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.: 1188.11 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 <u>Federal Register</u> 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.

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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 electronically, via the Central Data Exchange (CDX), using the Agency's e-PMN software. 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 388 existing chemicals. Presented in Attachment 5 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.

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 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

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.

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 June 8, 2012 (77 FR 21096, April 9, 2012). EPA received no comments during the comment period.

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 email. The individuals contacted were:

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Jim Ford, Director, Federal Government Affairs American Petroleum Institute 1220 L Street, NW Washington, D.C. 20005 Tel: (202) 682-8210 Fax: (202) 682-8031 E-mail: fordj@api.org

Brigid Klein, General Counsel Consumer Specialty Products Association 900 17th Street, NW, Suite 300 Washington, D.C. 20006 Tel: (202) 833-7309 Fax: (202) 872-8114 E-mail: bklein@cspa.org John Carroll, Chair, Enzyme Technical Association Director, Regulatory Affairs Novozymes North America, Inc. 77 Perry Chapel Church Road P.O. Box 576 Franklinton, NC 27525 Tel.: (919)494-3150 Fax: (919)494-3420 E-mail: john@novozymes.com

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EPA received no responses to its solicitation for consultations. A copy of EPA's consultation email to the above potential respondents is included in Attachment 6.

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.

EPA has developed e-PMN software for use in preparing and submitting PMNs and other TSCA section 5 notices such as SNUNS, and support documents electronically to the Agency via (CDX). 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 <u>http://www.epa.gov/cdx</u>. The use of CDX for submission of TSCA section 5 notices and support documents is consistent with the Government Paperwork Elimination Act (GPEA), that requires Federal agencies to provide electronic submission, maintenance, or disclosure of information, when practicable as a substitute for paper.

The e-PMN software and electronic submission via CDX changes the way that companies interact with the Agency regarding many TSCA section 5 submissions including SNUNs. Companies register with EPA to submit their data electronically to the Agency via CDX and the Agency benefits from receiving electronic submissions. Data systems that once were populated manually are now populated electronically, reducing the potential for error that exists when data are entered by hand. Agency personnel are able to communicate more efficiently with submitters electronically compared to using U.S. mail or courier services. PMN/SNUN electronic reporting software allows for more efficient data transmittal, and the software's validation mechanism should help industry users submit fewer incomplete notices, which ultimately will save EPA and industry processing resources and reduce transaction times. EPA believes the adoption of electronic communications reduces the reporting burden on industry by reducing both the cost and the time required to review, edit, and transmit data to the Agency. It also allows submitters to share a draft notice within the company during the creation of a notice and to save a copy of the final file for future use.

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.

EPA will ensure secure transmission of SNUN data submitted through CDX via the Transport Layer Security (TLS) 1.0 protocol. TLS 1.0 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, "Guidelines for the Selection and Use of Transport Layer Security (TLS) Implementations"

<u>http://csrc.nist.gov/publications/nistpubs/800-52/SP800-52.pdf</u>. 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 of record. This assures the submitter that the Agency has received exactly what the submitter sent to EPA. The current version of the e-PMN encrypts using Federal Information Processing Standards (FIPS)-validated RSA BSAFE Crypto-J. EPA may incorporate other encryption modules into future versions of e-PMN. Information submitted via CDX is processed within EPA by secure systems certified for compliance with FIPS.

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 <u>known</u> to or <u>reasonably</u> <u>ascertainable</u> 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. 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 <u>http://www.epa.gov/opptintr/newchems</u>.

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 followup 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

For the past two years, submitters have been able to generate TSCA section 5 notices, including SNUNs, using the e-PMN available at the EPA New Chemicals Program website (<u>https://cdx.epa.gov/ssl/pmn/download.asp</u>). The e-PMN software is available as a free internet download. The data being transmitted electronically via CDX is encrypted to protect CBI. The software works with Windows, Macs, Linux, and UNIX-based computers, using XML for more efficient data

transmittal to Agency data systems. 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.

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

Because companies will be registered with EPA to submit their data electronically to the Agency via CDX, the Agency in turn is be 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). Previously, these communications were sent through the mail. An electronic means of communication provides significant time and resource savings for both parties.

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, 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 consistent with the analysis presented in the supporting statement prepared for the previous ICR.

