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: New Information Collection Activities for Electronic Submissions under TSCA Section 5

EPA ICR No.: 2327.01 OMB Control No.: 2070-NEW

1(b) Short Characterization

The Government Paperwork Elimination Act (GPEA, Pub. L. 105-277) requires that, when practicable, federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (October 13, 2005; 70 FR 59848; FRL-7977-1) provides that any requirement in Title 40 of the Code of Federal Regulations to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency publishes a notice that electronic document submission is available for that requirement

In light of GPEA and CROMERR, EPA is developing a proposed rule entitled, "TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revisions to Notification Regulations" (RIN 2070-AJ41) to amend the Toxic Substances Control Act (TSCA) section 5 Notification regulations and related provisions to phase-out paper-based submissions and facilitate the introduction and use of a new electronic reporting mechanism. This action would enable, and eventually require, manufacturers, importers, and processors of TSCA chemical substances to use the Internet, through EPA's Central Data Exchange (CDX), to submit TSCA section 5 notices to the Agency. These include Premanufacture Notices (PMNs) (40 CFR 720, Attachment 3), Significant New Use Notices (SNUNs) (40 CFR 721, Attachment 4), Test Market Exemption Applications (TMEAs) (40 CFR 720), Low Volume Exemption notices (LVEs) (40 CFR 723.50), Low Exposure/Low Release Exemption (LoRex) notices (40 CFR 723.50) (see Attachment 5), Biotechnology notices for genetically modified microorganisms (40 CFR 725, Attachment 6), Notices of Commencement of Manufacture or Import (NOCs) (40 CFR 720.102) and other support documents (e.g., correspondence, amendments and test data).

The Agency is proposing to introduce CDX reporting in two phases over a two-year period. During the first year following the effective date of the final rule, the Agency would allow submissions via CDX, optical disc, and paper. Regardless of the delivery method, EPA would require that all submissions be generated with new "ePMN" computer software. Paper submissions would no longer be accepted for any new notices and support documents (including NOCs) beyond the first year after the final rule's effective date. Disc-based submissions (e.g., CDs and data DVDs) for all new notices and support documents would no longer be accepted beyond the second year after the final rule's effective date. After this, all submitters would be

required to submit electronically via CDX using the ePMN software. The Agency is proposing this phased approach because it would allow submitters to gain experience in using the ePMN software and the submission delivery system. Note that the proposed CDX and ePMN software amendments to the PMN notification requirements in 40 CFR 720 would apply to the SNUN requirements in 40 CFR 721.25(a). EPA is also proposing to amend the TSCA section 5 User Fee regulations at 40 CFR 700.45 to add a new User Fee Payment Identity Number field to the PMN form. This would enable the Agency to match more easily a particular user fee with its notice submission.

This rule-related Information Collection Request (ICR) addresses the incremental paperwork activities related to submitting Section 5 information to EPA electronically and describes the changes that will ultimately be incorporated into the ICRs that currently approved under OMB Control No. 2070-0012 and 2070-0038 (EPA ICR No. 0574, *Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances*; and, EPA ICR No. 1188, *TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals*, respectively).

At this time, the Agency does not have electronic reporting capability for all TSCA section 5-related notices and support documents. Examples are the Notice of Bona Fide Intent to Manufacture ("bona fide"), prenotice communications, and TSCA Inventory Correction Requests. EPA may consider offering electronic reporting of these and other submissions in the future.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

Section 5(a)(1)(A) of TSCA requires persons to notify EPA at least 90 days before they manufacture or import a new chemical substance for commercial purposes. Section 3(9) of TSCA defines a "new chemical substance" as any substance that is not on the Inventory of Chemical Substances compiled by EPA under section 8(b) of TSCA. Section 5(a)(2) of TSCA 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 chemical substance for that use.

2(b) Practical Utility/Users of the Data

ePMN Software

The proposed change to phase-out paper-based submissions in favor of CDX reporting, including use of the ePMN reporting software, for TSCA section 5 notices and support documents, is in concert with broader government efforts to move to modern, electronic methods of information gathering. The required use of CDX for submission of TSCA section 5 notices and support documents would be consistent with the Government Paperwork Elimination Act

(GPEA, Pub. L. 105-277), which requires that, when practicable, federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public.

The ePMN software and electronic submission via CDX would change the way that companies interact with the Agency regarding many TSCA section 5 submissions. Companies would be registered with EPA to submit their data electronically to the Agency via CDX and the Agency in turn would be able to communicate back electronically with submitters. This promotes efficiency in communications and cost savings in submissions and correspondence. Two examples of routine communications from EPA that would now go through CDX rather than the U.S. mail are the Acknowledgment Letter (acknowledging receipt of a notice), and the Incomplete Letter (stating why a notice has been declared incomplete). PMN reporting software allows for more efficient data transmittal, and the software's validation mechanism should help industry users submit fewer incomplete notices, which ultimately would save EPA and industry processing resources and reduce transaction times. EPA believes the adoption of electronic communications would reduce the reporting burden on industry by reducing both the cost and the time required to review, edit and transmit data to the Agency.

All information sent via CDX would be transmitted securely to protect CBI. Furthermore, if anything in the submission has been claimed CBI, a sanitized copy of the notice must be provided by the submitter. The new ePMN software would facilitate the creation of this sanitized non-CBI version, eliminating the need for the submitter to do this manually. It also would allow submitters to share a draft notice within their company during the creation of a notice and to save a copy of the final file for future use. A "Profiler," available in the software, would also allow for certain information to be kept on file by the submitter to avoid re-entering the same information into a new form.

The Agency would also benefit from receiving electronic submissions. Data systems that once were populated manually would now be populated electronically, reducing the potential for human error that exists when data are entered by hand. Agency personnel would also be able to communicate more efficiently with submitters electronically, compared to using U.S. mail.

User Fee Payment Identity Number

As required by 40 CFR part 700 (Attachment 2), respondents must pay a fee when they submit PMNs, MCANs, certain PMN exemption application notices, and SNUNs to the Agency. The amended PMN form would include a new User Fee Payment Identity Number field to enable the Agency to match more easily a particular user fee with a particular notice submission. A User Fee Payment Identity Number would be required and may be a check number, a wire transfer number, or a "Pay.gov" transaction number used to transmit the user fee.

E-mail address for Principal Contacts

The second new information element on the amended PMN form would be optional and consist simply of the e-mail addresses for the principals listed on the Submitter Identification section of the PMN form. This information will help facilitate electronic communications with the proper point of contact from the submitting entity.

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, except where a test rule under TSCA section 4 has been promulgated for the chemical substance or mixture subject to the SNUR. 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

The proposed rulemaking serves as the public notice for this ICR. Interested parties should submit comments to the address listed at the end of this document. Responses will be taken into account in developing the final rulemaking.

3(c) Consultations

In addition to the public notice and comment period, OMB regulations, 5 CFR 1320.8(d)(1), 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. In accordance with this regulation, EPA will solicit consultation feedback from nine potential ICR respondents and data users with respect to this proposed rule ICR.

3(d) Effects of Less Frequent Collection

The frequency of the submission of information under TSCA section 5 is not under the Agency's control. Manufacturers of new chemical substances typically submit a PMN, SNUN, or MCAN at least 90 days prior to anticipated manufacturing or distribution of the substance for non-exempt commercial use. Submission of information thus is on an as-needed, on-occasion basis, initiated by respondents. Subsequent reporting would only be required if EPA determined that a specific use of a substance constituted a significant new use. Less frequent collection

would mean respondents not being required to submit data at all, which may present a violation of TSCA.

3(e) General Guidelines

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

3(f) Confidentiality

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

Based on its experience, EPA expects that most information included in TSCA section 5 notices will be CBI. EPA has developed an elaborate system to prevent unauthorized disclosure of CBI. This system includes procedures for logging material in and out of the Confidential Business Information Center (CBIC) at EPA headquarters and procedures for photocopying and transmitting CBI. These procedures apply to CBI submitted by manufacturers as well as CBI generated by EPA staff in the course of their review. Access to CBI is restricted to persons who need the information for their work. No one is allowed access to CBI without first undergoing instruction on procedures for handling CBI. Special procedures 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. These procedures are detailed in the current "TSCA CBI Protection Manual". EPA believes these procedures protect confidential information while providing the public with as much information as possible.

Any information being sent via CDX would be transmitted using secure technologies to protect CBI. The ePMN software would encrypt PMN submissions using a Federal Information Processing Standards (FIPS) compliant encryption module. The encryption module employs a public key algorithm which converts readable text into encrypted text. This public key is

downloaded from CDX to the ePMN software, and the corresponding private key is sent to EPA's New Chemical System (NCS). The encryption remains while your submission is transmitted via CDX to NCS. Your file can be decrypted only with the NCS's private key when it has reached its final destination. The NCS is the only party that possesses the private key, which converts the encrypted text back into readable text.

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

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

This information collection affects companies that manufacture, process or import chemical substances. These companies are typically found in NAICS major groups 325 (Chemical Manufacture) and 324 (Petroleum and Coal Products).

Universe of Affected Entities and Forms (on an annual basis)
Based on Average Submissions between 2003 and 2007

Number of Companies	305
Number of Companies (PMNs ONLY)	200
Average Number of Notices per Company	5.3
Average Number of PMNs per Company	3.6
Number of PMNs	720
Number of SNUNs - New Chemicals	8
Number of SNUNs - Existing Chemicals	10
Number of MCANs	3
Number of TMEAs	8
Number of LVE/LOREXs	419
Number of TERAs	2
Number of Tier I / IIs	3
Number of 5e Tests	12
Number of NOCs	443
% of Companies that are New in Subsequent Years	25%

4(b) Information Requested

(i) Data items, including record keeping requirements

With the exceptions of the new ePMN software and the minor revisions to the PMN form that will be incorporated into that software, that is, the required User Fee Payment Identity Number, optional E-mail address for Principal Contacts, and software-generated format for Biotech notices (EPA Form 6300-07, *TSCA Biotechnology Notice for Online Submissions*), the data items presently approved under OMB Control Numbers 2070-0012 and 2070-0038 are otherwise unchanged. In addition to these data items, respondents would also be required to register with CDX and complete the electronic signature agreement by completing

(ii) Respondent Activities

Register with EPA's CDX and Complete Electronic Signature Agreement

In order to submit electronically to EPA via CDX, one must first register with that system. To register in CDX, the CDX registrant (also referred to as "Electronic Signature Holder" or "Public/Private Key Holder") downloads two forms. This "Submitter" via CDX may be the Technical Contact, the Agent, the Senior Authoring Company Official (SACO), or the secretary of the SACO and is distinct from the definition of the submitter of the PMN form itself under TSCA. When these forms are filled out, signed, and returned to EPA, they will enable CDX to perform two important functions: (1) Authentication of Identity, and (2) Verification of Authorization. For authentication of identity, the submitter completes the Electronic Signature Agreement form along with a signature and date, has the form notarized, and mails it back to EPA.

The Verification of Authorization Form requires the signatures of the submitter and a senior authorizing company official, the person who normally signs the form at the bottom of page 2. There are separate parts to this form for the following: (1) the submitter and senior authorizing company official are the same, (2) the submitter is a paid employee of the company, (3) the submitter is an outside consultant for the company, (4) the submitter is also a legally co-bound and authorized representative agent for the company, and (5) the submitter and the legally co-bound and authorized representative agent for the company are two separate people. When these forms are received, EPA activates the submitter's registration in CDX and sends him or her an email notification.

Use the ePMN Software to Prepare TSCA Section 5 Notices

In all cases, respondents would use the ePMN software to:

- ***generate*** the submission materials for TSCA section 5 notices, including forms (i.e., the PMN form (EPA Form 7710-25), the NOC (EPA Form 7710-56) and the TSCA Biotechnology Notice for Online Submissions (EPA Form 6300-07)) as well as submission materials that do not require a standardized form or format; and,

- ***populate*** the submission materials with the relevant information

There are no required or official forms for certain TSCA section 5 notices, such as LVE modifications, LoRex Exemption modifications, and TMEAs. For biotechnology notices, no EPA-approved forms exist. To allow for electronic and paper submission of these notices using the ePMN software, the Agency is proposing the following:

(1) For exemption modifications, submitters would use the ePMN form by checking the "modification" box on page 1, filling in contact information on page 3, and including the previous exemption number and chemical identity information. A submitter may send a cover letter with the new revisions to the original exemption notice or the pertinent pages of the ePMN form.

