Information Collection Request (ICR) for the Electronic Reporting of TSCA Section 4, Section 5 NOC and Supporting Documents, 8(a) PAIR, and 8(d) Submissions (EPA No. 2412.02, OMB No. 2070-0183)

1 IDENTIFICATION OF THE INFORMATION COLLECTION

1.1 Title of the Information Collection

Electronic Reporting of TSCA sections 4, 5 Notice of Commencement (NOCs) and Supporting Documents, 8(a) Preliminary Assessment Information Rule (PAIR), and 8(d) Submissions.

1.2 Short Characterization/ Abstract

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 promulgated a final rule entitled, "Electronic Reporting under the Toxic Substances Control Act (TSCA)" to amend the respective Toxic Substances Control Act (TSCA) section 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 require manufacturers, importers, and processors of TSCA chemical substances to use the Internet, through EPA's Central Data Exchange (CDX), to submit the respective TSCA section reports to the Agency. Paper submissions will no longer be accepted

This ICR covers mandatory electronic reporting of information submitted in response to certain testing and reporting requirements related to TSCA sections 4, 8(a) Preliminary Assessment Information Rules), and 8(d) health and safety information to EPA. The public will use CDX to access the Chemical Information Submission System (CISS) web-based reporting tool to report data, reports and other documents to the Agency. that the final rule requires that all such submissions be generated with the CISS reporting tool.

This ICR also covers mandatory electronic reporting of TSCA section 5 Notices of Commencement (NOCs) and support documents for TSCA section 5 notices submitted to EPA before April 6, 2010. The e-PMN final rule (75 FR 773)(FRL-8794-5) requires submitters of NOCs and support documents whose original notices were submitted to EPA prior to April 6, 2010 ("legacy notices") to submit those NOCs and support documents to EPA in hard copy. At the time the final rule was published, EPA believed the hard-copy submission of these documents was necessary because the Agency intended to operate two different databases; one for storing section 5 notices submitted to EPA after April 6, 2010 and another for storing legacy notices. EPA originally intended to enter legacy notices only into EPA's "legacy database," i.e., the database used prior to April 6, 2010, and so a subsequent NOC or support document will not

have been able to be linked up with its original or "parent" legacy notice if it was entered into EPA's new database. Since publication of the e-PMN final rule, EPA's electronic reporting program has evolved and EPA now has the ability to house both legacy notices and notices submitted after April 6, 2010 in the same database. The "Electronic Reporting under the Toxic Substances Control Act" final rule amends the e-PMN rule to submit NOCs and legacy notices electronically to EPA via CDX using the e-PMN software.

This rule-related Information Collection Request (ICR) addresses the incremental paperwork activities related to submitting sections 4, 5, 8(a) PAIR, and 8(d) data, reports, and other documents to EPA electronically and describes the changes that will ultimately be incorporated into the ICRs upon their renewal date that are currently approved under OMB Control No. 2070-0033, No.2070-0012, No.2070-0054, No. 2070-0004, and 2070-0012. (EPA ICR No. 1139.09 *TSCA Section 4 Test Rules, Consent Orders, Test Rule Exemptions, and Voluntary Data Submission*, EPA ICR No. 0586.13, *TSCA 8(a) Preliminary Assessment Information Rule (PAIR),* EPA ICR No. 0575.13 *Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies,* and EPA ICR No. 0574.15 *Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances*, respectively).

In addition, as described in section 2.2 of this supporting statement, OPPT initiated a voluntary pilot program to accept certain health and safety data submissions in an electronic format. The voluntary use of a cover sheet, known as the TSCA Health & Safety Study Cover Sheet (EPA Form No. 7710-58, see Appendix B), facilitated the submission of information by displaying certain basic data elements, permitted EPA more easily to identify, log, track, distribute, review and index submissions, and to make information publicly available to the mutual benefit of both industry and EPA.[1] Data elements that were featured in the voluntary form have been adopted as submission metadata in the CISS electronic reporting tool. The CISS metadata are addressed in this rule-related ICR.

2 NEED FOR AND USE OF THE COLLECTION

2.1 Need/Authority for the Collection

2.1.1 Paperwork Reduction Act (PRA)

The PRA requires Federal agencies to manage information resources to reduce information collection burdens on the public; increase program efficiency and effectiveness; and improve the integrity, quality, and utility of information to all users within and outside the agency, including capabilities for ensuring dissemination of public information, public access to government information, and protections for privacy and security (44 USC 3506).

[1] The collection of information related to the voluntary cover sheet was previously approved by OMB under OMB Control No. 2070-0156. That OMB Control Number was discontinued as of November 30, 2013. See http://www.reginfo.gov/public/do/DownloadNOA?requestID=253621.

2.1.2 Toxic Substances Control Act (TSCA)

TSCA section 2 expresses the intent of Congress that EPA carry out TSCA in a reasonable and prudent manner, and in consideration of the impacts that any action taken under TSCA may have on the environment, the economy, and society (15 USC 2601). Electronic reporting was not available when TSCA was enacted and when several underlying reporting requirements were subsequently promulgated by EPA. EPA believes that it is now reasonable and prudent to manage and leverage its information resources, including information technology, to require the use of electronic reporting in the implementation of certain TSCA provisions. Electronic reporting can reduce burden and costs for the regulated entities by eliminating the costs associated with printing and mailing this information to EPA, while at the same time improving EPA's efficiency in reviewing submitted information, making decisions and disseminating information to the public.

TSCA also gives EPA broad authority to regulate the manufacture (including import) and processing of chemical substances. The underlying requirements promulgated under this broad authority and amended by this rule require manufacturers (including importers) and processors of chemical substances and mixtures to:

- Perform testing to generate data relevant to a determination whether the manufacture, distribution in commerce, processing, use, or disposal of such chemicals or mixtures presents an unreasonable risk of injury to health or the environment (TSCA section 4).

- Report such data as EPA may reasonably require, including information that is necessary to facilitate the evaluation of the potential adverse human health and environmental effects from exposure to identified chemical substances, mixtures, or categories (TSCA section 8(a)).
- Submit lists and/or copies of ongoing and completed unpublished health and safety studies concerning identified chemical substances, mixtures, or categories (TSCA section 8(d)).

- Notify EPA at least 90 days before commencing the manufacture of a new chemical substance for commercial purposes (TSCA section 5(a)(1)(A)).

- Notify EPA at least 90 days before manufacturing or processing the chemical substance for any use of a chemical substance that EPA has determined, by rule, to be a "significant new use" (TSCA section 5(a)(2)).

2.2 Practical Utility/Users of the Data

The CISS reporting tool, e-PMN software, and electronic submission via CDX will change the way that companies interact with the Agency. 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. 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 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.

2.2.1 Section 4, Section 8(a), and Section 8(d)

Chemical Information Submission System (CISS)

EPA developed the CISS reporting tool for use in submitting data electronically to the Agency. The tool is available for use with Windows, Macs, Linux, and UNIX based computers, using "Extensible Markup Language" (XML) specifications for efficient data transmission across the Internet. The CISS is a tool that provides user-friendly navigation, works with CDX to secure online communication, creates a completed Portable Document Format (PDF) for review prior to submission, and enables data, reports, and other information to be submitted easily as PDF attachments.

All information sent by the submitter via CDX is transmitted securely to protect CBI. Furthermore, if anything in the submission is claimed as CBI, a non-CBI copy of the submission must be provided by the submitter. The guidance document will instruct users on how to submit and substantiate CBI information using CISS.

The Agency ensures secure transmission of the data, reports, and other documents sent from the user's desktop through the Internet via the Transport Layer Security (TLS) 1.0 protocol. TLS 1.0 and its successors is an approach for securing Internet transactions and is endorsed by the National Institute of Standards and Technology (NIST) as a means for protecting data sent over the Internet.

In addition, CISS enables the submitter to electronically sign, encrypt, and transmit submissions, which EPA subsequently provides back to the submitter as an unaltered copy of record. This assures the submitter that the Agency has received exactly what the submitter sent to EPA. The CISS reporting tool encrypts using a module based on the 256-bit Advanced Encryption Standard (AES) adopted by NIST, and EPA may incorporate other encryption modules into future versions of the tool (such versions might be developed before or after the final rule is to take effect depending upon availability and suitability). Information submitted via CDX is processed within EPA by secure systems certified for compliance with Federal Information Processing Standards.

Fielded CISS Meta-data

In order to facilitate the efficiency in communications and cost savings in submissions and correspondence for both EPA and respondents, EPA has incorporated the following data elements into the reporting tool.

1. Submission Type	*Identifies the submission, including the type of submission*

	and whether it is the initial submission, a follow-up or a final report.
2. Summary of Attachment	*Allows the respondent to provide a summary or abstract of the attached study or report, any internal company tracking number, an EPA tracking number, and an indication of the number of studies submitted.*
3. Chemical Identification	*Identifies the chemical(s) addressed in the submission.*
4. Title of Attachment	*Identifies the title of the attached study or report.*
5. Indexing Terms	*Allows the respondent to identify the proper terms to use for indexing purposes, which facilitates the search and retrieval of the information.*
6. Study/Report Information	*Provides specific information regarding the attached study or report, including the source, date of the study or report, sponsor(s), and the length of the document.*
7. Submitter Information	*Identifies the submitter and/or technical contact, including name, title, company, mailing address, phone and e-mail address.*
8. Comments	*Allows the submitter to provide any additional comments, so as to avoid the need for or use of a separate cover letter.*

Each of these data elements were previously incorporated into a voluntary instrument for certain TSCA submissions. The voluntary TSCA Health & Safety Study Cover Sheet was initiated and developed by industry representatives – in particular, the American Chemistry Council (ACC) – in an effort to begin familiarizing companies with standard requirements and concepts of electronic reporting. The voluntary cover sheet was developed as a first step in standardizing data and terms to promote the acceptance and implementation of electronic TSCA submissions to and communications with the Agency. EPA and industry representatives agreed that the submission of this information would achieve efficiencies through industry-industry and industry EPA cooperation, engender more efficient systems and result in significant money and time savings. Now that EPA is moving to broad-based electronic reporting of information under TSCA, EPA is requiring the submission of this meta-data in order to ensure that industry and the government alike fully realize the benefits of electronic reporting.

