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

3 IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title and Number of the Information Collection

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

EPA ICR No.: 2327.02 OMB Control No.: 2070-0173

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 developed a final 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 will 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 introducing CDX reporting in two phases over a two-year period. During the first year following the effective date of the final rule, the Agency will allow submissions via CDX, optical disc, and paper. Regardless of the delivery method, EPA will require that all submissions be generated with new "e-PMN" computer software. Paper submissions will 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 will no longer be accepted beyond the second year after the final rule's effective date. After this, all submitters will be required to submit electronically via CDX using the e-PMN software. The Agency is incorporating this phased

approach because it will allow submitters to gain experience in using the e-PMN software and the submission delivery system. Note that the final CDX and e-PMN software amendments to the PMN notification requirements in 40 CFR 720 will apply to the SNUN requirements in 40 CFR 721.25(a). EPA is also amending 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 will 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.

4 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

e-PMN Software

The phase-out of paper-based submissions in favor of CDX reporting, including use of the e-PMN 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 will 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 e-PMN software and electronic submission via CDX will change the way that companies interact with the Agency regarding many TSCA section 5 submissions. Companies will be registered with EPA to submit their data electronically to the Agency via CDX and the Agency in turn will be able to communicate back electronically with submitters. This promotes efficiency in communications and cost savings in submissions and correspondence. 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 will save EPA and industry processing resources and reduce transaction times. EPA believes the adoption of electronic communications will 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 will 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 e-PMN software will facilitate the creation of this sanitized non-CBI version, eliminating the need for the submitter to do this manually. It also will 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, will 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 will also benefit from receiving electronic submissions. Data systems that currently are populated manually will now be populated electronically, reducing the potential for human error that exists when data are entered by hand. Agency personnel will 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 will 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 will 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 is optional and consists simply of the e-mail addresses for the principals listed on the Submitter Identification section of the PMN form. This information 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 Notice of Proposed Rulemaking (December 22, 2008; 73 FR 78261) served as the public notice for this ICR. EPA specifically sought comments on the following:

- Whether the proposed 2-year phase-in period following promulgation of the final rule, during which time paper and/or optical disc submissions would be accepted, is reasonable or necessary to allow sufficient time to transition to the new Internet-based method, and
- Did industry have information that could further inform EPA's estimate regarding burden. For example, EPA asked whether submitters intended on submitting notices via CDX as soon as it becomes available, or if not, when during the 2-year phase-in period would they expect to begin using CDX?

The public comments overwhelmingly supported the 2-year phase-in period following promulgation of the final rule. Commenters agreed that the 2-year phase-in period is reasonable and necessary to allow sufficient time for transition to the new electronic reporting method.

Although EPA did not receive any comments directly related to its burden estimate, EPA did receive positive feedback on the proposed electronic submittal system. Commenters strongly supported the Agency's effort to move to electronic methods of information gathering. Commenters agreed with the Agency's statements that this change will allow for more effective and efficient reviews of section 5 notices and that the changes will improve communication with

submitters. One commenter appreciated aspects of the e-PMN software such as the ability of the e-PMN software to check for completeness of a PMN submission and create non-CBI versions of notices. Another commenter was pleased to see the addition of the new User Fee Payment Identity Number field to track payments. EPA retained the 2-year phase-in period for electronic submissions which is supported by the comments received. Since EPA did not receive any comments directly related to its burden estimate, no changes were made.

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 final 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 will only be required if EPA determined that a specific use of a substance constituted a significant new use. Less frequent collection will 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 will be transmitted using secure technologies to protect CBI. The e-PMN software will 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 e-PMN 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 e-PMN software are also provided with a set of public and private keys, so that correspondence containing any potential confidential business information will remain encrypted during transmission via CDX and can be opened only by the submitter within the e-PMN software.

3(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 e-PMN 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 will 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

To register in CDX, the CDX registrant (also referred to as "Electronic Signature Holder" or "Public/Private Key Holder") downloads two forms: the Electronic Signature Agreement and the Verification of Company Authorizing Official form. Registration enables CDX to perform two important functions: Authentication of identity and verification of authorization. Within the "Electronic Signature Agreement" form, the Authorized Official (AO) agrees to certain CDX security conditions. On the "Verification of Company Authorizing Official" form, the AO designates himself/herself as the AO and attests to the completeness and accuracy of the submitted information.

There is a third form generated by CDX that the AO needs to fill out if the AO wants to authorize other persons to submit support documents on his or her behalf, including a paid employee of the company, an outside consultant for the company, or an authorized representative agent for the company. This form is entitled, "Authorization and Verification for Section 5

Notice Support Submitter by Company Authorizing Official." On this form, the AO designates various persons to submit support documents on his or her behalf, and attests to the completeness and accuracy of the submitted information. Persons designated by the AO to submit on his or her behalf must also sign this form along with the Electronic Signature Agreement form, in order to be "linked" to the AO by EPA; and therefore, be able to submit support documents via CDX on the AO's behalf.

When these forms are received, EPA activates the submitter's registration in CDX and sends him or her an e-mail notification.

Use the e-PMN Software to Prepare TSCA Section 5 Notices

In all cases, respondents will use the e-PMN 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 e-PMN software, the Agency is finalizing the rule as follows:

(1) For exemption modifications, submitters will use the e-PMN 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 e-PMN form.

(2) For a TMEA, the submitter will check the "TMEA" box on page 1 of the e-PMN 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 will have their own menu option. Instead of selecting "Premanufacture Notice," a submitter will select "Biotech," which will prompt the software to present the submitter a header page with choices of biotech notices, and space to fill in contact information. The e-PMN software will populate this information in a new form entitled, "TSCA Biotechnology Notice for Online Submissions" (EPA Form 6300-07). The additional information will be submitted as an attachment(s).