(2) For a TMEA, the submitter would check the "TMEA" box on page 1 of the ePMN form, and either fill out the form or attach a cover letter for the body of the submission containing the information required by 40 CFR 720.38.

(3) Biotechnology notices would have their own menu option. Instead of selecting "Premanufacture Notice," a submitter would select "Biotech," which would prompt the software to present the submitter a header page with choices of biotech notices, and space to fill in contact information. The ePMN software will populate this information in a new form entitled, "TSCA Biotechnology Notice for Online Submissions" (EPA Form 6300-07). The Additional information would be submitted as an attachment(s).

Notice Type	**Use of ePMN Software**
PMN	Form 7710-25 generated and finalized by ePMN software.
Low Volume Exemption (LVE)	Form 7710-25 generated and finalized by ePMN software.
Test Market Exemption Application (TMEA)	ePMN software to generate finalized submission either using 7710-25 or cover letter and attached information.
NOC	ePMN software to generate finalized submission using Form 7710-56.
Biotechnology Notices	ePMN software to generate finalized "header" sheet (EPA Form 6300-07, *TSCA Biotechnology Notice for Online Submissions*) with contact data, add attachment with notice information, include signature page.
Modifications to Previous Notices	Form 7710-25 generated and finalized by ePMN software. Fill in pages 1, 2, and 3 of the Form, plus either applicable pages of Form, cover letter, or attachment.
Support Documents	ePMN software to generate finalized "header" sheet identifying reason for submission and contact data.

Finalize and Submit

A respondent's activities to finalize and a submit TSCA section 5 notices will depend on the chosen submission method. The ePMN software will require users to complete a finalization process before preparing the information for submission to EPA. During the finalization step,

the ePMN software checks that all legally required information is included and provides warnings for certain kinds of missing, incomplete or incorrect data.

Paper

After the ePMN finalization step is complete, respondents will print submission materials using the ePMN software, and sign them as required, and deliver the submission to EPA via US Mail or courier.

Optical disc

After the ePMN finalization step is complete, respondents will prepare the data generated by the ePMN software in XML for transfer to an optical disc. With limited exception, discs would be submitted with an original signed hard copy of page 2 (Certification page) and a hard copy of page 3 (a copy of page 3 is needed for contact information in the event that the disc is not readable). A disc-based TMEA submission would only need to be accompanied by a hard copy of the completed page 3. For biotechnology notices, a signed hard copy of a biotech certification would need to accompany the disc. Discs would need to be delivered only by courier service to avoid damage to the disk from the Agency's mail screening equipment.

Using ePMN Software to Submit Electronically to EPA via CDX

After the ePMN finalization step is complete, the ePMN software will prompt respondents to log-in to CDX. Respondents will the simply transmit the information to EPA online by clicking on the ePMN software's "send" button.

5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a) Agency Activities

The Agency activities described in ICRs that currently approved under OMB Control No. 2070-0012 and 2070-0038 remain unchanged, except as described below:

- convert to an electronic reporting system
- scan paper-based Section 5 submissions to create electronic data for inclusion in Agency data systems
- transfer data submitted on optical disc to Agency data systems
- acknowledge receipt of submissions and notify respondents of any submission deficiencies
- provide technical assistance to respondents

5(b) Collection Methodology and Management

For the past few years, submitters have been able to generate TSCA section 5 notices using an electronic version of the PMN form (EPA Form 7710-25) available at the EPA New Chemicals Program website (https://cdx.epa.gov/ssl/pmn/download.asp). The form, which used

Adobe Acrobat software, only allows submitters to complete and save the form electronically, and then print out and mail it to EPA as hard copy. Each company has to purchase Adobe Acrobat software to fill out the form. For those who wish to fill out the PMN form by hand or typewriter, a PDF version of the form is available from EPA's New Chemical website (http://www.epa.gov/opptintr/newchems/pubs/pmnpart1.pdf and http://www.epa.gov/opptintr/newchems/pubs/pmnpart2.pdf).

The ePMN software will be available as a free internet download. The Agency will also make available free optical discs containing the software. The data being transmitted electronically via CDX will be encrypted to protect CBI. The software will work with Windows, Macs, Linux, and UNIX-based computers, using XML for more efficient data transmittal to Agency data systems that once was performed manually.

Once CDX is implemented as a mechanism for submission of Section 5 notices and the ePMN requirements are in place, respondents submitting new Section 5 notices such as PMNs, NOCs, SNUNs, and related support documents such as correspondence, amendments and test data will initially have the option to use ePMN software to submit by paper, optical disc, or via CDX. Each of these submissions must be generated using the ePMN software and need to undergo a "finalization" step in the generation of the documents. After a two-year phase-in period, all submissions will be required to be submitted electronically via CDX.

However, NOCs and support documents that are submitted to the Agency for review after implementation of CDX-based submissions but that are related to Section 5 notices that were submitted to the Agency for review before implementation of CDX-based submissions will still have to be submitted by paper. The Agency is taking this position because although the Section 5 notices received after implementation of the new system will be entered into a newly created database, Section 5 notices submitted before promulgation of this rule will only exist in the "legacy" database, i.e., the database used prior to promulgation of this rule. This will similarly be the case for SNUNs and related support documents. Support documents that are submitted to the Agency for review after implementation of CDX-based submissions but that are related to SNUNs that were submitted to the Agency for review before implementation of CDX-based submissions will also still have to be submitted by paper. The Agency would prefer to allow everything to be submitted electronically; however, at this time the Agency does not have the resources to enter placeholders for old files in the new system to accommodate support documents and NOCs that will ultimately be submitted to the Agency for Section 5 notices and SNUNs submitted prior to the effective date of this rule.

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. However, since the Agency has no system for collecting official signatures for forms submitted on an optical disc, such as a CD, original signatures will have to accompany the disc and any paper forms submitted during the phase-in period.

The electronic submission software will change 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 will reduce both the cost and the time required to enter, review, edit and transmit data to the Agency. The

electronic submission software will also improve data quality because it will facilitate 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 will 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). Usually, these communications are sent through the mail. An electronic means of communication will provide significant time and resource savings for both parties.

The Agency is introducing the electronic submission software in two phases. The first year, the Agency will allow the submission of information for notices and support documents via CDX, optical disc, and using paper forms generated with the ePMN software. All paper submissions will be eliminated after the first year for all new Section 5 notices and support documents whose parent notices were submitted after the new system was implemented. Disc submissions generated using the ePMN software will be eliminated at the end of the second year for all new Section 5 notices and support documents whose original notices were submitted after the new system was implemented. After the second year, only electronic submissions via CDX will be allowed for new Section 5 notices and support documents whose related notices were submitted after the new system was implemented. Support documents whose parent notices were submitted before the new system was implemented will still need to be mailed as hard copy to the Agency. The Agency considers two years sufficient time for submitters to have gained experience using the ePMN software and confidence in the CDX delivery system.

The Adobe electronic form now in use for filling out the PMN form uses a “header” page at the beginning of the PMN form. The “header” page asks for certain information for the purpose of adding or spawning additional pages requested by the submitter. This page is not part of the SNUN that is presently submitted to the Agency. In the new ePMN software, there are header pages for support documents, and attachments that identify submitters and the nature of their communications. These header pages allow the software to identify and store data correctly in the Agency’s databases when submitted by paper.

Submitters will be required to use the ePMN software to generate Section 5 notices and support documents regardless of whether they are submitted via CDX ordelivered on a disc, or submitted on paper. A notice may be submitted on paper; however, for the notice to be declared complete, the entire PMN form must be generated and “finalized” using the software. Copying another form will not suffice. Disc submissions must be accompanied by an original, signed, hard copy of page 2 of the new e-PMN form (the Certification page), and page 3, (contact information in case the submitted disc is unreadable). All ePMN software users, regardless of how a document will be submitted, need to undergo a “finalization” step in generating a document.

During the "finalization" step, the e-PMN software checks that all legally required information is included, provides warnings where necessary, and saves data in a read-only format acceptable to the Agency. Section 5 notices whose data have not undergone the "finalization" step will be declared incomplete. This step is necessary to allow for an accurate and efficient transfer of data from an optical disc or a paper-based form to the EPA data systems. The word, "finalized", will be in the file name and the name will end with "_tsca". The "finalized" file (folder) will contain the CBI and non-CBI data in XML format that are non-editable. The CBI and non-CBI attachments will also be in this folder in their native format. Attachments must be submitted in one of EPA's approved formats for the Agency to be able to open the files.

The biggest difference between the old and new methods of data entry on the e-PMN form is the user interface. Data now will be entered through a series of pages or screens on the computer as opposed to being entered on the form itself. Most screens will represent a page of the printed e-PMN form. For those submitters who would like to see how their data looks on the e-PMN form once filled out, the new software will allow the submitter to navigate between the e-PMN form and a PDF version. The PDF or printed version will have the look of the original or current paper PMN form; however, submitters should not submit the PDF to the Agency because the submission will be in the wrong format and thus declared incomplete. Only the "finalized" read-only XML file folder will be accepted by the Agency.

The questions and pagination on the new e-PMN form will be the same as on the old PMN form, except that fields on the print form have been expanded to make more room for submitter information, which will result in the total number of pages being greater. Fields on the new print form have been realigned to make the form easier to scan. Once the old PMN form is phased out, submitters will no longer be able to use that form, and Section 5 notices using the old form will be considered incomplete.

Other changes to the e-PMN form will be the addition of a new required field on page 1 of the e-PMN form, a User Fee Payment Identity Number, to enable the Agency to more easily match a particular user fee with a particular notice submission. For example, the User Fee Payment Identity Number may be a check number, a wire transfer transaction number, or a "pay.gov" transaction number used to transmit the user fee. This information is presently in the submitter's possession. Also, EPA will request optional e-mail addresses for the principals listed on the Submitter Identification section of the e-PMN form.

The e-PMN software will include 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, similar to the existing PDF PMN form, the new e-PMN software will allow for the creation of a sanitized non-CBI version from the complete Section 5 notices submission containing CBI. It also will allow submitters to share a draft notice within their company during the creation of a Section 5 notices and to save a copy of the final file for future reference. The software will allow the submitter to create a profile with his/her contact information, which will save 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 to aid persons subject to this information collection 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

The reporting and recordkeeping requirements associated with TSCA section 5 are applicable to all affected entities, regardless of the size of the firm. However, OPPT has taken a number of steps intended to minimize the burden placed on small businesses. TSCA section 26(d) established the TSCA Assistance Office, now known as the Environmental Assistance Division (EAD), to provide technical and other non-financial assistance to manufacturers, importers and processors of chemical substances and mixtures. This office has established a toll-free hotline to assist small businesses complying with TSCA rules. It provides material such as copies of Federal Register notices, advisories, and other information on request, performs on-site field visits and consultations, and has hired a contractor to assist small businesses, free of charge, in complying with TSCA requirements. In addition, "small business concerns" submit a reduced fee of $100 (rather than $2,500) for each TSCA section 5 notice submitted pursuant to the user fee regulation at 40 CFR 700.45(a)(1).

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 incremental burden and costs estimates associated with the proposed electronic submission requirements for TSCA Section 5 Notices. The proposed rule would impact 305 respondents – 295 New Chemicals program respondents and 10 Existing Chemical program respondents. Although respondents would experience some incremental burden increases as a result of the ePMN rule, EPA expects that section 5 notice submitters will experience overall burden and cost savings associated with electronic form completion and submission via CDX.

This ICR Supporting Statement analyzes only the incremental paperwork burdens and costs that would be imposed by the proposed rule related to rule familiarization, CDX registration, CDX electronic signature, setting up a Pay.gov account. In addition, this Supporting Statement assesses the unit-level (as opposed to aggregate) changes in burden for each type of TSCA section 5 notice that would result from implementation of the proposed rule. Appendix 1 provides a complete year-by-year analysis of the proposed rule's aggregate impact on the estimated paperwork burdens and costs on the New and Existing Chemicals Programs, as addressed in *Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances*, (EPA

ICR No. 0574.13, OMB Control No. 2070-0012) and *TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals* (EPA ICR No 1188.08; OMB Control No. 2070-0038).

6(a) Estimating Respondent Burden

6(a)(i) New Rule-related Burdens

EPA expects that respondents would incur minimal additional burdens and costs in carrying out the additional paperwork activities that would be imposed by the rule. This includes the burden associated with activities that facilitate submission of an e-PMN: CDX registration, CDX electronic signature, setting up a Pay.gov account, and rule familiarization. These activities occur only once during the first year that an activity is undertaken.