EPA staff will be the primary users of the standardized meta-data. EPA employees will use the meta-data collected through CDX in manner very much like they use the information presently collected via the voluntary cover sheet, i.e., to identify the submission when it reaches EPA without having to examine portions of a submission that may be very lengthy and complex, and to subsequently use the information to distribute, locate and track the submission as the

submission moves through Agency reviews and decision points, to index the data, and to identify the data within EPA databases in making the data publicly available.

Incorporating the data elements into the electronic reporting tool is expected to result in the following benefits to both Industry and EPA:

EPA Benefits	Industry Benefits
• expedited processing • reduced errors • improved data quality • more timely EPA access and scientific review • improved communication between EPA and industry submitters • quicker public availability • overall time and money savings	• improved internal company cataloguing • more efficient preparation and submission • standardized keywords • improved data quality • quicker decisions (where applicable) • improved understanding of EPA's needs • quicker access to relevant studies by industry toxicologists through EPA databases • significant potential cost savings from non-initiation/non-duplication of studies through rapid availability in EPA databases

2.2.1 Section 5 NOC and Supporting Documents

e-PMN Software

The e-PMN software facilitates the creation of this sanitized non-CBI version, eliminating the need for the submitter to do this manually. It also allows submitters to share a draft NOC and any support documents within their company during the creation of the NOC or support document and to save a copy of the final file for future use. A "Profiler," available in the software, also allows for certain information to be kept on file by the submitter to avoid re-entering the same information into a new form.

3 NON-DUPLICATION, CONSULTATIONS AND OTHER COLLECTION CRITERIA

3.1 Non-Duplication

3.1.1 Fielded CISS Meta-data

The fielded meta-data provide summary information specific to the other collections described in this supporting statement. There is no duplicative collection.

3.1.2 CDX Registrations

EPA has determined that approximately 80 percent of the same companies that will engage in electronic reporting under rule will also be engaged in electronic reporting under the e-PMN and Chemical Data reporting rules and under EPA's Toxic Release Inventory program. Users who have previously registered with CDX with the CISS flow for TSCA section 5 submissions (e-PMN), TSCA Inventory Chemical Data Reporting rule submissions (eCDR-web), or the Toxic Release Inventory TRI-ME web reporting flow will be able to add the "Submission for Chemical Safety and Pesticide Program (CSPP)" CDX flow to their current registration. This would allow a single authorized company official (or designee(s)) to avoid needing to complete the CDX registration process multiple times and allow a given individual to avoid needing to complete multiple electronic signature agreements.

3.1.3 Public Notice Required Prior to ICR Submission to OMB

The notice of proposed rulemaking *http://www.epa.gov/oppt/chemtest/ereporting/index.html* served as the public notice for this ICR, pursuant to 44 USC 3504 and 5 CFR 1320.11. EPA received comments from an anonymous party that was supportive of the rulemaking effort, and from an industry trade association that expressed general support with some substantive concerns. The public comments are available in rulemaking docket online at Regulations.gov (Docket ID No. EPA-HQ-OPPT-2011-0519) and are addressed in the final rule preamble.

3.2 Consultations

As explained earlier in this supporting statement, the involvement and initiative of industry representatives in years past has significantly influenced EPA's preparations for electronic reporting under TSCA, particularly with respect to the standardized submission meta-data that evolved from the voluntary TSCA Health and Safety Study Cover Sheet that was developed by industry as steppingstone to electronic reporting under sections 4 and 8 of TSCA. Based on positive feedback during outreach activities for the ePMN rulemaking efforts, EPA expects industry to respond favorably to this final rule. The Agency believes that the overall benefits of using the CISS reporting tool, ePMN software, and submission through CDX exceed those associated with maintaining a paper-based reporting approach. The Agency also recognizes that there is the potential for costs and burdens associated with predictable or unanticipated technical difficulties in electronic filing or with conversion to an electronic format. Since the use of CDX has been in existence for a number of years and has undergone a number of enhancements, EPA expects the potential for difficulty to be minimal. In addition, EPA expects that reduced reporting costs to submitters will ultimately exceed the transition costs.

The Agency will offer a webinar open to the public for potential users to gain access to the CISS reporting tool before its release. The webinar will be recorded and available at: http://www.epa.gov/oppt/chemtest/ereporting/index.html.

3.3 Effects of Less Frequent Collection

The information collected through the CISS tool is the minimum metadata needed to help organize and upload files in CISS, so they can be automatically processed. The CISS tool is designed to avoid repetitive entry of data, and where possible, key metadata such as submitter and chemical identity information will reuse information already provided to CDX or the EPA registry systems (Facility Registry and Substance Registry). Similarly the information collected through CDX registration and the electronic signature agreement will be collected once and reused across all eTSCA submissions for that registrant. Reducing the frequency of collection of registration and ESA information would not be possible, as EPA and federal wide security requirements mandate users must provide identity and access information in order to gain access and file reports electronically through CDX. The metadata collected through the CISS tool is needed to characterize the submission in a manner that allows EPA to automate the handling of the submission. Collecting these metadata on a less than per submission basis would undermine the automated features of CISS and force EPA and industry to perform additional manual operations to properly process the submission, defeating the benefits of automation.

General Guidelines

This collection does not exceed any of the Paperwork Reduction Act guidelines at 5 CFR 1320.6, and is consistent with the requirements of the PRA, OMB implementing regulations (5 CFR 1320.6), and OMB Guidance.

3.4 Confidentiality

3.6.1 Section 4, Section 8(a), and Section 8(d)

All information sent by the submitter via CDX is transmitted securely to protect CBI. The CISS reporting tool enables the user to submit CBI in an electronic format. The reporting tool guides the user through the process of submitting CBI by prompting the submitter to check a CBI checkbox if using a form or by submitting a scanned document containing CBI by bracketing, underlining, or otherwise marking the confidential information on the document to be submitted prior to scanning. Documents containing information claimed as CBI must be submitted in an electronic format, in accordance with the recordkeeping requirements and the following regulations:

TSCA section 4 test rules and ECAs.

Documents required under TSCA section 4 that may contain information claimed as CBI include study plans submitted in accordance with test rules (40 CFR §790.50) and study plans submitted in accordance with an ECA (40 CFR §790.62). The CISS reporting tool will allow the submitter to indicate if a study plan contains information claimed as CBI by checking the appropriate box. Then, the submitter will be prompted to submit the study plan document in an electronic format. The submitter will need to indicate which information in the study plan contains information claimed as CBI by marking the specific information claimed as confidential and designating it with the words “confidential business information,” “trade secret,” or another appropriate phrase

in the document prior to scanning. Subsequently, if CBI is claimed in either a study plan for test rules or a consent agreement, the submitter will be prompted by the CISS reporting tool to substantiate those claims by answering the substantiating questions pursuant to 40 CFR §790.7 in a document submitted in an electronic format.

TSCA section 8(a) PAIR.

The CISS reporting tool will include areas for indicating CBI on Form 7710-35, Manufacturer's Report—Preliminary Assessment Information (40 CFR §712.28 and §712.30). If CBI is indicated on the Form, the reporting tool will prompt the submitter to certify that the Confidentially Statements are true by prompting the submitter to select the Confidentiality Certification Statement.

TSCA section 8(d).

Documents submitted under 8(d) that contain information claimed as CBI must be indicated as such by using the CISS reporting tool. The CISS reporting tool will allow the submitter to indicate if the document contains CBI by checking the appropriate box. Then, the submitter will be prompted to submit the document in an electronic format. In submitting a document that contains CBI, the CISS reporting tool will prompt the submitter to submit two copies of the document in an electronic format. The copy containing CBI must identify the confidential information by bracketing or underlining the information and labeling the copy "confidential," "proprietary," or "trade secret." The second copy will need to have all confidential information deleted. Once CBI is claimed, the CISS reporting tool will prompt the submitter to substantiate their claims (40 CFR 716.55).

3.6.2 Section 5 NOC and Supporting Documents

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 will be CBI. EPA has developed a robust 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 is transmitted using secure technologies to protect CBI. The e-PMN software encrypts the submission 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 remains encrypted during transmission via CDX and can be opened only by the submitter within the e-PMN software.

3.5 Sensitive Questions

This information collection does not include questions of a sensitive nature other than CBI, which is discussed above.

4 THE RESPONDENTS AND THE INFORMATION REQUESTED

4.1 Respondents/ NAICS Codes

Submitters of TSCA sections 4, 5 NOC and Supporting Documents, 8(a) PAIR, and 8(d) reports are manufacturers and importers of chemical substances, mixtures or categories. Respondents affected by this collection are included primarily in the following NAICS categories:

- Chemicals and Allied Products Manufacturers
- Paper Manufacturing
- Petroleum and Coal Products Manufacturing
- Plastics and Rubber Products Manufacturing
- Primary Metal Manufacturing
- Computer and Electronic Product Manufacturing

4.2 Information Requested

4.2.1 Data Items, Including Recordkeeping Requirements for Section 4, Section 8(a), and Section 8(d)

With the exceptions of the CISS reporting tool and related meta-data fields, data items presently approved under OMB Control Numbers 2070-0033, No.2070-0012, No.2070-0054, and No. 2070-0004 are otherwise unchanged. In addition to these data items, respondents will also be required to register with CDX and complete the electronic signature agreement.

