10	\$4,778	\$47,780	\$143,340
Totals	15	\$45,116	\$249,470	\$748,410

Note: Estimates may contain some rounding error caused by rounding dollar values to the nearest whole dollar.

6(d) Reasons for Change in Burden

There is a net increase of 562 hours (from 861 hours to 1,423 hours) in the total estimated respondent burden compared with that currently in the OMB inventory. This increase reflects EPA's updated estimates of an anticipated increase in the number of SNURs promulgated from three to five per year and an increase in the estimated number of SNUNs received from five to ten per year. Additionally, estimated number of chemicals per SNUR is estimated to fall from 41 to 20. All of these changes are adjustments.

Regulatory Flexibility Analysis

TSCA section 5(a)(c) affects new uses of chemicals and requires those interested in engaging in such a use to notify the Agency of his/her intentions. Because the rule only covers uses which a small business intends to undertake, a small business is not expected to

⁷ The 3.94 person-months estimate is from a memorandum from Michael Shapiro, Economics and Technology Division, to Susan Hazen, Office of Toxic Substances (Shapiro, 1984).

immediately be affected by the SNUR unless it is considering such a use in the future. Although there may be some small businesses that may decide to participate in SNUR related activities associated with certain chemicals, it is impossible to estimate the number at this time. Additionally, the Agency has received few SNUNs related to existing chemical SNURs in the past, suggesting that few, if any small businesses would be affected. This, coupled with the low unit costs associated with filing a SNUN, suggests that the overall impact will be low for any business which may choose to file a SNUN or notify customers of SNUR activity. These costs are not differentiated between small and large businesses.

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 be approximately 71 hours per response. According to the Paperwork reduction Act, Aburden@ means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to review instructions; develop, acquire, install and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information ; and transmit or otherwise disclose the information. 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. In addition, the OMB control numbers for EPA's regulation, after initial display in the final rule, are listed in 40 CFR part 9.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPPT-2008-0220, 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-2008-0220 and OMB Control No. 2070-0038, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: Document Control Office (DCO), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, Mail Code: 7407T, 1200 Pennsylvania Ave., NW, Washington, D.C. 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

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ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for the proposed rule under docket identification number EPA-HQ-OPPT-2008-0220. These attachments are available for online viewing at www.regulations.gov or otherwise accessed as described in section 6(e) of the supporting statement.

- Attachment 1:** 15 U.S.C. 2604 – Section 5 of the Toxic Substances Control Act. Also available at online at the US House of Representatives' [US Code website](#)
- Attachment 2:** 40 CFR Part 721 – Significant New Uses Of Chemical Substances. Also available online at the National Archives and Records Administration's [Electronic CFR Website](#)
- Attachment 3:** EPA Form 7710-25 – Premanufacture Notice. Also available online at <http://epa.gov/oppt/newchemicals/pubs/pmnforms.htm>
- Attachment 4:** Calculation of Hourly Wage Rates
- Attachment 5:** Selection Criteria -- TSCA Section 8(a) Rule vs. SNUR
- Attachment 6:** Selected SNUR Case History Abstracts
- Attachment 7:** Copy of Consultations Message Sent by EPA to Potential Respondents