Rule familiarization, for example, will be incurred by all companies during the first year following promulgation of the e-PMN rule, regardless of whether the e-PMN is submitted via paper, optical disc, or CDX. In addition, respondents that submit section 5 notices for the first time in subsequent years will incur rule familiarization burden the first year they submit a section 5 notice. Those respondents that submit e-PMNs again in subsequent years do not incur a subsequent rule familiarization burden. However for the sake of this ICR analysis, EPA annualized the expected 1st-year rule familiarization responses. The other activities (CDX registration, CDX electronic signature, setting up a Pay.gov account), while they are incurred only once, will be incurred in the year in which the respondents adopt electronic reporting via CDX.

Activity	Brief Assessment of Burden	Burden Estimate per Respondent
CDX registration	Based on the CROMERR Cost Benefit Analysis, EPA assumes that companies will spend 11 minutes per employee to register with CDX (EPA, 2004). Furthermore, EPA assumes that an average of four technical staff members and one manager will need to register for each company (5 employees/firm)	55 minutes (0.9 hours)
CDX electronic signature (labor)[1]	*Authentication of Identity*: Based on the CROMERR Cost Benefit Analysis, EPA assumes that companies will spend 15 minutes preparing, submitting, and filing an electronic signature agreement form to EPA per employee (EPA, 2004). This burden will apply to one manager and four technical staff members per company (5 employees/firm) for a subtotal of 75 minutes. *Verification of Authorization*: One manager will spend an additional 30 minutes accessing, preparing, and submitting verification forms for all authorized submitters to EPA	105 minutes (1.8 hours)

[1] The burden associated with CDX Electronic Signatures does not include costs associated with contacting EPA's CDX helpdesk to notify a change of submitter status, should one occur.

Activity	Brief Assessment of Burden	Burden Estimate per Respondent
E-payment via Pay.gov account[2]	Although establishment of a Pay.gov account will be optional, for the purposes of this ICR, companies are assumed to set up an account by which to make section 5 notice-related payments. One manager per company will establish a Pay.gov ID account, log into the system, and fill out an e-PMN payment form.	8 minutes (0.1 hours)
Rule Familiarization	Management and technical staff will spend time familiarizing themselves with the new requirements for electronically submitting their section 5 notices via CDX. EPA estimates that one manager will spend 33 minutes and one technical staff member will spend 16 minutes per company on rule familiarization.	49 minutes (0.8 hours)

EPA projects that one third of first year submissions and two thirds of all second year submissions will be made via CDX. All submissions must be made via CDX by the third year and beyond. The actual rates of adoption of CDX in years one and two of the rule could be higher or lower than EPA's projections. However, lacking any data on which to base other projections, EPA is assuming an even rate of adoption over the two-year phase-in period.

Also, EPA is proposing to modify certain data elements of the PMN form. The first modification is the removal of the 'Agent Signature Block' data field from the PMN form. EPA does not estimate the burden savings from removing the 'Agent Signature Block' because a review of previously submitted notices has shown that fewer than five percent of submissions have a completed "Agent Signature Block," and expected burden savings are insignificant. In addition, EPA is proposing to add two new data fields: (1) User Fee Payment Identification Number, and (2) optional email address of principals listed in the Submitters Identification section. EPA anticipates that these new fields will increase the technical burden by 10 minutes and 1 minute, respectively.[3]

6(a)(i)(A) Rule-related Burden – New Chemicals Program (2070-0012)

EPA estimates that the ePMN rule would impose an estimated program change increase of 353 annual burden hours on respondents, and that roughly 98 of the 295 new chemicals program respondents (about 1/3rd of respondents) will implement the rule provisions each year during the 3-year phase-in. This program change increase is associated with the time required to complete company-level paperwork activities related to the proposed ePMN rule requirements, i.e., CDX Registration, CDX Electronic Signature, E-Payment (Pay.gov ID), and Rule Familiarization.

[2] EPA's time estimate is based on best professional judgment of completing a TSCA User Fee form on the pay.gov website. This time estimate does not include the time required to click 'submit' for an e-PMN form and wait for payment processing.

[3] Based on Engineering Estimates of reporting e-mail address for TRI Reporting. Memo entitled TRI Reporting Burden Estimates from Hilary Eustace, David Cooper and Susan Day, Abt Associates, to Paul Borst, US EPA.., July, 2004.

Table 1
Annual New Chemicals Program Reporting Burden Under the e-PMN Rule

Type of Notice	Avg. Annual Responses[1]	Hrs. per Response	Total Reporting Hrs.
CDX Registration	98	0.9	90
CDX Electronic Signature	98	1.8	172
E-Payment (Pay.gov ID)	98	0.1	13
Rule Familiarization (Annualized)	98	0.8	78
Total			**353**

[1]*Average Annual Responses computed as the average of the number of notices filed annually from 2003 through 2007 based on OPPT, 2008, then adjusted by 15% to reflect only valid submissions. For section 5 notices not subject to the ePMN rule (R&D, Bona Fide, 5(e) Non-Testing, Instant Photographic and Correction Requests), the average annual number of responses is assumed to equal the number presented in the previous ICR*

6(a)(i)(B) Rule-related Burden – Existing Chemicals Program (2070-0038)

EPA estimates that the ePMN rule would impose an estimated program change increase of 10 annual burden hours on respondents, and that roughly 3 of the 10 existing chemicals program respondents (about 1/3rd of respondents) will implement the rule provisions each year during the 3-year phase-in. This program change increase is associated with the time required to complete company-level paperwork activities related to the proposed ePMN rule requirements, i.e., CDX Registration, CDX Electronic Signature, E-Payment (Pay.gov ID), and Rule Familiarization.

Table 2
Annual Existing Chemicals Program Reporting Burden Under the e-PMN Rule

Type of Notice	Avg. Annual Responses[1]	Hrs. per Response	Total Reporting Hrs.
CDX Registration	3	0.9	2.7
CDX Electronic Signature	3	1.8	5.4
E-Payment (Pay.gov ID)	3	0.1	0.3
Rule Familiarization (Annualized)	3	0.8	2.4
Total			**10.8**

[1] *EPA assumes that about one third of the respondents will adopt CDX submissions each year- (10/3) ~ 3 responses.*

6(a)(ii) Anticipated Burden Reductions Resulting from the Rule

EPA expects that section 5 notice submitters will experience overall burden and cost savings associated with completing TSCA section 5 notices electronically via the ePMN software and submitting those notices electronically via CDX. Specifically, EPA expects burden reduction for activities related to form completion, recordkeeping, and postage upon implementation of the ePMN rule. Respondents are expected to experience these burden reductions due to the efficiencies and reduced time associated with using the new ePMN

software to fill out section 5 notices and using CDX to submit these notices. Respondents are expected to realize burden savings each time a section 5 notice is submitted. Recordkeeping and postage savings would be realized in years when electronic reporting via CDX is used. The proposed rule would require that all notices be generated using the new ePMN software beginning in the first year following rule promulgation; however, form completion burden savings will be realized by all submitters immediately. Although respondents would be able to submit TSCA section 5 notices to EPA on optical discs during the first 2 years of rule implementation, EPA does not project any burden savings for this type of submission vehicle. Rather, EPA assumes that the overall amount of time and money invested in the preparation and submission of notices via optical disc would be similar to that required for paper-based submissions.

Firms that are subject to a New or Existing Chemical SNUR may respond to the SNUR in one of a few ways. The manners which firms may response are addressed in *TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals* (EPA ICR No 1188.08; OMB Control No. 2070-0038) and *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012). This rule-related ICR analyzes the incremental difference in reporting burden that would be brought about by the ePMN proposed rule when firms respond to a SNUR by submitting a SNUN via CDX and does not consider the burdens of other SNUR response options because they are unaffected by the proposed rule.

6(a)(ii)(A) Expected Recordkeeping Burden Reductions

EPA expects that recordkeeping burden for TSCA section 5 respondents will decrease due to the ePMN rule. Specifically, EPA assumes that recordkeeping burden will be reduced by half due to the efficiencies in creating and storing electronically section 5 notices and supporting documents. For most section 5 notices, baseline recordkeeping burden is estimated to be two hours. For these notices, one technical and one clerical staff member will each save 30 minutes on recordkeeping. For section 5(e) test notices, baseline recordkeeping burden is estimated to be 35 hours because of the need to copy and file relevant records. This includes records related to: manufacturing, importing, or processing volumes; shipment amounts and customer information; labels (documentation of labeling procedures and copies of labels); MSDS; and compliance with any additional restrictions on use, disposal, and discharge limitations. Therefore, for section 5(e) test notices, EPA estimates that one technical and one clerical staff member will each save 8.8 hours on recordkeeping. For Notices of Commencement (NOC), baseline recordkeeping burden is estimated to be 15 minutes. Therefore, for NOCs, one technical and one clerical staff member will each save four minutes on recordkeeping.

Table 3
Anticipated New & Existing Chemicals Program Recordkeeping Burden Hour Savings Under the ePMN Rule

Type of TSCA Section 5 Notice (New and Existing Chemicals Programs)	Current Estimated Recordkeeping Burden Per Response	Estimated Recordkeeping per Burden Response after Rule Implementation	Burden Saved Per Response
Full PMN	2.00	1.00	1.00
SNUN[1]	2.00	1.00	1.00
LVE	2.00	1.00	1.00
LoREX	2.00	1.00	1.00
MCAN	2.00	1.00	1.00
TME	2.00	1.00	1.00
TERA	2.00	1.00	1.00
Tier I	2.00	1.00	1.00
Tier II	2.00	1.00	1.00
5(e) Test submissions	35.0	17.5	17.5
NOC	0.25	0.125	0.125

[1]The recordkeeping burden for Existing Chemical SNUNs has been adjusted from the estimate of 5.67 hours calculated in *TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals* (EPA ICR No 1188.08; OMB Control No. 2070-0038), to 2 hours here, to be consistent with *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012) and the Economic Analysis for the proposed ePMN rule.

EPA expects no recordkeeping burden reductions or increases for the following:

- ***R&D exemption:*** Potential users of this exemption incur burdens related 3rd-party notification and recordkeeping. Users of this exemption do not need to submit information to EPA and, therefore, they will not need to register with CDX and will not be affected by the ePMN rule. Reductions in recordkeeping burden are linked with the respondents' use of the ePMN software to prepare and submit information electronically, and subsequent utilization of electronic storage of records related to the submission.

- ***Instant photographic film articles exemption notices:*** Submissions of instant photographic film articles exemption notices are very infrequent. EPA has not received any such notifications in many years and does not expect to receive any such notices during the course of the next several years. Therefore, EPA does not expect that any associated burden will be imposed upon respondents.

- ***Non-Testing 5(e) submissions:*** Respondents would not be permitted to make this type of submission via CDX under the ePMN rule. Reductions in recordkeeping burden are linked with the respondents' use of the ePMN software to prepare and submit information electronically, and subsequent utilization of electronic storage of records related to the submission.

- ***Bona Fides:*** Respondents would not be permitted to make this type of submission via CDX under the ePMN rule. Reductions in recordkeeping burden are linked with the respondents' use of the ePMN software to prepare and submit information electronically, and subsequent utilization of electronic storage of records related to the submission.

- ***Correction requests:*** Respondents would not be permitted to make this type of submission via CDX under the ePMN rule. Reductions in recordkeeping burden are linked with the respondents' use of the ePMN software to prepare and submit information electronically, and subsequent utilization of electronic storage of records related to the submission.

6(a)(ii)(B) Expected Reporting Burden Reductions

6(a)(ii)(B)(1) New Chemicals Program Burden (2070-0012)

The unit burdens for the various types of notices traditionally submitted on paper to EPA under the New Chemicals program are estimated in the ICR entitled *Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances*, approved under OMB Control No. 2070-0012. EPA expects that the electronic submission option will reduce burden associated with reporting for PMN, New Chemical SNUN, LVE, LoREX, MCAN, TME, TERA, Tier I and II Exemptions, 5(e) Test, and slightly increase burden associated with NOC submissions.[4] The burden estimates for each of these submission types includes 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 CBI, and maintaining a file of the submission (EPA, 1994).