Fielded CISS Meta-data

EPA has incorporated the following data elements into the reporting tool.

1. Submission Type	*Identifies the submission, including the type of submission and whether it is the initial submission, a follow-up or a final report.*
2. Summary of Attachment	*Allows the respondent to provide a summary or abstract of the attached study or report, any internal company tracking number, an EPA tracking number, and an indication of the number of studies submitted.*
3. Chemical Identification	*Identifies the chemical(s) addressed in the submission.*
4. Title of Attachment	*Identifies the title of the attached study or report.*
5. Indexing Terms	*Allows the respondent to identify the proper terms to use for indexing purposes, which facilitates the search and retrieval of the information.*
6. Study/Report Information	*Provides specific information regarding the attached study or report, including the source, date of the study or report, sponsor(s), and the length of the document.*
7. Submitter Information	*Identifies the submitter and/or technical contact, including name, title, company, mailing address, phone and e-mail address.*
8. Comments	*Allows the submitter to provide any additional comments, so as to avoid the need for or use of a separate cover letter.*

4.2.2 Data Items, Including Recordkeeping Requirements for Section 5 NOCs and Supporting Documents

With the exceptions of the new e-PMN software and the minor revisions to the PMN form 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 are required to register with CDX and complete the electronic signature agreement.

4.3 Respondent Activities

4.3.1 Respondent Activities for Section 4, Section 8(a), and Section 8(d)

Registering with CDX.

Registration enables CDX to perform two important functions: (i) Authentication of identity, and (ii) Verification of authorization. To submit electronically to EPA via CDX, individuals must first register with that system at, *http://cdx.epa.gov/epa_home.asp*.

To register in CDX, the CDX registrant (also referred to as "Electronic Signature Holder" or "Public/Private Key Holder") agrees to the Terms and Conditions, provides information about the submitter and organization, selects a user name and password, and follows the procedures outlined in the guidance document for CDX available at *http://www.epa.gov/cdr/tools/CDX_Registration_Guide_v0_02.pdf*.

Users who have previously registered with CDX with the eTSCA flow for TSCA section 5 submissions, or the Toxic Release Inventory TRI-ME web reporting flow will be able to add the "Submission for Chemical Safety and Pesticide Program (CSPP)" CDX flow to their current registration. TSCA section 4, 5, and 8 will be available under the new CISS reporting tool.

Preparing the submission.

All submitters will be required to use CISS to prepare their submissions. The CISS guides users through a "hands-on" process of creating an electronic submission. Once a user completes the relevant data fields, attaches appropriate PDF files, and completes metadata information, the web-based tool validates the submission by performing a basic error check and makes sure all the required fields and attachments are provided and complete. Further instructions on submitting voluntary submissions, such as under MOUs, are available, and instructions for uploading PDF attachments and completing metadata information will be available through the CISS reporting guidance.

Completing the submission to EPA.

The web-based tool, as appropriate, also allows the user to choose "Print," "Save," or "Transmit through CDX." When "Transmission through CDX" is selected, the user is asked to provide the user name and password that was created during the CDX registration process. The CISS then encrypts the file and submits it via CDX.

Correspondence through CDX.

The user will login to the application and check the status of their submissions. Upon successful receipt of the submission by EPA, the status of the submissions will be flagged as Completed. The CDX inbox is currently used to notify the users of any correspondence related to user

registration. Information on accessing the CDX user inbox is provided in the guidance document for CDX http://www.epa.gov/cdr/tools/CDX_Registration_Guide_v0_02.pdf.

There are no required forms for sections 4 or 8(d) reports. To allow for electronic submission of data, reports, and other information under section 4 and 8(d) reporting fields from the TSCA Health and Safety Cover Sheet will be utilized and attachment information will be submitted using the CISS tool. Specific data elements used from the TSCA Health and Safety Cover Sheet include:

- Submission type
- Summary Abstract
- Chemical Substance Identity
- Report/study Title
- Report/Study Information

For section 8(a), Form 7710-35 will be generated using the CISS reporting tool.

Section of TSCA	**Use of CISS Reporting Tool**
Section 4 Test Rules	
Letters of Intent to conduct testing	CISS to generate and finalize submission using attached information
Extension Request	CISS to generate and finalize submission using attached information
Modification Request	CISS to generate and finalize submission using attached information
Exemption Request	CISS to generate and finalize submission using attached information
Hearing Request	CISS to generate and finalize submission using attached information
Data required to be developed under rules at 40 CFR §799	CISS to generate and finalize submission using attached information
ECAs	
Submission or Modification of Study Plan	CISS to generate and finalize submission using attached information
Request to Modify Test Schedule	CISS to generate and finalize submission using attached information
Section 8(a) PAIR	Form 7710-35 generated and finalized by the CISS reporting tool
Section 8(d)	
Submission of underlying data	CISS to generate and finalize submission using attached information
Preliminary reports of ongoing studies	CISS to generate and finalize submission using attached information

Copies of Studies	CISS to generate and finalize submission using attached information
Requests for extension of time	CISS to generate and finalize submission using attached information
Requests for withdrawal of a chemical	CISS to generate and finalize submission using attached information
MOU	CISS to generate and finalize submission using attached information

4.3.2 Respondent Activities for Section 5 NOCs and Supporting Documents

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 NOC (Form 7710-56).
- ***populate*** the submission materials with the relevant information

There are no required or official forms for certain TSCA section 5 support documents. To allow for electronic and paper submission of these notices using the e-PMN software, the Agency is finalizing the rule as follows:

TSCA Section 5 NOC and support documents	
NOC	Form 7710-56 generated and finalized by e-PMN software
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 NOC and support documents will depend on the chosen submission method. The e-PMN software requires 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.

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

After the e-PMN finalization step is complete, the e-PMN software prompts respondents to log-in to CDX. Respondents will 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

5.1 Agency Activities

5.1.1 Agency Activities for Section 4, Section 8(a), and Section 8(d)

The Agency activities described in the ICRs that are currently approved under OMB Control No. 2070-0033, No.2070-0012, No.2070-0054, and No. 2070-0004 remain unchanged, except as described below:

- Convert to an electronic reporting system
- acknowledge receipt of submissions and notify respondents of any submission deficiencies
- provide technical assistance to respondents

5.1.2 Agency Activities Section 5 NOCs and Other Support Documents

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
- acknowledge receipt of submissions and notify respondents of any submission deficiencies
- provide technical assistance to respondents

5.2 Collection Methodology

5.2.1 Collection Methodology and Management for Section 4, Section 8(a), and Section 8(d)

This final rule establishes standards and requirements for the use of EPA's electronic Central Data Exchange (CDX) system that allows submissions of reports electronically in place of hard copy submissions. EPA estimated that this final rule will result in burden reduction for the affected companies because the time required to enter, review, edit, and submit their reports using CDX will be reduced compared to the existing paper-based process.

In addition to the quantifiable cost savings, EPA believes that this rule will result in other benefits. For example, electronic reporting will allow for faster review and transmission of submissions to EPA. For studies containing CBI, electronic reporting will also improve security and transmission of CBI data to EPA. Additionally, all information submitted electronically could be linked in an improved tracking system, which will facilitate document management efforts. This will allow companies to manage past and future submissions easier.

The Agency will be able to communicate electronically with the submitter. For the most part, these transactions have taken place through the standard paper mail process for both submitters and the Agency. Having the means of communicating electronically should provide significant time and resource savings for both parties.

The major difference between the old and new methods of data entry is the user interface. Data now will be entered through a series of pages or screens on the computer. A submission sent to the Agency over the Internet will necessitate an electronic signature. GPEA gives the Agency the authority to accept such signatures. Respondents submitting notices will only need to register once per user for all future submissions.

5.2.2 Collection Methodology and Management for Section 5 NOCs and Supporting Documents

The e-PMN software is available as a free internet download. The Agency is also making the software available for free on optical discs until April 6, 2012. The data being transmitted electronically via CDX is encrypted to protect CBI. The software works with Windows, Macs, Linux, and UNIX-based computers, using XML for more efficient data transmittal to Agency data systems that once was performed manually.

An electronic signature is required for TSCA section 5 NOCs and support documents submitted to the Agency via CDX. Electronic signatures are granted as part of the CDX user-registration process.

EPA believes this change to electronic communications potentially reduces the reporting burden on industry because it reduces both the cost and the time required to enter, review, edit and transmit data to the Agency. The electronic submission software improves data quality because it facilitates data correction and validation by highlighting fields with omitted data prior to submission. The protection of encrypted TSCA CBI data and the generation of an electronic

Copy of Record that is returned to the submitter are other critical advantages of submitting data electronically through CDX.

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

5.3 Small Entity Flexibility

5.3.1 Small Entity Flexibility for Section 4, Section 8(a), and Section 8(d)

This final rule will streamline the submission process by establishing standards and requirements for the use of EPA's electronic Central Data Exchange (CDX) system. As a result, the rule will reduce the burden of the TSCA section submissions for industry, including small businesses.