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.

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

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

6(a) Estimating Respondent Burden

Number Of Significant New Use Notices Projected

During the years 2008 through 2011, EPA proposed two existing chemical SNURs under TSCA section 5(a)(2). This activity may increase over the next three-year period as EPA initiates a comprehensive approach to enhance the Agency's existing chemicals management program. However, EPA cannot estimate future SNUR activity with certainty.

Therefore, based on past ICRs and the best professional judgment of Agency staff, 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 ICR².

EPA may receive SNUNs as a result of SNURs. 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 7 SNUNs per year, based on fiscal year (FY) 2001 – FY2011 submissions. Of those SNUNs, only a fraction result from existing chemical SNURs promulgated under section 5(a)(2).

Year	Anticipated Number of SNURs	Anticipated Number of SNUNS
First Year	5	7
Second Year	5	7
Third Year	5	7
Three Year Totals	15	21

Table 2: Anticipated Number of SNURs and SNUNs

Using SNUN submission data from the ten year period of FY2001 through FY2011, EPA estimates that the average firm submits 1.65 SNUNs. This may be an overestimate because it was not determined whether the SNUN submissions were in response to new or existing chemical SNURs. The exact number of firms engaging in new uses cannot be estimated, however given the estimated number of SNUNs and firms submitting SNUNs, EPA estimates a total of 4.24 firms will be impacted annually (7 SNUNs/1.65 firms). Given the uncertainty in projecting possible new uses for existing chemicals, it is not possible to determine whether a large or small number of firms would be affected by any given SNUR.

(i) 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:

² 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. 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.

- 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/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 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 demonstrated³. 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.

(ii) 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 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 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 is subject to the rule. From 2007 to 2011, 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 two SNURs applying to existing chemicals were proposed during the same time period but were not finalized. These SNURs proposed to regulate an average of seven chemicals. The Agency typically notifies the manufacture(s) of chemicals subject to a SNUR prior to its issuance. Therefore it

³ 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.

is estimated that no more than 0.167 hours (10 minutes) of technical labor time per chemical is used to verify that a chemical is subject to the rule. This is equivalent to 1.17 hours (0.167 hours/chemical x 7 chemicals/SNUR) per SNUR.

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	0.83

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. <u>These activities are only required of first-time submitters of any section 5</u>. <u>notice</u>. It is not known how many submitters of SNUNs from existing chemical SNURs will be firsttime submitters of any section 5 notices, therefore, EPA assumes that all submitters will incur these costs. These activities are estimated to require the following burdens, 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 forFirst-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

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.

Baseline reporting and recordkeeping burden for Existing Chemical SNUNs is estimated to be 92.2 hours reporting burden and 1 hour recordkeeping burden (for a total of 93.2 hours) based on the estimates in EPA ICR No. 1188.10. However, the 93.2 hours for response burden per SNUN submission is adjusted in this ICR because recordkeeping burden has been miscalculated. Prior to the e-PMN final rule, the estimate of SNUN reporting burden was 105 hours based on the1994 Regulatory Impact Analysis of Amendments(RIA) to Regulations for TSCA Section 5 Premanufacture Notifications (EPA, 1994). Reporting burden was adjusted to 92.2 hours in EPA ICR No. 1188.10 with an additional hour added for recordkeeping burden so that total reporting and recordkeeping burden is estimated to be 93.2 hours. However, the RIA estimate of 105 hours accounted for both reporting and recordkeeping because the burden estimates "include the time spent reading and becoming familiar with the form, gathering the required information and preparing the report, producing sanitized responses for items claimed as confidential business information, and *maintaining a file of the submission*" (emphasis added) (EPA 1994, pg. III-14). Therefore, the 1 hour recordkeeping burden included in EPA's 93.2 hour estimate of response burden for submitting a SNUN double counts recordkeeping burden. Correcting for this error revises the total estimated response burden for SNUN submissions in this ICR to 92.2 hours/SNUN (Table 5).