The convenience of an automated electronic form may reduce the time required to read and become familiar with the form. The ePMN software will also enable the submitter to create a sanitized version of the form containing CBI, decreasing the effort to do this manually. Maintaining electronic files may also be less burdensome than hardcopy files. In addition, burden reduction may result from eliminating or reducing some of the activities associated with paper submission, such as printing, photocopying, and mailing paper notices. Furthermore, electronic data submission will reduce the time required for EPA staff to review the information, because there will be no need for manual data entry or processing.

Table 4
Anticipated New Chemicals Program Reporting Burden Savings Under the ePMN Rule

Type of New Chemicals Program Notice	Current Estimated Response Burden	Estimated Response Burden after ePMN rule	Burden Saved Per Response
Full PMN	105 hrs. (EPA, 1994)	92.2 hrs.	12.8 hrs.
New Chemical SNUN	105 (EPA, 1994)	92.2	12.8
LVE	105 (EPA, 1994)	92.2	12.8
LoREX	105 (EPA, 1994)	92.2	12.8
MCAN	302 (EPA, 1994)	288.2	13.8
TME	98 (EPA, 1994)	86.2	11.8
TERA	521 (EPA, 1997)	507.2	13.8
Tier I	114 (EPA, 1997)	110.2	3.8
Tier II	114 (EPA, 1997)	110.2	3.8
5(e) Test submissions	155	150.7	4.3
NOC	0.5	0.6	(0.1)

[4] Reporting burden for NOCs is expected to increase slightly because the very small amount of clerical burden that is reduced is offset by the increase of 11 minutes in reporting time due to two new data fields on the e-PMN form. The total increase in reporting burden for NOCs is less than 0.1 hours.

EPA expects no reporting burden reductions or increases for the following:

- ***R&D exemption:*** Potential users of this exemption incur burdens related 3rd-party notification and recordkeeping. Users of this exemption do not need to submit information to EPA and, therefore, they will not need to register with CDX and will not be affected by the ePMN rule.

- ***Instant photographic film articles exemption notices:*** Submissions of instant photographic film articles exemption notices are very infrequent. EPA has not received any such notifications in many years and does not expect to receive any such notices during the course of the next several years. Therefore, EPA does not expect that any associated burden will be imposed upon respondents.

- ***Non-Testing 5(e) submissions:*** Respondents would not be permitted to make this type of submission via CDX under the ePMN rule.

- ***Bona Fides:*** Respondents would not be permitted to make this type of submission via CDX under the ePMN rule.

- ***Correction requests:*** Respondents would not be permitted to make this type of submission via CDX under the ePMN rule.

6(a)(ii)(B)(2) Existing Chemicals Program Burden (2070-0038)

As a result of the ePMN rule, existing chemical SNUN respondents will experience a reduction in reporting burden due to the efficiencies and reduced time associated with using the ePMN software to complete a SNUN, and using CDX to submit the notice. Reporting burden savings are expected to be realized each time a SNUN is submitted. The proposed rule would require that all SNUNs be generated using the ePMN software beginning in the first year following rule promulgation. Consequently, form completion burden savings will be realized by all SNUN submitters immediately**.**

Table 5
Anticipated Existing Chemicals Program Reporting Burden Savings Under the ePMN Rule

Type of Existing Chemicals Program Notice	Current Estimated Response Burden	Estimated Response Burden after ePMN rule	Burden Saved Per Response
Existing Chemical SNUN	105	92.2	12.8

[1]The reporting burden for Existing Chemical SNUNs has been adjusted from the estimate of 113.25 hours calculated in *TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals* (EPA ICR No 1188.08; OMB Control No. 2070-0038), to 105 hours here, to be consistent with *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012) and the Economic Analysis for the proposed ePMN rule.

6(b) Estimating Respondent Cost

The average annual respondent labor costs associated with the paperwork activities described in this rule-related ICR (i.e., CDX registration, CDX electronic signature, setting up a Pay.gov account, and rule familiarization) are estimated to be $19,998. As indicated in Tables 6 and 7, this estimate is composed of the following costs: $19,404 for New Chemicals program respondents and $594 for Existing Chemicals program respondents. The wage rates indicated in these tables were derived as described in section 6(b)(1) of this supporting statement.

Table 6
Average Annual New Chemicals Program Respondent Cost Calculation

Activity / Notice	Avg. Annual # of Companies / Responses	Total Burden and Wage Rate by Labor Category						Total Avg. Costs Per Company / Notice	Total Company / Notice Cost ($)
		Managerial		Technical		Clerical			
		Hrs	Wage ($)	Hrs	Wage ($)	Hrs	Wage ($)		
CDX Registration	98	0.2	58.71	0.7	51.35	0	25.54	48	4,704
CDX Electronic Signature	98	0.8	58.71	1.0	51.35	0	25.54	98	9,604
E-Payment (Pay.Gov ID)	98	0.1	58.71	0.0	51.35	0	25.54	8	784
Rule Familiarization (Annualized)	98	0.3	58.71	0.6	51.35	0	25.54	44	4,312
Total									**19,404**

Table 7
Average Annual Existing Chemicals Program Respondent Cost Calculation

Activity / Notice	Avg. Annual # of Companies / Responses	Total Burden and Wage Rate by Labor Category						Total Avg. Costs Per Company / Notice	Total Company / Notice Cost ($)
		Managerial		Technical		Clerical			
		Hrs	Wage ($)	Hrs	Wage ($)	Hrs	Wage ($)		
CDX Registration	3	0.2	58.71	0.7	51.35	0	25.54	48	144
CDX Electronic Signature	3	0.8	58.71	1.0	51.35	0	25.54	98	294
E-Payment (Pay.Gov ID)	3	0.1	58.71	0.0	51.35	0	25.54	8	24
Rule Familiarization (Annualized)	3	0.3	58.71	0.6	51.35	0	25.54	44	132
Total									**594**

6(b)(i) Derivation of Wage Rates

To determine the per-company and per-form costs, the unit burden hour estimates are multiplied by fully loaded hourly rates for the appropriate categories of labor conducting these activities.[5] Loaded hourly rates are the product of wages, benefits, and overhead. Hourly wage rates are divided into three categories: managerial, technical, and clerical. Average wage and salary data for these categories are obtained from the Employer Costs for Employee Compensation (ECEC) report from the Bureau of Labor Statistics (BLS) for all goods-producing,

[5] Employer Costs for Employee Compensation, Private industry workers, Goods-producing industries, white-collar occupations, as published by the U.S. Department of Labor, Bureau of Labor Statistics. Table 11 of the *Employer Costs for Employee Compensation Summary*, December 2007.

private industries. The additional cost of benefits, such as paid leave and insurance, is also derived from information provided in the ECEC report.

Loading factors for benefits are calculated separately for managerial, technical, and clerical labor by dividing the benefits percentage of total compensation by the wage percentage of total compensation. Based on information provided by the chemical industry and chemical industry trade associations, an additional loading factor of 17 percent is applied for general overhead. This approach is used for consistency with Office of Pollution Prevention and Toxics economic analyses for two major rulemakings: *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* (EPA, 2002), and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002a). This loading factor is added to the benefits loading factor, then applied to the base wage. The new wage rates are calculated using current data on salaries and benefits for these three labor categories. The fully loaded 2007 hourly wage rates are shown in Table 8. Details on the calculation of the wage rates can be found in Attachment 10.

Table 8
Loaded Hourly Wage Rates by Labor Category 2007

Labor Category	Occupational Type	Average Hourly Wage	Benefit (% wages)	Overhead (% wages)	Loaded Hourly Rate
Managerial	*Management, business, and financial*	$36.44	44.1%	17%	**$58.71**
Technical	*Professional and related*	$32.52	40.9%	17%	**$51.35**
Clerical	*Office and administrative support*	$15.78	44.9%	17%	**$25.54**

Source: BLS, 2007. Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Private industry workers, by occupational group and full-time and part-time status, December 2007. Table 11. http://www.bls.gov/news.release/ecec.t11.htm

6(c) Estimating Agency Burden and Cost

The conversion to an electronic reporting system as well as the adoption of CDX to facilitate form submission and processing are expected to create long term burden reductions and efficiencies for EPA. Because the current ePMN program is based entirely on paper submissions, the Agency first will need to convert to an electronic reporting system. EPA estimates incurring a one time cost of $200,000 spread out over the first two years to convert the New Chemicals section 5 notice program to an electronic system.[6] In addition, annual costs will be associated with the operation and maintenance (O&M) of CDX for the ePMN data flow. EPA developed an estimate of CDX O&M costs attributable to the ePMN program by apportioning the overall CDX maintenance cost estimated in the CROMERR *Cost Benefit Analysis, Final* (EPA, 2004) to individual programs. This approach yields an estimate of $57,353 per year per program. Note

[6] US EPA, 2004. Cross-Media Electronic Reporting Rule (CROMERR) Cost Benefit Analysis. Final. November 17, 2004.pg 19. Following the methodology in the CROMERR Cost Benefit Analysis, this cost is distributed over the first two years following promulgation of the rule.

that although the ePMN data flow will be smaller than the data flows included in the CROMERR analysis, the CROMERR analysis does not include costs associated with operations and, therefore, the $57,353 might be considered a lower bound estimate of total O&M.

The Agency will also incur costs associated with providing technical assistance to section 5 notice submitters. This technical assistance will include conducting a beta or pilot test of the new submission process with approximately 50 submitters and conducting approximately three training sessions around the country to demonstrate the tool and other outreach, including a hotline. Although EPA is not able to quantify the costs at this time, these Agency activities are likely to require both labor and extramural resources.

Agency burden savings are expected due to the elimination of the need to process paper forms, reduced quality assurance/quality control (QA/QC) and O&M costs for the existing system. Potential Agency burden savings associated with the e-PMN rule are characterized based on information in the *Business Case Analysis of EPA's Central Data Exchange* (EPA, 2007) regarding the estimated monetary benefit from using CDX. Of the six Program Data Flows studied in the CDX *Business Case Analysis*, monetary benefits from using CDX as compared to a paper submission baseline were quantified for two flows: TRI (Toxic Release Inventory) and e-NOI (electronic Notice of Intent under the National Pollution Discharge Elimination System). Benefits ranged from 11 percent savings (e-NOI) to 22 percent savings (TRI) compared to the cost of the baseline process. For this analysis, an average savings of 16.5 percent savings annually was assumed. However, because EPA is proposing to phase-in electronic reporting via CDX over a two-year period, Agency savings will not be fully realized until the end of the two-year phase-in period.

6(d) Bottom Line Burden Hours and Cost

Table 9. Total Annual Bottom Line Burden and Costs / Master Table

Collection Activity	Annual Burden Hours	Annual Costs
Annual Respondent Burden and Costs		
Additional New Chemicals Program Burden Under the ePMN Rule (Table 1)	353	$19,404
Additional Existing Chemicals Program Burden Under the ePMN Rule (Table 2)	10	$594
Respondent Total	363	$19,998.00

6(e) Reason for Changes in Burden

Not applicable. This request describes new paperwork activities related to the implementation of the proposed ePMN rulemaking. These activities include CDX registration, CDX electronic signature, setting up a Pay.gov account for online fee payments, and rule familiarization. New Chemicals program respondents would incur an annual average of 353 additional hours of rule implementation burden, and Existing Chemicals program respondents an annual average of 10 additional hours. The estimated total annual rule-related burden is 363 hours. This increase is a program change.

EPA expects that this increase will be offset by substantial burden reductions brought on by efficiencies related to electronic reporting upon implementation of the final rule. These expected reductions are summarized in section 6(b) and described in detail in Appendix 1.

6(f) Burden Statement

The estimated annual respondent burden for this rule-related collection is 363 hours and includes an estimated average burden per response of 0.9 hours for CDX registration, 1.8 hours for requesting a CDX electronic signature, 0.1 hours for establishing an account for electronic fee payments, and 0.8 hours for rule familiarization. According to the Paperwork Reduction Act, "burden" 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. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

The Agency has established a public docket for the proposed rule under Docket ID No. EPA-HQ-OPPT-2008-0296, 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-2008-0296 and OMB Control No. 2070-NEW, 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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LIST OF APPENDICES

Appendix 1: **Impact Analysis of the Proposed TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting Rule [RIN 2070-AJ41] on Paperwork Burdens Approved under Existing EPA ICRs**

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-2008-0296**. These attachments are available for online viewing at www.regulations.gov or otherwise accessed as described in section 6(f) of the supporting statement.