As estimated in the Economic Analysis for the final rule[2], all small parent entities potentially affected by this final rule will have a cost impact of less than one percent of their annual revenue. The estimated ratios range from less than 0.0001 percent to 0.015 percent, depending on the NAICS sector and employment size category, with an average of 0.001 percent.[3] No small parent entities are expected to have a cost impact of greater than one percent of annual revenue. Since the estimated regulatory costs represent a small fraction of a typical parent entity's revenue (i.e., less than one percent), the impacts of this regulation are likely to be minimal.

5.3.2 Small Entity Flexibility for Section 5 NOCs and Supporting Documents

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).

5.4 Collection Schedule

5.4.1 Section 4

This information collection activity does not involve more than one submission per activity. Required testing is conducted only once, and each related submission is a one-time on occasion

[2] Economic Analysis for the Electronic Reporting of TSCA Section 4, Section 5 NOC and Supporting Documents, 8(a) PAIR, and 8(d) Submissions, Draft, November 2011.

[3] Using the seven percent discount rate.

submission. The testing period is based on the individual rule, consent order, or VTA, the standard time required to conduct the required test according to the testing guidelines, according to the timing established in the approved test plan, or timing otherwise established by the Agency.

The time period for screening level testing, like that conducted under the HPV Challenge Program is usually less than a year. The typical time period for other types of testing is around three years, although it can be longer and varies according to the chemical and the test required.

5.4.2 Section 8(a) PAIR

Information collection under PAIR occurs after publication of a *Federal Register* notice establishing the reporting period for the listed chemical substances, mixtures or categories. Respondents are asked to respond once, within 30 days of the effective date of the final PAIR rule (which is usually 30 days after publication of the rule in the *Federal Register*).

5.4.3 Section 8(d)

The collection scheduled under this ICR is chemical-specific in nature and occurs once in an established time frame between 60 days and 2 years. Reporting of information is only required when the subject matter information (i.e., the lists of studies and final study reports) is available. Availability of study reports on the list may occur after the established reporting period for the list, and must still be submitted when they become available. In any case, submission of the list or any study report for a listed study occurs once for each chemical covered by a TSCA section 8(d) rule. Studies previously submitted to OPPT are exempt.

Amendments adding substances are made to the Health and Safety Data Reporting Rule subsequent to the Interagency Testing Commission's (ITC) semiannual addition of substances and categories of substances to the TSCA section 4(e) Priority List. Other substances are added when there is a demonstrated need for the information.

5.5.4 Collection Schedule for Section 5 NOCs and Supporting Documents

Submission of information under this collection is on an as-needed, on occasion basis, initiated by the respondents.

6 ESTIMATING THE BURDEN AND COST OF THE COLLECTION

This section presents the total burden and cost estimates associated with the final rule that will require electronic submission for TSCA section 4, section 5 NOC (not previously submitted online), 8(a) PAIR, and 8(d) reports. As a result of the new electronic reporting requirements, respondents for all TSCA sections subject to this rule must use the CDX electronic reporting system to submit the information to EPA.

This ICR Supporting Statement presents the total paperwork burden and costs associated with the requirements of the final electronic reporting rule. These requirements include:

- Familiarization with the new electronic reporting requirements set forth in the final electronic reporting rule.
- Registration with CDX and completion of the electronic signature agreement.
- Submission of reports using the CDX reporting system for the following sections of TSCA:
  - Section 4: Submitting short- and long-term test study data, maintaining certain records related to testing, submitting a letter of intent, study plans, and progress reports, or an exemption application.
  - Section 5 NOC (not previously submitted online): Submitting an NOC when manufacture or importation of a substance or microorganism begins after a company has submitted a Premanufacture Notice (PMN) or Microbial Commercial Activity Notice (MCAN).
  - Section 8(a) PAIR: Submitting information that is known or reasonably ascertainable on PAIR listed chemical substances such as the substances' chemical identification, quantity produced or imported, chemical processes, employee exposure, environmental releases, uses and products.
  - Section 8(d): Submitting copies of unpublished health and safety studies for the section 8(d) listed substances or mixtures as well as submitting lists of reportable studies that are initiated or known about for each of the listed substances or mixtures.

Respondents subject to this final rule will still be required to fulfill all reporting and testing requirements for each relevant TSCA section.

6.1 Estimating Per-Respondent Burden

The methodology used in this analysis draws upon that used in previous ICR supporting statements for each affected TSCA section, as well as assumptions used in the e-PMN rule published in April 2010[4]. Estimates from previous ICRs were revised to reflect the current reporting universe, and the one-time cost incurred due to CDX registration activities.

As a result of the final electronic reporting rule, EPA estimates that respondents will incur a small amount of additional burden and costs in carrying out the additional paperwork activities that will be imposed by the final rule. This includes the burden associated with activities that facilitate submission of an electronic report: CDX registration, CDX electronic signature, and rule familiarization. These activities occur only once; during the first year of the ICR period. Besides this one-time burden, EPA expects that respondents will experience overall burden reduction from increased reporting efficiency and decreased material costs, as a result of the electronic reporting rule. These burden reduction estimates are not accounted for under this information collection, but are instead considered under the ICRs for each of the TSCA reports

[4] Supporting Statement for *TSCA Section 4 Test Rules, Consent Orders, Test Rule Exemptions, and Voluntary Data Submission(EPA ICR No. 1139.08);* Supporting Statement for *Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances (EPA ICR No. 0574.14)*; Supporting Statement for *TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR) (EPA ICR No. 0586.11)*; Supporting Statement for *Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies (EPA ICR No. 0575.12)*; *Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule,* April 2010.

that are subject to this rule. Therefore these burden reductions are presented in Appendix C of this document, and not the main ICR analysis.

EPA estimated the burden that management, technical, and clerical staff at companies submitting sections 4, 5 NOC (not previously submitted online), 8(a) PAIR, and 8(d) will incur under the final electronic reporting rule. EPA used a simplifying assumption that employees from each submitter company will need to register with CDX. Some companies may have already registered with CDX through other rules, such as e-PMN, e-CDR, or TRI-ME web, and individual employees would not need to register again. Determining how many new users from companies previously registered with CDX will need to register as a result of this rule proved impractical because different individuals within a company need to register with CDX separately with their own username and password. EPA assumed that an average of four technical staff members and one manager will need to register for each submitter company (EPA, 2009). The one-time CDX burden includes the following:

- *CDX Registration* – Based on the CROMERR *Cost Benefit Analysis*, EPA assumed that companies will spend eleven minutes per employee to register with CDX (EPA, 2004). Based on an average of four technical staff members and one manager that will need to register for each company, 55 minutes of burden per company will be incurred.

- *CDX electronic signature (labor burden)* – Based on the CROMERR *Cost Benefit Analysis*, EPA assumed that companies will spend 15 minutes preparing, submitting, and filing an electronic signature agreement (Authentication of Identity) form to EPA, per employee (EPA, 2004). One manager and four technical staff members per company will incur this burden, totaling 75 minutes of burden per company. In addition, EPA used its best professional judgment to estimate that a manager will spend an additional 30 minutes accessing, preparing, and submitting verification forms (Verification of Authorization) for all authorized submitters to EPA. The total burden incurred by companies submitting and then verifying electronic signature agreements will be 105 minutes. It should be noted that the burden associated with CDX Electronic Signatures does not include costs associated with contacting EPA's CDX help desk to notify a change of submitter status, should one occur.

- *CDX electronic signature (non-labor costs)* – Non-labor costs include a $0.44 stamp and a $0.02 standard business envelope for each of five signature agreements. The total non-labor cost for electronic signature agreements equals $2.30.

- *Rule Familiarization* – Management and technical staff will spend some time familiarizing themselves with the new requirements for electronic submission of their company's sections 4, and 8(d). Based on the time required to read and comprehend supporting electronic reporting regulatory documentation, EPA estimated that one manager will spend 33 minutes and one technical staff member will spend 16 minutes per company on rule familiarization (EPA, 2009).

The one-time CDX labor burden is presented below in Table 1.

Table 1: One-Time CDX Labor Burden (per Company)				
Burden Category	**Managerial (hours)**	**Technical (hours)**	**Clerical (hours)**	**Total (Hours)**
CDX Registration	0.18	0.73	0.00	**0.91**
CDX Electronic Signature	0.75	1.00	0.00	**1.75**
Rule Familiarization	0.55	0.27	0.00	**0.82**
Total	**1.48**	**2.00**	**0.00**	**3.48**

6.2 Estimating Respondent Costs

EPA estimated the respondent cost for the electronic reporting rule using the fully loaded hourly rates for workers of appropriate labor categories. These wage rates, presented in Error: Reference source not found, were derived as described in Appendix A.

Table 2: Hourly Industry Labor Costs (2010$)			
Wage Component	**Managerial**	**Technical**	**Clerical**
Hourly Wage Rate	$42.82	$36.93	$17.36
Benefit Costs	$19.64	$18.50	$8.67
Fringe and Overhead Factor	1.63	1.67	1.67
Total Hourly Cost	**$69.74**	**$61.71**	**$28.98**

EPA calculated the industry cost for respondents by multiplying the per-company burden shown in Table 1 by the hourly wage rate (Error: Reference source not found). Table 3 presents the total labor cost associated with one-time CDX registration, $227 per company.