Table 5: Adjusted Reporting and Recordkeeping Burden Hours for SNUN Submissions

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Existing Chemicals SNUN Submission Activity	Baseline Response Burden	Adjustment	Estimated
Reporting and Recordkeeping	93.2	-1	92.2

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 92.2 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 burdens are taken from the midpoint estimate burdens of each section of the SNUN form (EPA, 1994). The recordkeeping burdens per significant new use are 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 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

Manufacturers, processors, and importers of chemicals 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, 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 one hour of a technical employee's time per manufacturer, processor, or importer per chemical. EPA estimates that each SNUR will cover approximately 7 chemicals. Furthermore, EPA assumes that there are two manufacturers, processors, or importers per chemical.⁴ Therefore, the burden per SNUR is estimated to be 14 hours per SNUR.

Summary of Unit Burdens

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

The following table summarizes the burdens for the activities required under a SNUR, under compliance option 1.

Table V. Summary of Omit Duruens	
Collection Activity	Estimated Burden Hours
Chemical verification (per SNUR)	1.17
Rule Familiarization (per company)	0.83
CDX registration, electronic signature, and	2.8
Pay.gov account set-up (per company)	
SNUN preparation (per report)	92.2
Notifying customers (per SNUR)	14

Table 6: Summary of Unit Burdens

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: Historical Data December 2006 – December 2010* (BLS, 2011a).

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 2010 dollars. Table 7 contains the loaded wage rates for the managerial, technical and clerical occupation categories.

Wage ¹	Fringe Benefits ¹	Fringes as % of Wage	Overhead % of Wage ²	Fringe + Overhead Factor	Loaded Wages
(a)	(b)	(c) = (b)/(a)	(d)	(e)=(1)+(c)+(d)	(f) = (a) x (e)
\$17.36	\$8.67	48.37%	17%	1.67	\$28.98
\$36.93	\$18.50	47.58%	17%	1.67	\$61.71
		4E 020/	170/		
\$42.82	\$19.64	45.05%	1/%	1.63	\$69.74
	(a) \$17.36 \$36.93	Wage ¹ Benefits ¹ (a) (b) \$17.36 \$8.67 \$36.93 \$18.50	Wage1 Benefits1 % of Wage (a) (b) (c) = (b)/(a) \$17.36 \$8.67 48.37% \$36.93 \$18.50 47.58%	Wage ¹ Benefits ¹ % of Wage % of Wage ² (a) (b) (c) = (b)/(a) (d) \$17.36 \$8.67 48.37% 17% \$36.93 \$18.50 47.58% 17%	Wage1 Benefits1 Fringes as % of Wage Overhead % of Wage2 Overhead Factor (a) (b) (c) = (b)/(a) (d) (e)=(1)+(c)+(d) \$17.36 \$8.67 48.37% 17% 1.67 \$36.93 \$18.50 47.58% 17% 1.67

Table 7: Derivation of Loaded Wage Rates for the Private Manufacturing Sector in 2010\$

¹ Employer Costs for Employee Compensation Supplementary Tables: Historical Data December 2006 – December 2010, US Bureau of Labor Statistics, March 2011 (BLS, 2011a).

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 1.17 technical hours per SNUR. The total estimated cost per SNUR is estimated to be \$72.14 (1.17 hours per SNUR x \$61.71).

Costs for Rule Familiarization

EPA estimates rule familiarization costs will require 0.83 hours per firm and total costs are expected to be \$52.54.

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

First-time submitters of any 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 \$58.03 on CDX registration, \$114.01 on completing the Electronic Signature Agreements, \$2.30 mailing electronic signature agreements, and \$9.30 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 \$184.

Table 8: CDX Registration, CDX Electronic Signature, and Pay.gov Account Setup Cost for First-Time Submitters

Activity	Clerical Labor (at \$29.98/hour)	Technical Labor (at \$61.71/hour)	Managerial Labor (at \$69.74/hour)	Total Labor Cost (2010 dollars)
CDX registration	\$0.00	\$45.25	\$12.78	\$58.03
CDX electronic signature	\$0.00	\$61.71	\$52.30	\$114.01
Mailing cost				\$2.30
E-payment (Pay.gov ID)	\$0.00	\$0.00	\$9.30	\$9.30
Total	\$0.00	\$106.96	\$74.38	\$183.64

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 \$5,802. In addition, SNUN filers must pay a \$2,500 user fee to EPA. Thus, the total cost of filing a SNUN is approximately \$8,302.