Attachment 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 700 –General**. Also available online at the National Archives and Records Administration's Electronic CFR Website

Attachment 3: **40 CFR Part 720 – Premanufacture Notification**. Also available online at the National Archives and Records Administration's Electronic CFR Website

Attachment 4: **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 5: **40 CFR Part 723 - Premanufacture Notification Exemptions**. Also available online at the National Archives and Records Administration's Electronic CFR Website

Attachment 6: **40 CFR Part 725 – Reporting Requirements And Review Processes For Microorganisms**. Also available online at the National Archives and Records Administration's Electronic CFR Website

Attachment 7: **EPA Form 7710-25 – Premanufacture Notice.** Also available online at http://epa.gov/oppt/newchems/pubs/pmnforms.htm

Attachment 8: **EPA Form 7710-56 – Notice of Commencement of Manufacture or Import.** Also available online at http://epa.gov/oppt/newchems/pubs/pmnforms.htm

Attachment 9: **Screenshots of ePMN Software Tool**

Attachment 10: **Derivation of Industry Wage Rates and Agency Costs**

OMB Control Number 2070-NEW; EPA ICR Number 2327.01

New Information Collection Activities for Electronic Submissions under TSCA Section 5

Appendix 1

Impact Analysis of the Proposed TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting Rule [RIN 2070-AJ41] on Paperwork Burdens Approved under Existing EPA ICRs

TABLE OF CONTENTS

1.0 Introduction

This appendix analyzes the expected impact of the proposed TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting Rule [RIN 2070-AJ41] on the paperwork burden associated with the following existing approved ICRs:

- Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances (OMB Control No. 2070-0012)

- TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals (OMB Control No. 2070-0038).

The two ICRs have some similar information collection components; this appendix describes certain baseline adjustments made for consistency between burden estimates. In addition, this appendix also describes the program change-related burden increases and reductions that are the expected outcome of implementing the ePMN rule.

1.1 Terminology

1.1.1 Company-level Burden

Company-level burden includes those activities that facilitate submission of an ePMN: CDX registration, CDX electronic signature (i.e., authentication of identity and verification of authorization), setting up a Pay.gov account, and rule familiarization. All activities performed at the company-level occur only once during the first year that an activity is undertaken. Rule familiarization, for example, will be incurred by all companies during the first year following promulgation of the ePMN rule, regardless of whether the ePMN is submitted via paper, optical disc, or CDX. In addition, companies that submit section 5 notices for the first time in subsequent years will incur rule familiarization burden the first year they submit a section 5 notice. Those companies that submit ePMNs again in subsequent years do not incur a subsequent rule familiarization burden. All other company-level activities, while they are incurred only once, will be incurred in the year in which the company adopts electronic reporting via CDX.

1.1.2 Form-level Burden

Form-level burden includes form completion, recordkeeping, and postage. As a result of the ePMN rule, submitters will experience a reduction in form-level burden due to the efficiencies and reduced time associated with using the new ePMN software to fill out section 5 notices and using CDX to submit these notices. All form-level burden savings are expected to be realized each time a section 5 notice is submitted. Recordkeeping and postage savings will be realized in years when electronic reporting via CDX is used. Because all notices must be generated using the new ePMN software beginning in the first year following rule promulgation, however, form completion burden saving will be realized by all submitters immediately.

1.2 Assumptions

1.2.1 Respondents

This information collection affects companies that manufacture, process or import chemical substances. These companies are typically found in NAICS major groups 325 (Chemical Manufacture) and 324 (Petroleum and Coal Products). EPA estimates that there are 305 respondent companies that will submit TSCA section 5 notices to EPA. The Agency estimates 295 respondents under the New Chemicals Program and an additional 10 respondents under the Existing Chemicals Program.

Burden and cost calculations are based on the assumption that EPA will receive an annual average of 1,958 TSCA section 5 notices under the New Chemicals program and 10 TSCA section 5 notices under Existing Chemicals program. The estimated number of notices that will be submitted under the New Chemicals program is derived by averaging the number of notices received in years 2003 through 2007 for each of the submission types listed in the paragraph above, adjusting these averages by 15 percent to reflect only valid submissions and then summing these averages (See Table 1).

Table 1
Universe of Affected Entities and Forms (on an annual basis)
Based on Average Submissions between 2003 and 2007

Number of Companies	305
Number of Companies (PMNs ONLY)	200
Average Number of Notices per Company	5.3
Average Number of PMNs per Company	3.6
Number of PMNs	720
Number of SNUNs - New Chemicals	8
Number of SNUNs - Existing Chemicals	10
Number of MCANs	3
Number of TMEAs	8
Number of LVE/LOREXs	419
Number of TERAs	2
Number of Tier I / IIs	3
Number of 5e Tests	12
Number of NOCs	443
% of Companies that are New in Subsequent Years	25%

1.2.2 Number and Types of TSCA Section 5 Notices Submitted Under New Chemicals Program

The number of notices that EPA expects to be submitted each year is typically estimated by averaging the number of each type of submission received over the past three years according to data provided in the *OPPT New Chemicals Annual Report* (EPA, 2006) and adjusting it by 15 percent to reflect only valid submissions. However, for this ICR renewal, the numbers of notices

were averaged for the past five years (2003 through 2007) to provide a longer term picture of section 5 activity as part of the economic analysis for the ePMN rule **(**EPA, 2008.)

Prior to the 1995 amendments to the PMN rule, 70 to 80 percent of all TSCA section 5 notices were full PMN submissions. From 1995 through 2003, the increase in exemptions did not significantly change this distribution. However, since 2003, full PMN submissions accounted on average for approximately 60 percent of all TSCA section 5 submissions. EPA expects few persons to submit significant new use notices (SNUNs). The number of SNUNs submitted is a function of the number of chemicals regulated under Significant New Use Rules (SNURs), which are relatively few. Based on the average number of SNUNs received annually during the last five years, the Agency expects to receive approximately eight SNUNs annually.

The amendments also placed stricter control on bona fide notices, which are intended to establish bona fide intent on the part of the submitter to manufacture or import a chemical substance. These controls were established in response to the steadily increasing number of bona fide notices submitted to EPA. The amendments have caused a significant reduction in bona fide submissions. Historical EPA data suggests that EPA should expect 116 bona fide notices to be submitted annually.

On average, EPA expects LVE and LoREX exemptions to account for approximately 419 notices annually. TMEs are expected to average eight applications per year, or less than one percent of all TSCA section 5 notices. NOCs are expected to account for 443 notices annually, while correction requests are expected to account for nine notices annually, or less than one percent of all TSCA section 5 notices (EPA, 2006, and EPA, 2008).

The various exemptions available to submitters since the 1995 PMN amendments have reduced significantly the need for consent order development and post-notice data review. Historical EPA data indicate that such consent orders and post-notice data reviews will account for roughly two percent of the total TSCA section 5 notices. Based on historical data, EPA estimates 28 cases would be subject to TSCA section 5(e) consent order restrictions burden, with 12 cases requiring test data, and 16 non-testing TSCA section 5(e) cases. Testing is usually contracted out to a laboratory, thus the burden associated with testing requirements represents the time that personnel from the submitting firm would spend overseeing the testing, assumed to be 25 percent of the lab burden.

1.2.3 Number and Types of TSCA Section 5 Notices Submitted Under Existing Chemicals Program

During the years 2004 through 2007, EPA promulgated 3 existing chemical SNURs under TSCA Section 5(a)(2). However, EPA expects this activity to increase over the next three-year period as the Agency initiates work under the Security and Prosperity Partnership (SPP) to complete risk characterizations and take necessary actions on more than 6,750 chemicals by 2012**.** Therefore, EPA is estimating it will promulgate an average of 2 additional existing chemical SNURs per year (for a total of 5 existing chemical SNURs per year) under TSCA Section 5(a)(2) during the three-year period covered by this ICR renewal (see Table 2).

Table 2
Anticipated Number of SNURs and SNUNs
Under The Existing Chemicals Program

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**

EPA may receive SNUNs as a result of SNURs promulgated under either the New Chemicals Program or the Existing Chemicals Program. EPA develops SNURs under the New Chemicals Program in order to bind manufacturers and processors of chemicals reviewed under its Premanufacture Notice (PMN) review process to certain requirements. EPA also develops SNURs under the existing chemical program under TSCA Section 5(a)(2). This analysis covers only the SNURs developed under the Existing Chemicals Program, and therefore, only the costs and burdens associated with SNUNs received based on those SNURs are estimated here.

EPA's experience has been that the Agency has received on average only 10 SNUNs per year in response to the promulgation of a total of well over 1,000 SNURs under both its New and Existing Chemicals Programs. Of those SNUNs, only a fraction are the result of SNURs promulgated under Section 5(a)(2). For this rule-related ICR, however, as shown in Table 2, EPA is using the conservative estimate of 10 SNUNs per year for the existing chemicals program to take into account the increased level of activity EPA is expecting to occur because of the SPP program.

Given the uncertainty in projecting possible new uses for existing chemicals, EPA cannot determine the number of firms that would be affected by any given SNUR, or whether any one firm might engage in more than one new use of a chemical subject to a SNUR. Therefore, 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.

1.2.3.1 Possible Responses to a SNUR

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 four 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 intending not 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 manufactures or processes the substance or mixture in a manner that does not constitute a new use under the SNUR.

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

In addition, under current regulations at 40 CFR 721.5(a)(2), all manufacturers, processors, and importers of chemicals subject to SNURs are required to submit a SNUN regardless of whether they engage in a significant new use unless certain information can be documented [1]. However, without prior knowledge of chemicals that would be the subject of future SNURs, EPA cannot estimate the number of potentially affected entities subject to 40 CFR 721.5(a)(2).

2.0 Impacts of ePMN Proposed Rule on New Chemicals Program Burdens

2.1 Reporting Burden

As shown in Tables 3, 4 and 5, the total respondent reporting burden associated with this information collection is estimated to total 114,337 hours in the first year following promulgation of the e-PMN rule, and 114,096 hours in both the second and third years following promulgation. This burden estimate is calculated by multiplying the hours of reporting burden by the number of each type of notice that EPA expects to receive and summing across the notice types. Note that burden is adjusted to reflect the savings associated with the ePMN rule in each year of the phase-in period.

The baseline reporting burden hours for each type of notice were estimated in *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012). However, EPA expects that promulgation of the ePMN rule will affect the existing reporting burden hour estimates for each type of notice, as described in this section and summarized in Tables 3, 4 and 5.

Because the proposed ePMN rule allows the use of CDX to be phased-in over the three-year period, the number of companies and forms using CDX will vary across the phase-in period.

[1] Unless manufacturers, processors, and importers of chemicals subject to SNURs either have 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.

Therefore, burden hours are presented separately for each year of the phase-in period. Prior to the ePMN rule, only form-level burden was estimated for section 5 notices. Due to new activities that will occur at the company-level once electronic reporting via CDX is available, burden is broken out at the company and form level in the rule-related ICR.

Table 3
Revised New Chemicals Program Reporting Burden Under the ePMN Rule, Year 1

Type of Notice	Avg. Annual Companies/Responses[1]	Current Average Reporting Hours per Company/Response	Revised Average Reporting Hours per Company/Response	Revised Total Reporting Hours
COMPANY BURDEN				
CDX Registration	98	0	0.9	90
CDX Electronic Signature	98	0	1.8	172
E-Payment (Pay.gov ID)	98	0	0.1	13
Rule Familiarization	295	0	0.8	241
Total (Company)				**516**
FORM BURDEN				
PMN	720	105	92.2	66,414
SNUN	8	105	92.2	705
MCAN	3	302	288.2	980
Exemptions:				
TME	8	98	86.2	659
LVE/LoREX	419	105	92.2	38,629
TERA	2	521	507.2	862
Tier I and II	3	114	110.2	281
R&D	200	2.5	2.5	500
Instant photographic	0	0.5	0.5	0
Bona Fide	116	20	20	2,320
5(e) Test	12	155	150.7	1,793
Non-Testing 5(e) Burden	16	25	25	400
NOC	443	0.5	0.6	258
Correction Request	9	2	2	18
Total (Form)	**1,958**			**113,821**
Total (Combined Company and Form)				**114,337**

[1]Average Annual Responses computed as the average of the number of notices filed annually from 2003 through 2007 based on OPPT, 2008, then adjusted by 15% to reflect only valid submissions. For section 5 notices not subject to the ePMN rule (R&D, Bona Fide, 5(e) Non-Testing, Instant Photographic and Correction Requests), the average annual number of responses is assumed to equal the number presented in *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012).