Table 3: One-Time CDX Labor Cost (per Company)				
Burden Category	**Managerial (2010$)**	**Technical (2010$)**	**Clerical (2010$)**	**Total (2010$)**
CDX Registration	$12.55	$45.05	$0.00	**$57.60**
CDX Electronic Signature	$52.31	$61.71	$0.00	**$114.02**
Rule Familiarization	$38.36	$16.66	$0.00	**$55.02**
Total	**$103.22**	**$123.42**	**$0.00**	**$226.64**

6.3 Estimating Agency Burden and Cost

While 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 increased efficiencies for EPA (see Appendix C), there are associated one-time and recurring costs. Because the current reporting system for TSCA sections 4, 5 NOC, 8(a) PAIR, and 8(d) reports 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 to convert the reporting for the respective TSCA sections to an electronic system (See the economic analysis

for more details).[5] In addition, annual costs will be associated with the operation and maintenance (O&M) of CDX for the data flow. EPA developed an estimate of increased CDX O&M costs attributable to the rule by apportioning the overall CDX maintenance cost estimated in the CROMERR *Cost Benefit Analysis, Final* (EPA, 2004) to the individual programs for which it currently manages data. This approach yields an estimate of $57,353 per year per program (See the economic analysis for more details). Note that although the data flow for this rule 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 may be considered a lower bound estimate of total O&M.

Final annual Agency burden and costs are presented in Table 4. Since the Agency will incur a $200,000 one-time cost to convert the reporting for the respective TSCA sections to an electronic system, the Year 1 cost is higher than that in subsequent years. Both the Year 1 cost and subsequent year costs include the $57,353 recurring cost for operation and maintenance.

Table 4: Total Agency Burden and Cost for E-Reporting of TSCA Sections

TSCA Section	Annual Agency Burden	Annual Agency Cost (2010$)
All Sections: One-Time CDX Conversion Cost	--	$200,000
All Sections: Recurring O&M CDX Cost	--	$57,353
Total Cost (Year 1)	--	**$200,000**
Total Cost (Subsequent Years)	--	**$57,353**

6.4 Estimating the Respondent Universe

In order to estimate the number of affected facilities and the number of submissions per facility for each section, EPA used information on the number of annual submissions across all affected entities and the number of companies submitting reports for each section annually.

6.4.1 Average Number of Annual Submissions

To estimate the average number of annual submissions sent to EPA under each TSCA section affected by this rule, EPA used past submission statistics from the Office of Pollution, Prevention and Toxics (OPPT). The number of submissions for section 4, section 8(a), and section 8(d) was counted using from 2006 to 2010, a five-year reporting period. The number of NOCs submitted each year was counted from 2008 to 2010 for PMNs received prior to April 2010. The total number of submissions for each section was divided by the number of reporting years to estimate the average number of submissions per year. Results are listed in Table 5.

6.4.2 Average Number of Pages Submitted

EPA estimated the average number of pages submitted for each section as follows:

[5] US EPA, 2004. Cross-Media Electronic Reporting Rule (CROMERR) Cost Benefit Analysis. Final. November 17, 2004.

- **Section 4** – EPA used the HPV Test Rule Docket (#00274D) as a representative sample of section 4 test rule submissions. The page length of each document in the HPV Test Rule Docket was averaged. The average page length of the HPV Test Rule Docket was assumed to be equivalent to the average page length of a section 4 test rule submission, at 35 pages.
- **Section 5 NOC (not previously submitted online)** – Since section 5 NOC reporting only involves a one-page from, EPA assumed that the average page length for a section 5 NOC submission was one-page.
- **Section 8(a)** PAIR – Since section 8(a) PAIR reporting only involves a two-page form (EPA, 2007b), EPA assumed that the average page length for section 8(a) PAIR submissions was two pages.
- **Section 8(d)** – The average number of pages submitted for section 8(d) reports is 20 pages, which was taken directly from the latest version of the TSCA Section 8(d) ICR (EPA, 2007c).

6.4.3 Average Number of Submitters

To estimate the average number of annual submitters under each type of TSCA section affected by this rule, EPA used statistics on the total number of submitters during a specified time period for each type of TSCA report divided by the number of reporting years. The number of submitters for section 4, section 8(a), and section 8(d) was counted from 2006 to 2010, a five-year reporting period. The number of NOC submitters was not available for the same time period; EPA used the number of section 5 notice submitters from 2003 to 2007 (EPA, 2009). The average annual number of submitters under each TSCA section is presented in Table 5.

As noted earlier, some submitter companies may have already registered with CDX through other rules, such as e-PMN, e-CDR, or TRI-ME web, and individual employees would not need to register again. However, different individuals within a company need to register with CDX separately with their own username and password. Therefore, the Agency used the most conservative assumption that all affected submitters will register with CDX and, thus, incur the associated burden/cost. This assumption will result in overestimating the costs associated with the final rule.

6.4.4 Average Number of Submissions per Submitter

EPA estimated the average number of annual submissions per submitter by dividing the average number of annual submissions by the average number of annual submitters for each type of TSCA section. The average number of submissions per submitter was rounded to the nearest integer and is reported in Table 5.

Table 5 presents the submission statistics for each TSCA section covered in this analysis.

Table 5: TSCA Submission Summary				
TSCA Section	**Average Number of Annual Submissions[1]**	**Average Number of Pages Submitted**	**Average Number of Submitters**	**Average Number of Submissions per Submitter[2]**
Section 4	148	35	24	6
Section 5 NOC	364	1	305	1
Section 8(a) PAIR	33	2	15	2
Section 8(d)	33	20	9	4
TOTAL	**578**	**58**	**353**	**--**

Notes:
[1] Although EPA estimated that 364 NOC submissions will be received each year, there is only a finite number of PMNs submitted before April 2010. Therefore, after all of these PMNs have commenced, there will be no NOC submissions subject to this rule.. EPA estimated the total outstanding NOC submissions from PMNs submitted before April 2010 at 10,027 at the start date of this rule.
[2] The average number of submissions per submitter is rounded to the nearest integer.

6.5 Total Respondent Burden and Cost

Table 6 presents the total and average annual respondent burden and cost for this ICR. In the first year, industry is expected to incur a total burden of 1,228 hours and $80,000. EPA assumes no CDX registration activities will occur in the second and third year of the ICR period, and, therefore, the annual average burden for industry over the three-year ICR period is approximately 409 hours and $27,000.

Table 6: Total and Average Annual Respondent Burden and Cost Associated with this ICR									
Activity	**Number of Submitters**	**Total Burden per Activity (hours)**	**Total Cost per Activity (2010$)**	**No. of Responses/ Respondent (Year 1)**	**Total Number of Responses (Year 1)**	**Total Annual Burden Hours (Year 1)**	**Total Annual Cost (Year 1)**	**Average Annual Burden for ICR Period**	**Average Cost Burden for ICR Period**
	(a)	**(b)**	**(c)**	**(c)**	**(e)=(a)*(c)**	**(g)=(b)*(e)**	**(g)=(b)*(e)**	**(j)=)(i)/3**	**(j)=)(i)/3**
CDX Registration	353	0.91	$57.60	1	353	321	$20,333	**107**	**$6,778**
CDX Electronic Signature	353	1.75	$114.02	1	353	618	$40,247	**206**	**$13,416**
Rule Familiarization	353	0.82	$55.02	1	353	289	$19,422	**96.49**	**$6,474**
TOTAL	**353**	**--**	**--**	**--**	**--**	**1,228**	**$80,002**	**409**	**$26,668**

6.6 Bottom Line Burden

EPA estimates that industry will incur a total of 1,228 hours in burden as a result of new activities stemming from mandatory electronic reporting requirements. These new activities include rule familiarization, CDX registration, and CDX electronic signature agreements. These activities occur only once during the first year of the analysis.

Table 7: Total Estimate of Annual Burden Hours	
	Total Burden Hours
Current OMB Inventory	0
Change in Burden due to Adjustments	0
Change in Burden due to Program Changes (i.e., electronic reporting)	1,228
Total Change in Burden	***1,228***

6.7 Burden Statement

According to the Paperwork Reduction Act, "burden" refers to 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, burden 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.

To comment on 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, EPA has established a public docket for this ICR under Docket ID No. EPA-HQ-OPPT-2011-0519. The docket is available for public 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 WJC 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. An electronic version of the public docket is available through the Federal Docket Management System (FDMS) at www.regulations.gov. Use FDMS to submit or view public comments, access the index listing of the contents of the public docket, and to

access those documents in the public docket that are available electronically. Once in the system, select “search,” then key in the docket ID number identified above. Also, comments can be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Please include the EPA Docket ID No. EPA-HQ-OPPT-2011-0519 and OMB control number 2070-0183 in any correspondence.

Appendix A: Derivation of Wage Rates

This appendix describes the derivation of the fully loaded wage rates used in calculating costs of labor. All cost estimates are presented in fourth quarter, calendar year 2010 (Q4 2010) dollars.

The fully loaded unit labor cost for managerial, technical, and clerical labor in the regulated industry and for EPA staff was estimated by adding fringe benefits and overhead costs to the hourly wage or annual salary for each category following the method described in *Wage Rates for Economic Analysis of the Toxics Release Inventory Program* (EPA, 2002b). This appendix describes the method used to estimate the fully loaded unit labor costs for each labor category and presents the results of the derivation.

Industry Wage Rates

Wages and fringe benefit data for managerial, professional/technical, and clerical labor were taken from the BLS Employer Costs for Employee Compensation (ECEC) historical data for December 2010 (BLS, 2011).[6]

The costs of fringe benefits such as paid leave and insurance, specific to each labor category, were taken from the same BLS report (BLS, 2010). Fringe benefits as a percentage of wages were calculated separately for each labor category. For example, for December 2010, the average wage rate for technical labor was $36.93, and the average fringe benefit was $18.50. Therefore, fringe benefits as a percentage of wages were $18.50/$36.93, or approximately 50 percent (see Exhibit 1:).