Activity	Clerical Labor (at \$29.98/hour)	Technical Labor (at \$61.71/hour)	Managerial Labor (at \$69.74/hour)	Total Labor Cost (2010 dollars)
SNUN preparation	\$0.00	\$4,546.79	\$1,255.32	\$5,802
User fee				\$2,500
Total	\$0.00	\$4,546.79	\$1,255.32	\$8,302

Table 9: Unit Reporting Cost Estimates, Associated with Filing a SNUN by Labor Category

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 \$8,302. 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 \$0.36 to \$22.10 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 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 \$61.71 (i.e., the hourly wage for technical labor). EPA estimates that each SNUR will cover approximately 7 chemicals. Furthermore, EPA assumes that there are two manufacturers, processors, or importers per chemical⁵. Therefore, the burden per SNUR is estimated to be 14 hours per SNUR ([7 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 \$863.90 [(\$61.71per hour)*(14 hours per SNUR)].

⁵ The assumption that there are two manufacturers, processors, or importers per chemical follows from previous ICRs for these requirements.

<u>Summary</u>

Table 10 summarizes the unit costs estimated in this section. Reviewing a SNUR to verify that a chemical is included is estimated to cost \$419.63 per SNUR and notifying customers is \$863.90 per SNUR. The cost of completing and submitting a SNUN is approximately \$8,302.11. EPA estimates the costs associated with rule familiarization to be \$50.92 per company, and CDX registration activities to be \$183.64 per company.

Table 10. Summary of Onit Costs	
Collection Activity	Estimated Cost
Chemical verification (per SNUR)	\$72.14
Rule familiarization (per company)	\$52.54
CDX registration, electronic signature, and Pay.gov account set-up (per company)	\$183.64
SNUN preparation*	\$8,302.11
Notifying customers (per SNUR)	\$863.90

Table 10: Summary of Unit Costs

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

(iii) <u>Total Burden and Costs to Industry</u>

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, 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 five SNURs and receive seven SNUNs per year. Table 11 presents the annual burden and cost to the industry. EPA estimates the total annual industry burden of existing chemical SNUR action is 736 hours and \$63,799.

Information Collection Activity	Total Burden per Activity (hours)	Total Cost per Activity (2010\$)	Total Number of Units Annually	Total Annual Burden (hours)	Total Annual Cost (2010\$)
Rule familiarization (per firm)	0.83	\$53	4.24 firms	3.52	\$225
Preparation, submission, and recordkeeping for SNUN (per report)	92.2	\$8,302	7 SNUNs	645	\$58,114
CDX registration, electronic signature, Pay.gov set-up (per firm)	2.8	\$184	4.24 firms	11.88	\$781
Chemical verification (per SNUR)	1.17	\$72	5 SNURs	5.85	\$360
Notifying customers (per SNUR)	14	\$864	5 SNURs	70.00	\$4,320
Total Industry Burden and Cost				736	\$63,799

Table 11: Estimated Annual Respondent Burden and Cost

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

Table 12 presents the total burden and cost to the industry over the three-year ICR period. EPA estimates the total annual industry burden of existing chemical SNUR action is 2,208 hours and \$191,398.

Information Collection Activity	Total Burden per Activity (hours)	Total Cost per Activity (2010\$)	Total Number of Units	Total Annual Burden (hours)	Total Annual Cost (2010\$)
Rule familiarization (per firm)	0.83	\$53	12.72 firms	10.56	\$675
Preparation, submission, and recordkeeping for SNUN (per report)	92.2	\$8,302	21 SNUNs	1,936	\$174,342
CDX registration. electronic signature, Pay.gov set-up (per firm)	2.8	\$184	12.72 firms	35.64	\$2,342
Chemical verification (per SNUR)	1.17	\$72	15 SNURs	18	\$1,080
Notifying customers (per SNUR)	14	\$864	15 SNURs	210	\$12,960
Total Industry Burden and	2,210	\$191,398			

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

Table 13 presents the annual burden by collection activity. Chemical verification is expected to have a total burden of 5.85 hours annually. Notifying consumers is expected to have burden of 70 hours

annually. Companies are expected to incur a total of 3.52 hours for rule familiarization, 11.88 hours for CDX registration activities and a total of 645 hours for SNUN completion, each year.