Table 4
Revised New Chemicals Program Reporting Burden Under the ePMN Rule, Year 2

Type of Notice	Avg. Annual Companies/Responses[1]	Current Average Reporting Hours per Company/Response	Revised Average Reporting Hours per Company/Response	Revised Total Reporting Hours
COMPANY BURDEN				
CDX Registration	98	0	0.9	90
CDX Electronic Signature	98	0	1.8	172
E-Payment (Pay.gov ID)	98	0	0.1	13
Rule Familiarization	0	0	0.8	0
Total (Company)				**275**
FORM BURDEN				
PMN	720	105	92.2	66,414
SNUN	8	105	92.2	705
MCAN	3	302	288.2	980
Exemptions:				
TME	8	98	86.2	659
LVE/LoREX	419	105	92.2	38,629
TERA	2	521	507.2	862
Tier I and II	3	114	110.2	281
R&D	200	2.5	2.5	500
Instant photographic	0	0.5	0.5	0
Bona Fide	116	20	20	2,320
5(e) Test	12	155	150.7	1,793
Non-Testing 5(e) Burden	16	25	25	400
NOC	443	0.5	0.6	258
Correction Request	9	2	2	18
Total (Form)	**1,958**			**113,821**
Total (Combined Company and Form)				**114,096**

[1]Average Annual Responses computed as the average of the number of notices filed annually from 2003 through 2007 based on OPPT, 2008, then adjusted by 15% to reflect only valid submissions. For section 5 notices not subject to the ePMN rule (R&D, Bona Fide, 5(e) Non-Testing, Instant Photographic and Correction Requests), the average annual number of responses is assumed to equal the number presented in *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012).

Table 5
Revised New Chemicals Program Reporting Burden Under the ePMN Rule, Year 3

Type of Notice	Avg. Annual Companies/Responses[1]	Current Average Reporting Hours per Company/Response	Revised Average Reporting Hours per Company/Response	Revised Total Reporting Hours
COMPANY BURDEN				
CDX Registration	98	0	0.9	90
CDX Electronic Signature	98	0	1.8	172
E-Payment (Pay.gov ID)	98	0	0.1	13
Rule Familiarization	0	0	0.8	0
Total (Company)				**275**
FORM BURDEN				
PMN	720	105	92.2	66,414
SNUN	8	105	92.2	705
MCAN	3	302	288.2	980
Exemptions:				
TME	8	98	86.2	659
LVE/LoREX	419	105	92.2	38,629
TERA	2	521	507.2	862
Tier I and II	3	114	110.2	281
R&D	200	2.5	2.5	500
Instant photographic	0	0.5	0.5	0
Bona Fide	116	20	20	2,320
5(e) Test	12	155	150.7	1,793
Non-Testing 5(e) Burden	16	25	25	400
NOC	443	0.5	0.6	258
Correction Request	9	2	2	18
Total (Form)	**1,958**			**113,821**
Total (Combined Company and Form)				**114,096**

[1]Average Annual Responses computed as the average of the number of notices filed annually from 2003 through 2007 based on OPPT, 2008, then adjusted by 15% to reflect only valid submissions. For section 5 notices not subject to the ePMN rule (R&D, Bona Fide, 5(e) Non-Testing, Instant Photographic and Correction Requests), the average annual number of responses is assumed to equal the number presented in *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012).

2.2 Recordkeeping Burden

EPA also expects that recordkeeping burden will decrease due to the ePMN rule. Specifically, EPA assumes that recordkeeping burden will be reduced by half due to the efficiencies in creating and storing electronically section 5 notices and supporting documents. For most section 5 notices, baseline recordkeeping burden is estimated to be two hours. For these notices, one technical and one clerical staff member will each save 30 minutes on recordkeeping. For section 5(e) test notices, baseline recordkeeping burden is estimated to be 35 hours because of the need to copy and file relevant records. This includes records related to: manufacturing, importing, or processing volumes; shipment amounts and customer information;

labels (documentation of labeling procedures and copies of labels); MSDS; and compliance with any additional restrictions on use, disposal, and discharge limitations. Therefore, for section 5(e) test notices, EPA estimates that one technical and one clerical staff member will each save 8.8 hours on recordkeeping. For Notices of Commencement (NOC), baseline recordkeeping burden is estimated to be 15 minutes. Therefore, for NOCs, one technical and one clerical staff member will each save four minutes on recordkeeping.

As shown in Tables 6, 7, and 8, the total respondent recordkeeping burden associated with this information collection is estimated to equal 2,751 hours in the first year following the effective date of the ePMN rule, 2,276 hours in the second year, and 1,800 hours in the third year following the effective date of the final rule. This burden estimate is calculated by multiplying the estimated recordkeeping burden associated with each type of submission (as estimated in EPA 1994) by the estimated number of submissions for each notice and then summing across notice types. Note that recordkeeping burden is adjusted by the savings associated with electronic reporting via CDX in each year of the phase-in period.

Once a respondent submits information in an initial TSCA section 5 submission, the burden for maintaining or updating these records is minimal. The Agency had assumed an aggregate annualized recordkeeping burden of two hours for each PMN, SNUN, MCAN, or exemption submission, or biotech submission. This was based on the recordkeeping burden associated with essential technical requirements, such as records that demonstrate that the first commercial batch of chemical manufactured for commercial purposes under the exemption met certain eligibility criteria. The recordkeeping burden for 5(e) testing and non-testing 5(e) burden were 35 and 25 hours, respectively (EPA, 1994). The Agency expects that promulgation of the ePMN rule and the receipt of fewer submissions will reduce the recordkeeping burden from the current total of 4,056 hours to 1,800 hours by the third year. Tables 6, 7, and 8 summarize the overall respondent recordkeeping burden following implementation of the ePMN rule.

Table 6

Revised New Chemicals Program Respondent Recordkeeping Burden Under the ePMN Rule, Year 1

Type of Notice	Average Annual Responses via non-CDX[1]	Average Annual Responses via CDX[1]	Current Average Recordkeeping Hours per non-CDX Response	Revised Average Recordkeeping Hours per CDX Response	Total Recordkeeping Hours for non-CDX	Total Recordkeeping Hours for CDX	Total Recordkeeping Hours for all Responses
PMN	480	240	2	1	961	240	1,201
SNUN	5	3	2	1	10	3	13
MCAN	2	1	2	1	5	1	6
Exemptions:							0
TME	5	3	2	1	10	3	13
LVE/LoREX	279	140	2	1	559	140	698
TERA	1	1	2	1	2	1	3
Tier I / II	2	1	2	1	3	1	4
R&D	200	0	0.5	0.5	100	0	100
Instant photographic	0	0	0.25	0.25	0	0	0
Bona Fide	116	0	2	2	232	0	232
5(e) Test	8	4	35	17.5	278	69	347
Non-Testing 5(e) Burden	16	0	2.5	2.5	40	0	40
NOC	295	148	0.25	0.125	74	18	92
Correction Request	9	0	0.25	0.25	2	0	2
Total	**1,419**	**539**			**2,276**	**475**	**2,751**

[1]Average Annual Responses computed as the average of the number of notices filed annually from 2003 through 2007 based on OPPT, 2008, then adjusted by 15% to reflect only valid submissions. The CDX responses and non-CDX responses are determined by the % of responses that will utilize CDX for a given year: 33% for the first year, 67% for the second year, and 100% for the third year. For section 5 notices not subject to the ePMN rule (R&D, Bona Fide, Non-Testing 5(e), Instant Photographic and Correction Requests), the average annual number of responses is assumed to equal the number presented in *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012).

Table 7

Revised New Chemicals Program Respondent Recordkeeping Burden Under the ePMN Rule, Year 2

Type of Notice	Average Annual Responses via non-CDX[1]	Average Annual Responses via CDX[1]	Current Average Recordkeeping Hours per non-CDX Response	Revised Average Recordkeeping Hours per CDX Response	Total Recordkeeping Hours for non-CDX	Total Recordkeeping Hours for CDX	Total Recordkeeping Hours for all Responses
PMN	240	480	2	1	480	480	961
SNUN	3	5	2	1	5	5	10
MCAN	1	2	2	1	2	2	5
Exemptions:							0
TME	3	5	2	1	5	5	10
LVE/LoREX	140	279	2	1	279	279	559
TERA	1	1	2	1	1	1	2
Tier I / II	1	2	2	1	2	2	3
R&D	200	0	0.5	0.5	100	0	100
Instant photographic	0	0	0.25	0.25	0	0	0
Bona Fide	116	0	2	2	232	0	232
5(e) Test	4	8	35	17.5	139	139	278
Non-Testing 5(e) Burden	16	0	2.5	2.5	40	0	40
NOC	148	295	0.25	0.125	37	37	74
Correction Request	9	0	0.25	0.25	2	0	2
Total	**880**	**1,078**			**1,325**	**951**	**2,276**

[1]Average Annual Responses computed as the average of the number of notices filed annually from 2003 through 2007 based on OPPT, 2008, then adjusted by 15% to reflect only valid submissions. The CDX responses and non-CDX responses are determined by the % of responses that will utilize CDX for a given year: 33% for the first year, 67% for the second year, and 100% for the third year. For section 5 notices not subject to the ePMN rule (R&D, Bona Fide, Non-Testing 5(e), Instant Photographic and Correction Requests), the average annual number of responses is assumed to equal the number presented in the *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012).

Table 8

Revised New Chemicals Program Respondent Recordkeeping Burden Under the ePMN Rule, Year 3

Type of Notice	Average Annual Responses via non-CDX[1]	Average Annual Responses via CDX[1]	Current Average Recordkeeping Hours per non-CDX Response	Revised Average Recordkeeping Hours per CDX Response	Total Recordkeeping Hours for non-CDX	Total Recordkeeping Hours for CDX	Total Recordkeeping Hours for all Responses
PMN	0	720	2	1	0	720	720
SNUN	0	8	2	1	0	8	8
MCAN	0	3	2	1	0	3	3
Exemptions:							0
TME	0	8	2	1	0	8	8
LVE/LoREX	0	419	2	1	0	419	419
TERA	0	2	2	1	0	2	2
Tier I / II	0	3	2	1	0	3	3
R&D	200	0	0.5	0.5	100	0	100
Instant photographic	0	0	0.25	0.25	0	0	0
Bona Fide	116	0	2	2	232	0	232
5(e) Test	0	12	35	17.5	0	208	208
Non-Testing 5(e) Burden	16	0	2.5	2.5	40	0	40
NOC	0	443	0.25	0.125	0	55	55
Correction Request	9	0	0.25	0.25	2	0	2
Total	**341**	**1,617**			**374**	**1,426**	**1,800**

[1]Average Annual Responses computed as the average of the number of notices filed annually from 2003 through 2007 based on OPPT, 2008, then adjusted by 15% to reflect only valid submissions. The CDX responses and non-CDX responses are determined by the % of responses that will utilize CDX for a given year: 33% for the first year, 67% for the second year, and 100% for the third year. For section 5 notices not subject to the e-PMN rule (R&D, Bona Fide, Non-Testing 5(e), Instant Photographic and Correction Requests), the average annual number of responses is assumed to equal the number presented in *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012).

3.0 Impacts of ePMN Proposed Rule on Existing Chemicals Program Burdens

3.1 Reporting Burden

The baseline reporting burden hours for each type of notice were estimated in *TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals* (EPA ICR No. 1188.08; OMB Control No. 2070-0038). As explained in section 1.2.3.1, regulated parties may respond to a SNUR in different ways. Section 3.1.1 estimates the burden incurred when submitting a SNUN (option 1). Other possible responses to a SNUR are discussed in section 3.1.2.

3.1.1 Submitting a SNUN

There are three steps in the process: chemical verification, submitting the SNUN, and notifying customers.

3.1.1.1 Chemical Verification

When a SNUR is published, companies must review the rule to verify if any chemicals they manufacture are subject to the rule. From 2004 through 2007, 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 period. The Agency typically notifies the manufacturer(s) of chemicals subject to a SNUR prior to its issuance. Therefore, EPA estimated that a company spends no more than .167 hours (10 minutes) of technical labor per chemical to verify if a chemical it manufactures is subject to the rule. This is equivalent to 3.34 hours per SNUR (.167 hours/chemical x 20 chemicals/SNUR).