Notice Type	Use of e-PMN Software
PMN	Form 7710-25 generated and finalized by e-PMN software.
Low Volume Exemption (LVE)	Form 7710-25 generated and finalized by e-PMN software.
Test Market Exemption Application (TMEA)	e-PMN software to generate finalized submission either using 7710-25 or cover letter and attached information.
NOC	e-PMN software to generate finalized submission using Form 7710-56.
Biotechnology Notices	e-PMN 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 e-PMN software. Fill in pages 1, 2, and 3 of the Form, plus either applicable pages of Form, cover letter, or attachment.
Support Documents	e-PMN 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 e-PMN software will require users to complete a finalization process before preparing the information for submission to EPA. During the finalization step, the e-PMN software checks that all legally required information is included and provides warnings for certain kinds of missing, incomplete or incorrect data.

Paper

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

Optical disc

After the e-PMN finalization step is complete, respondents will prepare the data generated by the e-PMN software in XML for transfer to an optical disc. With limited exception, discs will 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 will 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 will need to accompany the disc. Discs will need to be delivered only by courier service to avoid damage to the disk from the Agency's mail screening equipment.

Using e-PMN Software to Submit Electronically to EPA via CDX

After the e-PMN finalization step is complete, the e-PMN software will prompt respondents to log-in to CDX. Respondents will the simply transmit the information to EPA online by clicking on the e-PMN 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 must 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 e-PMN 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 e-PMN 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 initially will have the option to use e-PMN software to submit by paper, optical disc, or via CDX. Each of these submissions must be generated using the e-PMN 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 be required to be submitted on 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 will 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 e-PMN 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 e-PMN 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 e-PMN 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 e-PMN 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 e-PMN software to generate section 5 notices and support documents regardless of whether they are submitted via CDX or delivered 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 e-PMN 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 notice 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 is 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 final electronic submission requirements for TSCA section 5 Notices. EPA estimates that the final rule will impact 305 respondents – 295 New Chemicals program respondents and 10 Existing Chemical program respondents. Although respondents will experience some incremental burden increases as a result of the e-PMN 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 will be imposed by the final 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 will result from implementation of the final rule. Appendix 1 provides a complete year-by-year analysis of the final 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 will incur minimal additional burdens and costs in carrying out the additional paperwork activities that will 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)
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 modified 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 adding 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 the new fields will increase technical burden by 10 minutes and one minute, respectively.[3]

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.

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

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

EPA estimates that the e-PMN rule will 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 one-third of respondents) will implement the rule provisions each year during the two-year phase-in. This program change increase is associated with the time required to complete company-level paperwork activities related to the final e-PMN rule requirements, i.e., CDX Registration, CDX Electronic Signature, E-Payment (Pay.gov ID), and Rule Familiarization.

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

Burden Estimates from Hilary Eustace, David Cooper and Susan Day, Abt Associates, to Paul Borst, US EPA.., July, 2004.

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 e-PMN 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 e-PMN rule. Respondents are expected to experience these burden reductions due to the efficiencies and reduced time associated with using the new e-PMN 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 will be realized in years when electronic reporting via CDX is used. The final rule requires that all notices be generated using the new e-PMN software beginning in the first year following rule promulgation; however, form completion burden savings will be realized by all submitters immediately. Although respondents will 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 will 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 will be brought about by the e-PMN final 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 final rule.

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

EPA expects that recordkeeping burden for TSCA section 5 respondents will decrease due to the e-PMN 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 e-PMN 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 final e-PMN rule.

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

- ***R&D exemption:*** Potential users of this exemption incur burdens related third 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 e-PMN rule. Reductions in recordkeeping burden are linked with the respondents' use of the e-PMN 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 will not be permitted to make this type of submission via CDX under the e-PMN rule. Reductions in recordkeeping burden are linked with the respondents' use of the e-PMN software to prepare and submit information electronically, and subsequent utilization of electronic storage of records related to the submission.

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

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.

Table 4
Anticipated New Chemicals Program Reporting Burden Savings Under the e-PMN Rule

Type of New Chemicals Program Notice	Current Estimated Response Burden	Estimated Response Burden after e-PMN 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)

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 e-PMN 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 will not be permitted to make this type of submission via CDX under the e-PMN rule.

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

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

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

As a result of the e-PMN rule, existing chemical SNUN respondents will experience a reduction in reporting burden due to the efficiencies and reduced time associated with using the e-PMN 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 final rule requires that all SNUNs be generated using the e-PMN 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 e-PMN Rule

Type of Existing Chemicals Program Notice	Current Estimated Response Burden	Estimated Response Burden after e-PMN 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 final e-PMN 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, 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 11.

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 e-PMN program is based entirely on paper

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.

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 e-PMN data flow. EPA developed an estimate of CDX O&M costs attributable to the e-PMN 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 that although the e-PMN 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 phasing-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 e-PMN Rule (Table 1)	353	$19,404
Additional Existing Chemicals Program Burden Under the e-PMN Rule (Table 2)	10	$594
Respondent Total	363	$19,998.00

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.

6(e) Reason for Changes in Burden

Not applicable. This request describes new paperwork activities related to the implementation of the final e-PMN 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 will 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 final 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

Appendices and attachments to the supporting statement are available in the public docket established for the final rule under docket identification number **EPA-HQ-OPPT-2008-0296**. They are available for online viewing at www.regulations.gov or otherwise accessed as described in section 6(f) of the supporting statement.

Appendix 1: **Impact Analysis of the Final 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

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: **EPA Form 6300-07 – EPA Biotech Form.** Generated only when preparing a biotech notice using e-PMN software.

Attachment 10: **Screenshots of e-PMN Software Tool**

Attachment 11: **Derivation of Industry Wage Rates and Agency Costs**