Trafarra attar						
Information Collection	No. of Respondents	No. of Responses / Respondent	Responses Subtotal	Annual Burden Hours per Response	Annual Burden Hours per Activity	
		Per Firm Act	tivities			
Rule familiarization	4.24	1	4.24	0.83	3.52	
CDX registration activities						
- CDX registration	4.24	1	4.24	0.92	3.89	
- ESA	4.24	1	4.24	1.75	7.42	
- Pay.gov account	4.24	1	4.24	0.13	0.57	
Preparation, submission, and recordkeeping for SNUN	4.24	1.65	7	92.2	645	
		Per SNUR Ac	tivities			
Chemical verification	5	1	5	1.17	5.85	
Notifying customers (per SNUR)	35	2	70	1	70.00	
·		Totals				
	61.20	1.33	98.96	98.00	736.25	

 Table 13: Annual Information Collection Tally for ICR Reporting Period (2012-2015)

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

Table 14 presents the total burden hours for the ICR period (2012–2015), organized by information collection. Chemical verification is expected to have burden of 17.55 hours over the three year period. Notifying consumers is expected to have burden of 210 hours over the three year period. Companies are expected to incur at total of 10.56 hours for rule familiarization, 35.64 hours for CDX registration activities and a total of 1,936 hours for SNUN completion, submission and recordkeeping over the three year 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	12.72	1	13	0.83	10.56					
CDX registration activities	12.72	1	13	2.80	35.64					
- CDX registration	12.72	1	13	0.92	11.67					
- ESA	12.72	1	13	1.75	22.27					
- Pay.gov account	12.72	1	13	0.13	1.70					
Preparation, submission, and recordkeeping for SNUN	12.72	1.65	21	92.2	1,936					
Per SNUR Activities										
Chemical verification	15	1	15	1.17	17.55					
Notifying customers (per SNUR)	105	2	210	1	210					

Table 14: Total Information Collection Ta	ly for ICR Reportin	g Period (2012-	2015)
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Some burden estimate subtotals may not calculate due to rounding of unit burden estimates

6(c) Estimating Agency Burden and Cost

(i) <u>SNUN Processing</u>

EPA's costs to review and process SNUNs are assumed to be the same as EPA costs to review PMNs. The list of review steps, estimates of extramural costs, and the percent of chemicals requiring a particular review step are derived from the costs for processing PMN submissions in Table VII-1 of EPA's *Regulatory Impact Analysis of Amendments to Regulations for TSCA Section 5 Premanufacture Notifications* (EPA, 1994). The Agency burden associated with processing a PMN has been adjusted to reflect burden reductions resulting from the ePMN rule that requires the electronic submission of all TSCA section 5 notices. Electronic submission of SNUN forms is expected to reduce Agency burden by 16.5 percent (EPA, 2009a, p.28). The Extramural Cost column shows costs for contractor support and other outside purchases for chemicals requiring the selected review step, and is inflated from 1993 prices using the Bureau of Labor Statistics (BLS) Employment Cost Index (ECI) data (BLS, 2011b). The not seasonally adjusted ECI for total compensation of private industry professional and related workers (Series ID CIU20100001200001) is used because it is the only series with continuous data since 1985, and that includes professional and technical labor, which perform the majority of Agency extramural activities. Table 15 contains the derivation of inflation factors for Agency extramural costs.

Item	Inflation index source ¹	Startin g year	Index for starting year (a)	Index for 2010 (b)	Inflation factor (b)/(a) ²
Agency extramural costs White collar labor; equipment; supplies	BLS ECI, NSA, Total comp, Private industry, Professional and related ,	1993	67.0	113.5	1.694
	4 th Q [BLS 2011 b]				

Table 15: Derivation of Inflation Factors for Agency Extramural Costs

¹ In 2006, the Bureau of Labor Statistics (BLS) Employment Cost Index (ECI) series "were rebased to December 2005 = 100 from June 1989 = 100." The change is reflected in the indices in this table and explained on the BLS website, Employment Cost Index News Release Text: Employment Cost Index, March 2006 (BLS, 2006).

The "Starting year" ECI index is SIC-OCS based: ECS11102I for private industry White Collar Workers. The index is Seasonally Adjusted (SA).