3.1.1.2 SNUN Submission

Table 9 shows the reporting burden estimates that were used in EPA ICR No 1188.08. That ICR used high-end estimate of 113.25 hours for the total reporting burden. The Agency has adjusted that estimate for the purposes for this analysis by using as a baseline the mid-point of the estimated burden range rather than the high-end of the range for the total reporting burden, which is 105 hours. This is done to ensure consistency with analyses presented in EPA ICR No. 0574.13 and in the Economic Analysis for the proposed ePMN rule.

Companies that chose to submit a SNUN in response to an Existing Chemical SNUR will be affected by the new requirements contained in the proposed ePMN rule. Only the burden estimates of those activities that will be affected by the use of the ePMN software and submission of the ePMN form for a SNUN via CDX have been adjusted in the rule-related ICR

As mentioned in the beginning of this section, the methodology used to estimate the reporting costs, recordkeeping costs, and burden for this ICR renewal is based largely on EPA's previous experience with SNURs, and is largely consistent with the analysis presented in EPA ICR No 1188.08. However, where necessary, adjustments have been made to the estimated costs and burdens for Existing Chemical SNUNs in the rule-related ICR to make them consistent with

the estimated costs and burdens developed for New Chemical SNUNs in EPA ICR No. 0574.13. EPA expects that SNUNs submitted under the Existing Chemicals Program will experience the same savings as SNUNs submitted under the New Chemicals Program, and therefore is making an adjustment to the cost and burden estimates in rule-related ICR

Table 9
Current Unit Reporting Burden Estimates Associated With Filing An Existing Chemical SNUN, By Labor Category

Activity	Secretarial 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 & 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: EPA, 1994.

Tables 10 through 12 show the revised reporting burden for submitters of SNUNs for years one through three of the proposed ePMN rule, which coincide with each of year of this ICR's approval. Once the ePMN rule becomes effective, the burden to respondents will include: 1) company-level reporting burden associated with rule familiarization and with using CDX to submit a SNUN, 2) form-level reporting burden for filling out and submitting, including mailing SNUNs; and 3) form-level recordkeeping burden associated with SNUN submissions.

Company-level burden includes those activities that facilitate submission of an ePMN form for a SNUN: CDX registration, CDX electronic signature, setting up a Pay.gov account, and rule familiarization. All activities performed at the company-level occur only once during the first year that an activity is undertaken. EPA is assuming that rule familiarization, for example, will be incurred by all companies during the first year following promulgation of the ePMN rule, regardless of whether the ePMN is submitted via paper, optical disc, or CDX. In addition, companies that submit SNUNs for the first time in subsequent years are assumed to incur the rule familiarization burden the first year of the rule. Those companies that submit SNUNs using the ePMN software again in subsequent years do not incur a subsequent rule familiarization burden. All other company-level activities, while they are incurred only once, will be incurred in the year in which the company adopts electronic reporting via CDX.

In generating estimates of burden changes for the submission of SNUNs due to the proposed ePMN rule, EPA projects that one third of first year submissions and two thirds of all second year submissions will be made via CDX. All submissions must be made via CDX by the third year and beyond. The actual rates of adoption of CDX in years one and two of the rule could be higher or lower than EPA's projections. However, lacking any data on which to base other projections, EPA is assuming an even rate of adoption over the two-year phase-in period. For Existing Chemical SNUNs, this means that EPA is assuming that companies will incur the burden associated with CDX registration, completing the Electronic Signature agreements, and setting up a Pay.gov account to submit the fee[2], at the rate of 3.3 (10/3) additional companies in each of year of the ICR's approval. At that point, all SNUN submissions will be made via CDX.

Form-level burden includes form completion, recordkeeping, and postage. As a result of the ePMN rule, submitters will experience a reduction in form-level burden due to the efficiencies and reduced time associated with using the ePMN software to complete a SNUN, and using CDX to submit the notice. All form-level burden savings are expected to be realized each time a SNUN is submitted. Recordkeeping and postage savings will be realized in years when electronic reporting via CDX is used.

Form completion burden saving will be realized by all SNUN submitters immediately because all SNUNs must be generated using the ePMN software beginning in the first year following rule promulgation**.** As a result of savings that EPA is estimating will accrue to submitters of SNUNs using the ePMN software, EPA is estimating that the baseline reporting burden of 105 hours will be reduced to 92.2 hours per SNUN. Companies will incur an additional company-level burden associated with the CDX-related activities described above.

[2] Use of Pay.gov to remit the SNUN submission fee will not be mandatory under the proposed e-PMN rule, but EPA assumes conservatively in the Economic Analysis for the proposed e-PMN rule that SNUN submitters will send the fee via a Pay.gov account.

In summary, companies submitting a SNUN in the first year of the ICR period are estimated to incur a total reporting burden of 939 hours (for all companies). Companies submitting in the second and third years are estimated to incur a total reporting burden of 931 hours. On a per-SNUN basis, in the year that a company registers with CDX, the reporting burden is estimated to be 95.8 hours. After a company has registered with CDX, the reporting burden is estimated to be 92.2 hours.

Table 10
Revised Existing Chemical SNUN Reporting Burden Under the ePMN Rule, Year 1

Type of Notice	Avg. Annual Additional Companies/Responses[1]	Current Average Reporting Hours per Company/Response	Revised Average Reporting Hours per Company/Response	Revised Total Reporting Hours
COMPANY BURDEN				
CDX Registration	3.3	0	0.9	3.1
CDX Electronic Signature	3.3	0	1.8	5.8
E-Payment (Pay.gov ID)	3.3	0	0.1	0.4
Rule Familiarization	10	0	0.8	8.2
Total (Company)				**17.5**
FORM BURDEN				
SNUN	10	105	92.2	**921.8**
Total (Combined Company and Form)				**939.3**

[1] The CDX responses and non-CDX responses are determined by the number of additional companies/responses that will utilize CDX for a given year: About one third of the companies each year- (10/3) ~ 3.3 companies.

Table 11
Revised Existing Chemical SNUN Reporting Burden Under the ePMN Rule, Year 2

Type of Notice	Avg. Annual Additional Companies/Responses[1]	Current Average Reporting Hours per Company/Response	Revised Average Reporting Hours per Company/Response	Revised Total Reporting Hours
COMPANY BURDEN				
CDX Registration	3.3	0	0.9	3.1
CDX Electronic Signature	3.3	0	1.8	5.8
E-Payment (Pay.gov ID)	3.3	0	0.1	0.4
Rule Familiarization	0	0	0.8	0.0
Total (Company)				**9.3**
FORM BURDEN				
SNUN	10	105	92.2	**921.8**
Total (Combined Company and Form)				**931.2**

[1] The CDX responses and non-CDX responses are determined by the number of additional companies/responses that will utilize CDX for a given year: About one third of the companies each year- (10/3) ~ 3.3 companies.

Table 12
Revised Existing Chemical SNUN Reporting Burden Under the ePMN Rule, Year 3

Type of Notice	Avg. Annual Additional Companies/Responses[1]	Current Average Reporting Hours per Company/Response	Revised Average Reporting Hours per Company/Response	Revised Total Reporting Hours
COMPANY BURDEN				
CDX Registration	3.3	0	0.9	3.1
CDX Electronic Signature	3.3	0	1.8	5.8
E-Payment (Pay.gov ID)	3.3	0	0.1	0.4
Rule Familiarization	0	0	0.8	0.0
Total (Company)				**9.3**
FORM BURDEN				
SNUN	10	105	92.2	**921.8**
Total (Combined Company and Form)				**931.2**

[1] The CDX responses and non-CDX responses are determined by the number of additional companies/responses that will utilize CDX for a given year: About one third of the companies each year- (10/3) ~ 3.3 companies.

3.1.1.3 Customer Notification

As noted above, unless manufacturers, processors, and importers of chemicals subject to SNURs either have 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. Because EPA does not expect 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, EPA assumes that manufacturers, processors, and importers most often will choose to notify their customers of SNUR regulatory activities. Because this notification may be accomplished by simply annotating an MSDS, EPA estimates the associated burden to be one hour of a technical labor per manufacturer, processor, or importer per chemical.

3.1.2 Alternative Options to Submitting a SNUN

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. However, because submitters will not be able to send requests for equivalency determinations using the e-PMN form or via CDX, the burden is assumed to be the same as for a SNUN in the New Chemicals Program ICR under the current paper submission system. That burden is the same as a PMN, which is 105 hours for reporting, and two hours for recordkeeping, for a total of 107 hours. This estimate is reduced from the estimate of 118.92 hours described in EPA ICR No 1188.08 to make it consistent with the burden for a PMN/SNUN in EPA ICR No. 0574.13 and the Economic Analysis for the proposed ePMN rule.

In complying with a SNUR, (i.e., the third option), a company would incur costs to ensure all provisions of the SNUR were implemented at the subject facility. Because the nature of such provisions will vary depending on the significant new uses identified in each respective SNUR, EPA is not able to estimate a cost for this option.

3.2 Recordkeeping Burden Associated with Submitting a SNUN

When submitting a SNUN, manufacturers must maintain records associated with the SNUN for five years. In addition to reporting burden hour savings EPA is expecting that SNUN submitters will realize as a result of the proposed ePMN rule, EPA also expects that submitters will realize a decrease in recordkeeping burden as well. Specifically, EPA assumes that recordkeeping burden will be reduced by half due to the efficiencies in creating and storing SNUNs and supporting documents electronically.

Table 13 shows the revised recordkeeping burden for submitters of SNUNs. This burden estimate is calculated by multiplying the estimated recordkeeping burden associated with a SNUN (EPA, 1994) by the estimated number of SNUNs. The recordkeeping burden is adjusted by the savings associated with electronic reporting via CDX in each year of the phase-in period.

Once a respondent submits information in an initial TSCA section 5 submission, the burden for maintaining or updating these records is minimal. The Agency had assumed an aggregate annualized recordkeeping burden of 2 hours for each SNUN. This was based on the recordkeeping burden associated with essential technical requirements, such as records that demonstrate that the first commercial batch of chemical manufactured for commercial purposes under the exemption met certain eligibility criteria.

The recordkeeping burden has been adjusted from the estimate of 5.67 hours used in the previous Existing Chemical SNUR ICR (EPA ICR No 1188.08), to 2 hours here, to be consistent with the New Chemicals ICR (EPA ICR No. 0574.13) and the Economic Analysis for the proposed ePMN rule. Under the proposed e-PMN rule, one technical and one clerical staff member are estimated to each save 30 minutes on recordkeeping, for a total recordkeeping burden of one hour, phased-in as CDX is adopted. Table 13 shows that in the first year of the ICR renewal period, when three companies are assumed to submit SNUNs via CDX, the total recordkeeping burden is estimated to be 17 hours. By year three, when the all 10 SNUNs expected each year will be submitted via CDX, the total record keeping drops to 10 hours. The total three-year recordkeeping burden is estimated to be 40 hours, or an annual average of slightly more than 13 hours.

Table 13
Revised Respondent Recordkeeping Burden For Existing Chemical SNUNs Under the ePMN Rule, Years 1 through 3

Year	Average Annual Responses via non-CDX	Average Annual Responses via CDX	Current Average Recordkeeping Hours per non-CDX Response	Revised Average Recordkeeping Hours per CDX Response	Total Recordkeeping Hours for non-CDX	Total Recordkeeping Hours for CDX	Total Recordkeeping Hours for all Responses
Year 1	6.7	3.3	2	1	13.3	3.3	16.7
Year 2	3.3	6.7	2	1	6.7	6.7	13.3
Year 3	0	10	2	1	0	10	10
TOTAL							**40.0**

4.0 Expected Net Changes to Annual Paperwork Burden Estimates

4.1 New Chemicals Program Reporting

The annual reporting burden under for TSCA section 5 notices submitted under the New Chemicals program is estimated to average 114,176 hours upon implementation of the ePMN rule. This reflects a net program change reduction of 29,274 hours over the 143,450 reporting hours presently approved under EPA ICR No. 0574.13 (OMB Control No. 2070-0012).

4.1.1 Program Change Burden Decrease

EPA estimates that respondents will realize a program change reduction of 29,627 annual burden hours when carrying out existing reporting activities. This burden reduction is associated with the efficiencies and time savings gained by preparing and submitting TSCA section 5 notices using the ePMN software. The burden savings relative to specific notice types are indicated in Table 14, while the number of responses and revised total burden estimates for TSCA section 5 notice submissions are indicated in Tables 3-5.