An additional loading factor of 17 percent was applied to wages to account for overhead.[7] This approach was used for consistency with Office of Pollution Prevention and Toxics (OPPT) economic analyses for two major rulemakings: *Economic Analysis of the Toxics Release Inventory Program*, June 2002 (EPA, 2002b), and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report*, August 2002 (EPA, 2002a). This overhead loading factor was added to the benefits loading factor, and the total was then applied to the base wage to derive the fully loaded wage. For example, the December 2010 fully loaded wage for technical labor is $36.93 × (1+ 0.50 + 0.17) = $61.71.

Fully loaded costs for managerial and clerical labor are calculated in a similar manner, as shown in Exhibit 1:.

[6] Past economic analyses used ECEC data series specific to white-collar workers in the manufacturing sector. However, those data sets were discontinued in March 2007, and these historical data were the best alternative. In a phone conversation (February 11, 2009), a BLS employee could not identify a better data set to use.

[7] The change was used in the 2003 PMN SNUR economic analysis (EPA, 2003b). In some earlier reports, the 17 percent had been applied to wages-plus-fringe benefits.

Exhibit 1: Industry Wage Rates (December 2010)						
Labor Category	**Wage ($/hour)[1]**	**Fringe Benefits ($/hour)[1]**	**Fringes as % Wage**	**Overhead % Wage[2]**	**Fringe + Overhead Factor**	**Loaded Wages ($/hour)**
	(a)	**(b)**	**(c) = (b)/(a)**	**(d)**	**(e)=(1)+(c)+(d)**	**(f) = (a) x (e)**
Managerial	$42.82	$19.64	45.87%	17%	1.63	$69.74
Technical	$36.93	$18.50	50.09%	17%	1.67	$61.71
Clerical	$17.36	$8.67	49.94%	17%	1.67	$28. 98

Notes:

[1]Employer Costs for Employee Compensation Supplementary Tables: December 2010, US Bureau of Labor Statistics, March 9, 2011 (BLS, 2011a)

[2]An overhead rate of 17 percent was estimated based on industry data gathered for the Revised Economic Analysis for the Amended Inventory Update Rule: Final Report (EPA, 2002a)

Agency Wage Rates

Unit wage rates for EPA staff were calculated based on annual federal salaries for the Washington-Baltimore area published by the Office of Personnel Management (OPM). The Agency loading factor of 1.6 is from an EPA guide entitled *Instructions for Preparing ICRs* (EPA, 1992, page 30, footnote 9). The 60 percent assumption was labeled "the benefits multiplication factor" in the EPA guide, but has been used in many EPA OPPT ICRs to reflect both fringe benefits and overhead for federal staff. For example, it was used in a supporting statement document for EPA ICR No. 1139.06 (EPA, 2000), with the following explanation:

> The annual costs per FTE are derived by multiplying the annual pay rate by 1.6 (the benefits multiplication factor). The multiplication factor used is recommended in EPA's Office of Policy, Planning, and Evaluation's *Instructions for Preparing ICRs* (June 1, 1992). An EPA internal phone call between Carol Rawie (OPPT/EETD/RIB) and Carl Koch (OPPE/RMD/IMB) on May 3, 1994, indicated that the 1.6 factor included not only benefits but also overhead.

Fully loaded costs for Agency labor for of the sections are shown below:

Exhibit 2: Agency Wage Rate for GS-13 Step 1 (Section 4) (January 2010)								
Labor Category	**Data Source for Wage Information**	**Date**	**Wage ($)**	**Fringe Benefit**	**Fringes as % wage**	**Overhead as % wage**	**Fringe + overhead factor**	**Loaded Wage ($)**
			(a)	**(b)**	**(c) = (b) / (a)**	**(d)**	**(e) = (c) + (d) + 1**	**(f) = (a) * (e)**
EPA staff FTE	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-13 Step 1 pay rates [a]	Jan-10	$89,033 (annual)	--	[Included in 60% overhead]	60% [b]	1.6	$142,453 (annual)
			$42.80 (hourly)					$68.48 (hourly)

Notes:
[a]The Agency salary is the unloaded federal GS-13 Step 1 salary ($89,033 for 2010), from the OPM salary table for the Washington-Baltimore-Northern Virginia Locality Pay Area (OPM, 2010). Hourly rates are based on annual salary divided by 2,080 hours.
[b]The 60 percent fringes-and-overhead rate is from an EPA guide, *Instructions for Preparing ICRs* (EPA, 1992).

Exhibit 3: Agency Wage Rate for GS-12 Step 1 (Section 8(a) PAIR) (January 2010)								
Labor Category	**Data Source for Wage Information**	**Date**	**Wage ($)**	**Fringe Benefit**	**Fringes as % wage**	**Overhead as % wage**	**Fringe + overhead factor**	**Loaded Wage ($)**
			(a)	**(b)**	**(c) = (b) / (a)**	**(d)**	**(e) = (c) + (d) + 1**	**(f) = (a) * (e)**
EPA staff FTE	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-12 Step 1 pay rates [a]	Jan-10	$74,872 (annual)	--	[Included in 60% overhead]	60% [b]	1.6	$119,795 (annual)
			$36.00 (hourly)					$57.60 (hourly)
Notes: [a]The Agency salary is the unloaded federal GS-12 Step 1 salary ($74,872 for 2010), from the OPM salary table for the Washington-Baltimore-Northern Virginia Locality Pay Area (OPM, 2010). Hourly rates are based on annual salary divided by 2,080 hours. [b]The 60 percent fringes-and-overhead rate is from the EPA guide, *Instructions for Preparing ICRs* (EPA, 1992).								

Exhibit 4: Agency Wage Rate for GS-13 Step 5 (Section 8(d) and Section 5 NOC) (January 2010)								
Labor Category	**Data Source for Wage Information**	**Date**	**Wage ($)**	**Fringe Benefit**	**Fringe as % wage**	**Overhead as % wage**	**Fringe + overhead factor**	**Loaded Wage ($)**
			(a)	**(b)**	**(c) = (b) / (a)**	**(d)**	**(e) = (c) + (d) + 1**	**(f) = (a) * (e)**
EPA staff FTE	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-13 Step 5 pay rates [a]	Jan-10	$100,904 (annual)	--	[Included in 60% overhead]	60% [b]	1.6	$161,446 (annual)
			$48.51 (hourly)					$77.62 (hourly)
Notes: [a]The Agency salary is the unloaded federal GS-13 Step 5 salary ($100,904 for 2010), from the OPM salary table for the Washington-Baltimore-Northern Virginia Locality Pay Area (OPM, 2010). Hourly rates are based on annual salary divided by 2,080 hours. [b]The 60 percent fringes-and-overhead rate is from an EPA guide, *Instructions for ICRs* (EPA, 1992).								

Appendix B

TSCA HEALTH & SAFETY STUDY COVER SHEET

Use of this form is voluntary, but recommended by EPA as a cover sheet for TSCA section 4, 8(d), and 8(e) submissions to expedite and improve the management, processing, quality, review, and public availability of data in TSCATS

TSCA CBI STATUS:

☐ **CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)**

Clearly mark the confidential information with bracketing and check the box in the appropriate section (☐ *Contains CBI)*. Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

1.0 SUBMISSION TYPE ☐ *Contains CBI*

☐ 8(d) ☐ 8(e) ☐ FYI ☐ 4 ☐ OTHER: Specify_____

☐ Initial Submission ☐ Follow-up Submission ☐ Final Report Submission

Previous EPA Submission Number or Title if update or follow-up: _____ Docket Number, if any: # _____

ITC Submission ☐ Yes ☐ No

☐ continuation sheet attached

2.1 SUMMARY/ABSTRACT ATTACHED

(may be required for Sec. 8(e); optional for Secs. 4, 8(d) & FYI) ☐ Yes ☐ No

2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID

2.3 FOR EPA USE ONLY 2.4 Study ___ of ____

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY ☐ *Contains CBI*

Reported Chemical Name (specify nomenclature if other than CAS name):

_____

CAS#_____-_____-___

Purity _____%

☐ Single Ingredient

☐ Commercial/Tech Grade

☐ Mixture *Trade Name:* _____ *Common Name*: _____

CAS Number NAME % WEIGHT

Other chemical(s) present in tested mixture

☐ continuation sheet attached

4.0 REPORT/STUDY TITLE ☐ *Contains CBI*

☐ continuation sheet attached

5.1 STUDY/TSCATS INDEXING TERMS

[CHECK ONE]

HEALTH EFFECTS (HE): ENVIRONMENTAL EFFECTS (EE): ENVIRONMENTAL FATE (EF):_____

5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes)

STUDY SUBJECT ROUTE OF VEHICLE OF

TYPE: _____ ORGANISM (HE, EE only): EXPOSURE (HE only): EXPOSURE (HE only)_____

*Other:*_____ *Other:*_____ *Other:* _____ *Other:*_____

6.0 REPORT/STUDY INFORMATION ☐ *Contains CBI* ☐ Study is GLP

Laboratory _____

Report/Study Date_____

Source of Data/Study Sponsor (if different than submitter) Number of pages _____

☐ continuation sheet attached

7.0 SUBMITTER INFORMATION ☐ *Contains CBI*

Submitter: _____ Title: _____ Phone: ( )_____

Company Name: _____Company

Address:_____

_____ _____

_____Submitter Address (if different):

_____

Technical Contact: _____ _____ Phone: ( )_____
☐ continuation sheet attached e-mail address_____
8.0 ADDITIONAL COMMENTS ☐ *Contains CBI*
☐ continuation sheet attached **Submitter Signature:** Date:_____
EPA Form No. 7710-58 (Revised 6/25/96)

Appendix C: Burden Reductions by TSCA Section

The main body of the ICR discussed the additional burden and costs to respondents from carrying out the additional paperwork activities that will be imposed by the final rule. This includes the burden associated with activities that facilitate submission of an electronic report: CDX registration, CDX electronic signature, and rule familiarization. These activities occur only once during the first year are accounted for under this information collection. However, besides this one-time burden, EPA expects that respondents will experience overall burden reduction as a result of the final rule from increased efficiency and decreased material costs. This burden savings are discussed in this appendix and will be accounted for under the ICRs for each of the TSCA reports that are subject to this rule. EPA estimated that section 4, section 5 NOC (not previously submitted online), 8(a) PAIR, and 8(d) submitters will experience overall burden reduction and cost savings associated with submitting reports electronically via CDX. Specifically, EPA expects burden reduction for activities related to reporting, recordkeeping, and postage upon implementation of the electronic reporting rule.. Respondents are expected to realize burden savings each time a TSCA section report subject to this rule is submitted.