The year 2010 ECI index is NAICS-SOC based: CIU2010000120000I (B) for private industry White Collar Workers. The index is Seasonally Adjusted (SA).

² Inflation factors are rounded to three decimal places in this table, but calculations in this report use the unrounded values. BLS CPI values were published with one decimal place through 2006 and with three decimal places after that.

Agency labor costs are calculated based on annual federal salaries for the Washington-Baltimore area published by the Office of Personnel Management effective January 2010 (OPM, 2010). EPA assumes that, on average, a federal GS-13, Step 5 full-time equivalent (FTE) will conduct its collection and administrative activities⁶. The average salary for a GS-13 Step 5 employee was \$100,904 in 2010 without fringe benefits and overhead costs. In order to derive the fully loaded salary, EPA multiplied the annual salary by an assumed loading factor of 1.6 to reflect federal fringe benefits and overhead, which results in a fully loaded annual salary of \$161,446.40 Dividing the fully loaded annual salary by 2,080 hours (i.e., the number of hours in a work year) yields an hourly FTE wage rate of \$77.62.

Total Agency costs are expected to be \$5,049, per SNUN, for submission review and processing, as shown in Table 16.

⁶ The GS-13, Step 5 is consistent with ICR OMB Control Number 2070-0012, EPA Tracking Number 0574.13, EPA 2007. Page 22 of 26

	EP	A staff (FTE) Cost	Extramu	ral Cost ²				DIQU	Weighted	Weighted
Review Steps	FTE fraction	Cost per FTE ¹	FTE Total (\$2010)	1993 dollars	2010 dollars	Unweighted Cost	Pct. of Cases	Weighted Cost ³	ePMN Burden Reduction⁴	Cost with ePMN Burden Reduction	FTE with ePMN Burden Reduction
	(a)	(b)	(c)=(a)*(b)	(d)	(e)	(f)=(c)+(e)	(g)	(h)=(f)*(g)	(i)	(j)=(h)*(1-(i))	(k)=(a)*(g)*(1-(i))
Pre-notice consultation	0.0024	\$161,446	\$387.47	\$4.00	\$6.78	\$394	41%	\$161.64	0.165	\$135	0.0008
Administrative prescreen/ notice receipt/user fee	0.0024	\$161,446	\$387.47	\$92.00	\$155.85	\$543	100%	\$543.32	0.165	\$454	0.0020
CRSS (Chemical Review and Search Strategy)	0.0025	\$161,446	\$403.62	\$268.00	\$454.00	\$858	100%	\$857.62	0.165	\$716	0.0021
SAT (Structure Activity Team)	0.0006	\$161,446	\$96.87	\$14.00	\$23.72	\$121	100%	\$120.58	0.165	\$101	0.0005
Engineering/Exposure	0.0015	\$161,446	\$242.17	\$56.00	\$94.87	\$337	100%	\$337.04	0.165	\$281	0.0013
Exposure/Fate	0.0008	\$161,446	\$129.16	\$0.00	\$0.00	\$129	100%	\$129.16	0.165	\$108	0.0007
Focus	0.0009	\$161,446	\$145.30	\$23.00	\$38.96	\$184	100%	\$184.26	0.165	\$154	0.0008
Standard Review Functions	0.0219	\$161,446	\$3,535.68	\$511.00	\$865.65	\$4,401	29%	\$1,276.38	0.165	\$1,066	0.0053
Division Directors Meeting	0.0129	\$161,446	\$2,082.66	\$113.00	\$191.43	\$2,274	15%	\$341.11	0.165	\$285	0.0016
Order Development/Negotiation Review	0.0171	\$161,446	\$2,760.73	\$22.00	\$37.27	\$2,798	3%	\$83.94	0.165	\$70	0.0004
Post Order Data Review	0.0886	\$161,446	\$14,304.	\$0.00	\$0.00	\$14,304	3%	\$429.12	0.165	\$358	0.0022
Order Modification	0.2167	\$161,446	\$34,985.43	\$0.00	\$0.00	\$34,985	3%	\$1,049.56	0.165	\$876	0.0054
New Chemical SNUR Development	0.0277	\$161,446	\$4,472.07	\$85.00	\$143.99	\$4,616	7%	\$323.12	0.165	\$270	0.0016
Notices of Commencement	0.0012	\$161,446	\$193.74	\$40.00	\$67.76	\$261	31%	\$81.06	0.165	\$68	0.0003
FOIA (Freedom of Information Act) Requests	0.0333	\$161,446	\$5,376.17	\$287.00	\$486.19	\$5,862	1%	\$58.62	0.165	\$49	0.0003
CBI (Confidential Business Information) Substantiation	0.0004	\$161,446	\$64.58	\$3.00	\$5.08	\$70	100%	\$69.66	0.165	\$58	0.0003
TOTAL								\$6,046	0.165	\$5,049	0.0256