4.1.2 Program Change Burden Increase

Off-setting the program change reduction, EPA estimates that the ePMN rule would impose an estimated program change increase of 353 annual burden hours on respondents. This program change increase, as indicated in Tables 3-5, is associated with the time required to complete company-level paperwork activities related to the proposed ePMN rule requirements, i.e., CDX Registration, CDX Electronic Signature, E-Payment (Pay.gov ID), and Rule Familiarization.

Table 14
Anticipated New Chemicals Program Reporting Burden Savings Under the ePMN Rule

Type of New Chemicals Program Notice	Current Estimated Response Burden	Estimated Response Burden after ePMN rule	Burden Saved Per Response
Full PMN	105 hrs.	92.2 hrs.	12.8 hrs.
New Chemical SNUN	105	92.2	12.8
LVE	105	92.2	12.8
LoREX	105	92.2	12.8
MCAN	302	288.2	13.8
TME	98	86.2	11.8
TERA	521	507.2	13.8
Tier I	114	110.2	3.8
Tier II	114	110.2	3.8
5(e) Test submissions	155	150.7	4.3
NOC	0.5	0.6	(0.1)

4.2 New Chemicals Program Recordkeeping

The annual recordkeeping burden related to TSCA section 5 notices under the New Chemicals program is estimated to average 2,276 hours upon implementation of the ePMN rule. This reflects an average net program change reduction of 2,357 hours over the 4,633 recordkeeping hours presently approved under EPA ICR No. 0574.13 (OMB Control No. 2070-0012).

As indicated in Table 15, EPA expects that recordkeeping burden for TSCA section 5 respondents will decrease due to the ePMN rule. Specifically, EPA assumes that recordkeeping burden will be reduced by half due to the efficiencies in creating and storing electronically section 5 notices and supporting documents. For most section 5 notices, baseline recordkeeping burden is estimated to be two hours. For these notices, one technical and one clerical staff member will each save 30 minutes on recordkeeping.

For section 5(e) test notices, baseline recordkeeping burden is estimated to be 35 hours because of the need to copy and file relevant records. This includes records related to: manufacturing, importing, or processing volumes; shipment amounts and customer information; labels (documentation of labeling procedures and copies of labels); MSDS; and compliance with any additional restrictions on use, disposal, and discharge limitations. Therefore, for section 5(e) test notices, EPA estimates that one technical and one clerical staff member will each save 8.8 hours on recordkeeping.

For Notices of Commencement (NOC), baseline recordkeeping burden is estimated to be 15 minutes. Therefore, for NOCs, one technical and one clerical staff member will each save four minutes on recordkeeping.

Table 15
Anticipated New & Existing Chemicals Program Recordkeeping Burden Hour Savings Under the ePMN Rule

Type of TSCA Section 5 Notice (New and Existing Chemicals Programs)	Current Estimated Recordkeeping Burden Per Response	Estimated Recordkeeping per Burden Response after Rule Implementation	Burden Saved Per Response
Full PMN	2.00	1.00	1.00
SNUN[1]	2.00	1.00	1.00
LVE	2.00	1.00	1.00
LoREX	2.00	1.00	1.00
MCAN	2.00	1.00	1.00
TME	2.00	1.00	1.00
TERA	2.00	1.00	1.00
Tier I	2.00	1.00	1.00
Tier II	2.00	1.00	1.00
5(e) Test submissions	35.0	17.5	17.5
NOC	0.25	0.125	0.125

[1]The "current" recordkeeping burden for Existing Chemical SNUNs has been adjusted from the estimate of 5.67 hours calculated in *TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals* (EPA ICR No 1188.08; OMB Control No. 2070-0038), to 2 hours here, to be consistent with *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012) and the Economic Analysis for the proposed ePMN rule.

4.2.1 Program Change Burden Decrease

As shown in Tables 6-8, the total respondent recordkeeping burden associated with this information collection is estimated to equal 2,751 hours in the first year following the effective date of the e-PMN rule, 2,276 hours in the second year, and 1,800 hours in the third year following the effective date of the final rule. EPA expects that the paperwork burden will be reduced by an average 2,357 annual hours per year over the first 3 years of the final rule's implementation. This is burden reduction reflects a program change. In following years, the annual recordkeeping burden is estimated to be 1,800 hours, reflecting full implementation of the ePMN final rule and adoption of electronic reporting and recordkeeping practices by respondents.

4.3 Net Burden Decrease - New Chemicals Program

EPA expects an average net burden reduction of 31,631 hours annually over the 148,083 total annual hours presently approved under EPA ICR No. 0574.13 (OMB Control No. 2070-0012), based on the changes described in sections 4.1 and 4.2.

4.4 Existing Chemicals Program Reporting and Recordkeeping

The annual reporting and recordkeeping burden under for TSCA section 5 notices submitted under the Existing Chemicals program is estimated to average 1,158 hours upon implementation of the ePMN rule. This reflects a net increase of 297 hours per year over the 861 annual hours presently approved under EPA ICR No. 1188.08 (OMB Control No. 2070-0038). This net increase is the result of both program changes and adjustments to the Agency's estimates.

4.4.1 Existing Chemicals Program Reporting and Recordkeeping – Adjustments

As described in sections 4.4.1.1 through 4.4.1.4, changes to EPA estimates have resulted in net adjustment increase of 426 hours.

4.4.1.1 Adjusted Baseline Number of Existing Chemical SNURs Promulgated

As explained in section 1.2.3, EPA expects the number of SNURs that will be promulgated to increase from 3 to 5 per year. The Agency typically notifies the manufacturer(s) of chemicals subject to a SNUR prior to its issuance. Therefore, EPA estimated that a technical employee will need no more than .167 hours (10 minutes) per chemical to verify if a chemical is subject to the rule. The Agency estimates that in the future, each SNUR will cover 20 chemicals, reduced from EPA's previous estimated of 41 chemicals per SNUR. Therefore, chemical verification will require 3.34 hours of technical labor per SNUR (0.167 hours x 20 chemicals), reflecting a 3.46 hour adjustment decrease per SNUR from the 6.8 hours (0.167 hours/chemical x 41 chemicals) previously estimated.

4.4.1.2 Adjusted Baseline Number of Existing Chemical SNUNs Submitted

EPA expects the number of SNUNs that will be submitted to EPA to increase from 5 to 10 per year. This adjustment corresponds to the increased number of SNURs that are expected to be promulgated annually, as explained in section 1.2.3.

4.4.1.3 Adjusted Baseline Number of Customer Notifications

Table 16 presents estimates of the customer notification burden and costs. EPA assumes that 5 SNURs will be promulgated per year and estimates that burden for customer notification is 40 hours per SNUR (1 hr/SNUR x 20 chemicals/SNUR x 2 firms/chemical). Therefore, the annual burden associated with customer notification is estimated to be 200 hours (40hrs/SNUR x 5 SNURs/year).

Table 16
Revised Customer Notification Burden Estimates Given Baseline Adjustments

Customer Notification Burden Calculations	Previous Estimates	Adjusted Estimates
Chemicals per SNUR [a]	41	20
Hours per manufacturers/processors/importers [b]	1.0	1.0
Manufacturers/processors/importers per chemical [c]	2	2
SNURs per year [d]	3	5
Total annual burden [e] = [a]*[b]*[c]*[d]	246	200

4.4.1.4 Adjusted Baseline Burden for Existing Chemical SNUN Submission and Recordkeeping

As explained in section 3.1.1.2, the baseline reporting burden for submitting an existing chemical SNUN was adjusted to the mid-point estimated of 105 hours, rather than the upper-bound estimate of 113.25 hours of reporting burden presently approved under EPA ICR No. 1188.08. The recordkeeping burden for SNUN activities was also adjusted, from 5.67 hours per response to 2 hours per response, to make this analysis consistent with that presented in EPA ICR No. 0574.13.

Table 17
Existing Chemical SNUN Reporting and Recordkeeping Burden Based on Previous Baseline Estimates

Activity	Responses	Unit Burden Hours	Annual Burden Hours
Chemical Verification	3 SNURs x 41 chems/SNUR requiring verification = 123 responses	0.167/chem.	20.5
Reporting Recordkeeping	5 SNUNs 5 SNUNs = 5 responses	113.250/SNUN 5.670/SNUN	566.25 28.35 = 594.6
Customer Notification	3 SNURs x 41 chems x 2 notifying firms/chem. = 246 responses	1.000/chem.	246
Total	374 Responses		861 hours (20+595+246)

Table 18
Existing Chemical SNUN Reporting and Recordkeeping Burden Based on Adjusted Baseline Estimates

Activity	Responses	Unit Burden Hours	Annual Burden Hours
Chemical Verification	5 SNURs x 20 chems/SNUR requiring verification = 100 responses	0.167/chem.	16.7
Reporting Recordkeeping	10 SNUNs 10 SNUNs = 10 responses	105/SNUN 2/SNUN	1050 20 = 1070
Customer Notification	5 SNURs x 20 chems x 2 notifying firms/chem. = 200 responses	1.000/chem.	200
Total	310 Responses		1,287 hours (17+1070+200)

Table 19
Existing Chemical SNUN Reporting and Recordkeeping Burden Change Based on Adjusted Baseline Estimates

Previous Baseline Burden Estimates	861 hours
Adjusted Baseline Burden Estimates	1,287 hours
Change	+426 hours

4.4.2 Existing Chemicals Program Reporting and Recordkeeping – Program Change Burden Increase

EPA estimates that the new electronic submission requirements of the ePMN rule would impose an estimated program change increase of about 12 total annual burden hours on respondents (accounting for the adjusted number of responses). This program change increase, as indicated in Tables 10-12, is associated with the time required to complete company-level paperwork activities related to the proposed ePMN rule requirements, i.e., CDX Registration, CDX Electronic Signature, E-Payment (Pay.gov ID), and Rule Familiarization.

4.4.3 Existing Chemicals Program Reporting and Recordkeeping – Program Change Burden Decreases

EPA expects that the adjusted baseline reporting and recordkeeping burden described in section 4.4.1 for SNUN-submitting respondents will further decrease due to the ePMN rule. Off-setting the 12 hour program change increase related to CDX registration, CDX electronic signature (i.e., authentication of identity and verification of authorization), setting up a Pay.gov account, and rule familiarization, EPA estimates that respondents will realize a total program change reduction of 128 annual burden hours over the adjusted, current SNUN response burden. This burden reduction is associated with the efficiencies and time savings gained by preparing and submitting TSCA section 5 notices using the ePMN software. Table 20 indicates the expected burden savings for Existing Chemical SNUN submissions while Tables 10-12 indicate the number of responses and revised burden estimates for Existing Chemical SNUN submissions upon ePMN rule implementation. Further, EPA assumes that recordkeeping burden will be reduced by half due to the efficiencies in creating and storing section 5 notices and supporting documents electronically. EPA anticipates that one technical and one clerical staff member will each save 30 minutes on recordkeeping. EPA estimates that respondents will realize an average program change reduction of 13 annual burden hours for recordkeeping (16.7 hours in the first year following the effective date of the e-PMN rule, 13.3 hours in the second year, and 10 hours in the third year). Therefore, EPA estimates that the annual reporting and recordkeeping burden associated with Existing Chemical SNUNs will be reduced by 141 hours.

Table 20
Anticipated Existing Chemicals Program Reporting Burden Savings Under the ePMN Rule

Type of Existing Chemicals Program Notice	Current Estimated Response Burden	Estimated Response Burden after ePMN rule	Burden Saved Per Response
Existing Chemical SNUN	105	92.2	12.8

[1]The reporting burden for Existing Chemical SNUNs has been adjusted from the estimate of 113.25 hours calculated in *TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals* (EPA ICR No 1188.08; OMB Control No. 2070-0038), to 105 hours here, to be consistent with *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances* (EPA ICR No. 0574.13; OMB Control No. 2070-0012) and the Economic Analysis for the proposed ePMN rule.

4.5 Net Burden Increase - Existing Chemicals Program

EPA expects an average net burden increase of 297 hours annually (426 hour adjustment increase and 129 hour net program change reduction) over the 861 total annual hours presently approved under EPA ICR No 1188.08 (OMB Control No. 2070-0038), based on the changes described in sections 4.4.1 through 4.4.3.