EPA estimated that companies submitting TSCA sections 4, 5 NOC (not previously submitted online), 8(a) PAIR, and 8(d) reports will realize the following burden reduction:

- Reduction in reporting burden (for clerical/administrative staff)
- Reduction in recordkeeping burden
- Elimination of material costs including paper and postage costs

The estimates for the baseline burden required for reporting and recordkeeping were taken from the most recent versions of the ICRs for TSCA sections 4, 5 NOC (not previously submitted online), 8(a) PAIR, and 8(d) reporting.

While some of the reporting and recordkeeping requirements will stay the same after the electronic reporting rule is implemented, other requirements will change as a result of this rule. Therefore, this appendix discusses the estimated burden for activities affected and unaffected by the final rule separately.

C.1 Reporting and Recordkeeping Burden Affected by the Final Rule

C.1.1 Burden Associated with Form Submission via CDX

The recurring burden associated with the time it takes to submit reports via CDX will be less than the reporting cost currently incurred by industry for submitting hard-copy reports, resulting in a cost savings to the industry.

EPA estimated the time it will take to prepare and submit a report electronically via CDX by conducting a simulation of this process for each of the TSCA sections. The electronic reporting simulation was created using a Microsoft Word document EPA created as a mock-up of the CDX electronic reporting system. The simulation document displayed the interface and drop-down menus of the actual CDX reporting system. Hyperlinks within the document were added in order to simulate the actual electronic reporting process. Five junior staff participated in this simulation

to estimate the time required of an industry clerical employee to submit an electronic report.[8] Each participant was given detailed instructions of how to navigate the simulation document in order to mimic the actual electronic reporting process.[9] Each participant was timed while conducting the simulation, after which all times were averaged for each section.

There was little deviation in the amount of time recorded by the five individuals who completed the simulation for each section. However, participants tended to spend more time on the first section of the simulation than other sections due to initial familiarization with the process.[10] Each individual completed the report simulations in a different order to reduce bias associated with the additional time required for familiarization. Since representatives were not actually uploading documents to a CDX server, an additional ten seconds was added to each time estimate to account for the lag time on a computer.. This recurring burden per submission was used when estimating the total cost and is presented below in Table C- 1.

The Voluntary TSCA Cover Sheet (found in Appendix B) is expected to be discontinued since EPA has incorporated in the final rule some of the data elements captured in the voluntary cover form for sections 4 and 8(d) reporting. This ICR addresses the incremental paperwork activities related to submitting the form electronically. This burden is accounted for in the recurring CDX burden for sections 4 and 8(d) presented in Table C- 1. This table presents the burden for filling out the CDX data elements for each section.

The previous Voluntary TSCA Cover Sheet ICR presented a 0.5 hour technical burden associated with filling out the voluntary cover sheet. However, this burden was never considered additive to the existing burden estimates provided by the underlying section 8(d) ICR since the Voluntary TSCA Cover Sheet was expected to be used in lieu of the letter that had been used in the past to transmit submissions to the Agency. Therefore, accounting for this separately in previous ICRs would have resulted in the double counting of this particular burden and EPA assumes no change will occur with electronic reporting.[11] Therefore, EPA assumes that any burden associated with filling out the data elements previously captured by the Voluntary Cover Sheet for sections 4 or 8(d) will be included in the recurring CDX burden presented in Table C-1.

[8] EPA assumed that five individuals will be a large enough sample size to generate an estimate for the average time required to submit an electronic report.

[9] For example, participants were told to click on a hyperlinked arrow icon which took them to a new part of the document with several options to simulate a drop-down menu. Participants were also told to search for a pre-selected document on shared computer drive in order to simulate the "Browse" and "Upload" features of the actual online CDX reporting system.

[10] EPA assumed that this additional time required for familiarization may model actual industry reporting practices since a new industry employee may be required to submit an electronic report and need additional time as compared to an experienced employee.

[11] OMB Control No. 2070-0156 (EPA ICR No. 1780.5 V*oluntary Cover Sheet for TSCA Submissions*)

Table C- 1: Recurring CDX Submission Cost (per Submission)	
TSCA Section	**Recurring Burden per Submission (hours)**
Section 4	0.06
Section 5 NOC	0.05
Section 8(a) PAIR	0.05
Section 8(d)	0.06

C.1.2 Reporting and Recordkeeping Burden Reduction

EPA estimated the reporting and recordkeeping burden reduction expected for each TSCA section affected by the rulemaking. Given that electronic reporting via CDX allows technical staff to enter information directly into the database for submission to EPA, the Agency generally assumes that the need for clerical/administrative staff to type or otherwise prepare records is eliminated (specific reporting burden activities for each affected TSCA section are described below). Recordkeeping activities associated with electronic reporting are expected to be similarly simplified; based on EPA's best professional judgment[12], recordkeeping burden for the affected TSCA section reporting is assumed to be cut in half. Specific estimates for each affected TSCA section are provided below.

Section 4

According to the latest TSCA section 4 Test Rules, Consent Orders, Test Rule Exemptions, and Voluntary Data Submission ICR (EPA, 2007a), companies incur a reporting burden for clerical/administrative staff of 20 hours for short-term studies and 40 hours for long-term studies. This burden is associated with typing and printing the study results. The weighted average of the burdens for the two types of studies is 26 hours, based on the annual number of studies presented in the ICR (35 short-term studies and 15 long-term studies each year). The weighted average is used in this analysis as the average reporting burden for clerical/administrative staff for all section 4 studies submitted. EPA assumed that the entire reporting burden for clerical/administrative staff associated with typing and printing the study results will be eliminated with electronic reporting.

Facilities must also maintain records of the information submitted to EPA. As a result, a company incurs a baseline one-hour recordkeeping burden under the current reporting system. EPA assumed that the recordkeeping burden associated with maintaining records of the information submitted to EPA will be reduced by 50 percent, resulting in an overall recordkeeping burden for section 4 reporting of 0.5 hours.

Section 5 NOC and Supporting Document

Since this final rule evaluates the burden associated with section 5 NOC reports that were submitted before the e-PMN final rule (April 2010), the ICR developed before the implementation of the e-PMN rule was used to identify the baseline industry burden. According to that ICR, companies incur a reporting burden for clerical/administrative staff of 0.25 hours.

[12] As described in the Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule (July 13, 2009).

This burden is associated with filling out the one-page NOC form. EPA assumed that the entire reporting burden for clerical/administrative staff associated with completing a section 5 NOC form will be eliminated with electronic reporting.

Facilities must also maintain records of the information submitted to EPA. As a result, a company incurs a baseline 0.25 hour recordkeeping burden under the current reporting system. As with recordkeeping for section 4 reporting, EPA assumed that the recordkeeping burden associated with maintaining records of section 5 NOC forms submitted will be reduced by 50 percent, resulting in an overall recordkeeping burden for section 5 NOC reporting of 0.125 hours.

Section 8(a) PAIR

Based on the latest TSCA section 8(a) PAIR ICR (EPA, 2007b), it is estimated that companies incur a reporting burden of 0.5 hours for clerical/administrative staff associated with submitting a section 8(a) PAIR form. This burden includes the time required to type the transmittal letter, photocopy the report, and mail the report package to EPA following management review and approval. EPA assumed that the entire reporting burden for clerical/administrative staff associated with submitting a section 8(a) PAIR will be eliminated with electronic reporting.

Companies must also maintain records of the information submitted to EPA. These records are used for compliance monitoring and enforcement purposes. A company incurs a baseline two-hour recordkeeping burden with the current reporting system. EPA assumed that the recordkeeping burden associated with maintaining records of the information submitted to EPA will be reduced by 50 percent, making the overall recordkeeping burden for section 8(a) PAIR forms one hour.

Section 8(d)

According to the latest Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies ICR (EPA, 2007c), companies incur a reporting burden for clerical/administrative staff of 0.12 hours per submission. This burden is associated with the time it takes a clerical/administrative employee to photocopy one submission. EPA assumed that the entire reporting burden for clerical/administrative staff associated with photocopying a submission will be eliminated with electronic reporting.

According to the latest ICR, there is no recordkeeping burden for section 8(d). There will be no change associated with this rulemaking.

C.1.3 Material Cost Savings

EPA assumed that electronic reporting will eliminate the need for postage and paper for reports required for submitting hard copies. EPA assumed average cost of one piece of paper is approximately $0.0076, and using the average number of pages per submission (see Table 5), EPA calculated the costs savings from no longer needing hard-copied reports. To estimate the costs savings in shipping costs, EPA estimated the approximate weight of each shipment based

(weights ranged from less than one pound for NOCs, PAIR submissions and Section 8(d) submission to 1.4 pounds for a TSCA Section 4 report) and then applied FedEx 2-day shipment costs (FedEx 2010). The industry is expected to save a total of between $16.83 and $18.17 per submission depending on submission type.