Notes:

¹ GS-13 Step 5 salaries loaded with benefits and overhead. ² Extramural costs consist of contracting support and other purchases directly attributable to the PMN review process inflated from 1993.

³Weighted costs were calculated using unrounded unit cost estimates, so results may differ from calculations using the rounded values shown in this table.

⁴ Electronic submission is expected to generate a cost savings of 16.5% to the Agency (EPA 2009a, p. 28).

Sources: FTEs per review step, 1993 extramural costs, and percents of cases are from EPA, 1994 Table VII-1, GS-13 salaries are from OPM, 2010.

September 28, 2012

Using the estimates of annual SNUR promulgation and SNUR notice submissions presented above, EPA's estimated costs are presented in Table 17. Processing SNUNs is estimated to cost the Agency \$35,343 annually. 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.

Activity	Total Burden per Activity (FTE)	Total Burden per Activity (Hours)	Total Cost per Activity (2010\$)	Total Number of Units	Total Annual Burden (hours)	Total Annual Cost (2010\$)
SNUN processing	0.0256	\$53	\$5,049	7 SNUNs	373.07	\$35,343

Table 17: Annual Agency Costs

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

Table 18 presents the total Agency cost for SNUN processing over the three year ICR period, \$106,029.

Activity	Total Burden per Activity (FTE)	Total Burden per Activity (Hours)	Total Cost per Activity (2010\$)	Total Number of Units	Total Annual Burden (hours)	Total Annual Cost (2010\$)
SNUN processing	0.0256	\$53	\$5,049	21 SNUNs	1,119	\$106,029

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

6(d) Reasons for Change in Burden

There is a decrease of 440 hours (from 1,176 hours to 736 hours) in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB (EPA ICR No. 1188.10). This change results from updates to the number of affected sites and responses and the correction of estimates in the previous ICR. More details on the changes are outlined below. The change is an adjustment.

Adjustment Changes

The currently approved ICR estimated that, on average, 10 SNUNs will be submitted annually. Upon review of past SNUN submissions from FY 2001 through FY 2011, this number was reduced from 10 SNUNs per year to 7 SNUNs per year. The previous ICR also assumed that one company will submit a single SNUN. However, reviews of past submissions indicate that the average company will submit 1.65 SNUNs. In addition, a review of SNUNs since 2008 reduced the number of expected chemicals that are affected from 41 to 7 per SNUR.

The previous ICR used an estimate of 93.3 hours for reporting and recordkeeping for a SNUN. This ICR adjusts that number to 92.2 because the 1 hour of recordkeeping included in the previous ICR is a result of double counting.

Activity	Annual Burden Increase Due from Adjustment (to Baseline) for Addendum Period	Total Burden Increase from Adjustment (to Baseline) for Addendum Period	
Rule familiarization (per firm)	1.03	3	
Preparation, submission, and	-286.6	-860	
recordkeeping for SNUN (per report)			
CDX registration (per firm)	1.9	6	
CDX signature	2.02	6	
e Pay	-0.45	-1	
Chemical verification (per SNUR)	-28.15	-84	
Notifying customers (per SNUR)	-130	-390	
Totals	-440.24	-1,321	

Table 19: Estimate of Changes in Annual Burden Hours from Previous ICR by Activity

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 8.1 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 <u>Federal Register</u>, 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-2011-0778, 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-2011-0778 and OMB Control No. 2070-0038, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: Pollution Prevention and Toxics Docket, Environmental Protection Agency Docket Center (EPA/DC), Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 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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