Table C- 2: Annual Material Cost Savings per Submission

TSCA Section	Photocopy Cost Savings	Postage Cost Savings	Total
Section 4	-$0.27	-$17.90	**-$18.17**
Section 5 NOC	-$0.02	-$16.82	**-$16.84**
Section 8(a) PAIR	-$0.15	-$16.82	**-$16.97**
Section 8(d)	-$0.01	-$16.82	**-$16.83**

C.2: Reporting and Recordkeeping Burden Not Affected by the Final Rule

Respondents will still be required to fulfill all reporting and testing requirements under the respective TSCA sections. Some of the reporting and testing burden figures will not change with the promulgation of the new electronic reporting rule. The respondent hours and cost associated with these requirements are presented below for each section.

Section 4

The respondent requirements under section 4 not affected by the final rule are listed in Table C- 3.

Table C- 3: Respondent Burden under TSCA Section 4 Not Affected by Electronic Reporting Rule						
Activity	**Per Report Labor Burden by Labor Category (hours)**			**Per Report Total Burden**	**Total Items Per Year**	**Total Industry Burden (hours)**
	Clerical	**Technical**	**Managerial**			
INTERIM REPORTS						
Letter of Intent and Study Plan	0	40	0	40	1	40
Prepare Progress Report	0	8	0	8	75	600
Subtotal	***0***	***48***	***0***	***48***	***76***	***640***
FINAL REPORTS						
Short-term Studies						
Record and Prepare Test for Submission	0	40	0	40	47	1,880
Laboratory Review	0	6	0	6	47	282
Corporate Review	0	0	6	6	47	282
Subtotal	***0***	***46***	***6***	***52***	*--*	***2,444***
Long-term Studies						
Record and Prepare Test for Submission	0	80	0	80	20	1,600
Corporate Review	0	0	9	9	20	180
Subtotal	***0***	***80***	***9***	***89***	*--*	***1,780***
Robust Summaries	0	12	0	12	5	60
FINAL REPORTS SUBTOTAL	0	138	15	153	72	4,284
EXEMPTION REQUESTIONS	0	2	0	2	0	0
TOTAL	**0**	**188**	**15**	**203**	**148**	**4,924**

Section 5 NOC and Supporting Documents

The respondent burden for section 5 NOC (not previously submitted online) reports only involves reporting and recordkeeping, most of which will be affected by the electronic reporting rule. The respondent burden that will remain unchanged is 0.5 hours of reporting burden for technical staff. There are 364 annual NOC responses, on average, which results in a total industry burden of 182 hours for technical staff that will not be affected by the electronic reporting rule.

Section 8(a) PAIR

The respondent requirements for section 8(a) PAIR submitters that are not affected by the electronic reporting rule are presented below in Table C- 4.

Table C- 4: Respondent Burden under TSCA Section 8(a) PAIR Not Affected by Electronic Reporting Rule

Activity	Per Report Burden by Labor Category (hours)			Total Burden Per Report	Number of Reports Each Year	Annual Industry Burden
	Clerical	Technical	Managerial			
Form Familiarization	0	1.92	1.44	3.36	33	110.88
Report Preparation	1.25	9.25	5.5	16	33	528.00
Trade Name Notification	1	0	2.2	3.2	33	105.60
CBI Substantiation	0.375	0	3	3.38	33	111.38
Report Submission	N/A*	0	0.5	0.5	33	16.5
TOTAL	**2.625**	**11.17**	**9.64**	**26.44**	**33**	**872.36**

*Burden affected by electronic reporting rule; presented in the following section.

Section 8(d)

The respondent requirements for section 8(d) submitters that will not be affected by the electronic reporting rule are presented below in Table C- 5.

Table C- 5: Respondent Burden under TSCA Section 8(d) Not Affected by Electronic Reporting Rule

Type of Response	Activity	Per Report Burden by Labor Category (hours)			Responses Per Firm	Number of Responses	Total Industry Burden
		Clerical	Technical	Managerial			
Search Files	Review of the rule	0.0	0.0	2.0	2.0		
	Site identification	0.0	0.0	3.0	3.0		
	Site file search	0.0	4.5	0.0	4.5		
Subtotal		***0.0***	***4.5***	***5.0***	***9.5***	***33***	***314***
Submit studies during the reporting period	Study tile lists	1.0	0.0	0.0	1.0		
	Robust summaries	0.0	11.0	0.0	11.0		
	CBI review	0.0	0.0	9.0	9.0		
Subtotal		***1.0***	***11.0***	***9.0***	***21.0***	***6***	***126***
Submit studies after the reporting	Post reporting period	0.0	0.0	1.0	1.0	1	1

period	submissions						
TOTAL							**441**

C.3: Agency Burden and Cost

As a result of the final rule, EPA expects that the Agency will have a burden savings due to the elimination of the need to process paper forms, and reduced quality assurance/quality control (QA/QC) and O&M costs for the existing system. Potential Agency burden savings associated with the electronic reporting rule are characterized based on information in the *Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule Business Case Analysis of EPA's Central Data Exchange* (EPA, 2007). In this analysis, an average savings of 16.5 percent annually was assumed based on the e-PMN rule.

Agency burden for each section was taken from the previous ICR and reduced by 16.5 percent. Agency costs were derived by multiplying the Agency burden by the respective Agency salary wage rate for the EPA employee that will handle each type of report. Agency wage rates for the GS and Step level responsible for handling each section report are derived in Appendix A.

Final annual Agency burden and costs savings by TSCA section are presented in Table C- 6.

Table C- 6: Total Annual Agency Burden and Cost for E-Reporting of TSCA Sections

TSCA Section	Annual Agency Burden	Annual Agency Cost
Section 4	349	$23,902
Section 5 NOC	304	$23,591
Section 8(a) PAIR	2,501	$157,376
Section 8(d)	58	$4,537
Total Cost	**3,212**	**$209,406**

C.4 Estimating the Respondent Universe

In order to estimate the number of affected facilities and the number of submissions per facility for each section, EPA used information on the number of annual submissions across all affected entities and the number of companies submitting reports for each section annually. These numbers are presented in Section 6.4.

C.5 Total Respondent Burden and Cost

This final rule ICR consolidates four existing ICRs: sections 4, 5, 8(a) PAIR, and 8(d). Therefore, the Agency estimated a change in burden for each respective TSCA section. The estimated burden hours have decreased compared to previous ICRs. Table C- 7 contains the burden by labor category, the total number of annual reports and the total industry burden under the baseline and the post compliance scenario.

Table C- 7 Baseline Burden, New Burden Estimates, and Change in Burden by TSCA Section						
TSCA Section	**Per Report Burden by Labor Category (hours)**			**Total Per Report**	**Number of reports each year**	**Annual Industry Burden**
	Clerical	**Technical**	**Managerial**			
Baseline						
Section 4	***62***	***188***	***15***	***265***	***602***	***34,233***
Section 5 NOC	***0.375***	***0.625***	***0***	***1***	***443***	***443***
Section 8(a) PAIR	***4.25***	***12.17***	***13.64***	***28.94***	***54***	***1,568***
Section 8(d): Search Files	0.0	4.5	5.0	9.5	34	323
Section 8(d): Submit studies during reporting period	2.0	11.0	9.0	22.0	6	132
Section 8(d): Submit studies post reporting period	0.1	0.0	1.0	1.1	1	1.1
Section 8(d)					***34***	***456***
New Burden Estimate						
Section 4	***1.12***	***188***	***15***	***204***	***148***	***4,962***
Section 5 NOC	***0.123***	***0.563***	***0***	***364***	***0.69***	***249***
Section 8(a) PAIR	***3.30***	***11.67***	***13.64***	***27.49***	***33***	***907***
Section 8(d): Search Files	0.0	4.5	5.0	9.5	33	314
Section 8(d): Submit studies during reporting period	1.1	11.0	9.0	21.1	6	126
Section 8(d): Submit studies post reporting period	0.0	0.0	1.0	1.0	1	1
Section 8(d)					**33**	***441***
Change in Burden						
Section 4	***-60.88***	***0.00***	***0.00***	***-60.88***	***-454***	***-29,271***
Section 5 NOC	***-0.25***	***-0.06***	***0.00***	***-0.32***	***-79.00***	***-194***
Section 8(a) PAIR	***-0.95***	***-0.50***	***0.00***	***-1.45***	***-21.20***	***-661***
Section 8(d): Search Files	0.00	0.00	0.00	0.00	-1.00	-9.50
Section 8(d): Submit studies during reporting period	-0.94	0.00	0.00	-0.94	0.00	-5.64
Section 8(d): Submit studies post reporting period	-0.10	0.00	0.00	-0.10	0.00	-0.10
Section 8(d)					***-1.04***	***-15.24***

The estimated changes in annual industry burden for each section are presented in Table C- 8 below.

Table C- 8Total Estimated Burden Comparison			
TSCA Section	**Current Inventory Burden (hours)**	**New Burden Estimate (hours)**	**Total Electronic Reporting Burden Reduction (hours)**
Section 4	34,233	4,962	-29,271
Section 5 NOC	443	249	-194
Section 8(a) PAIR	1,568	907	-661
Section 8(d)	456	441	-15
TOTAL	**36,700**	**6,559**	**-30,142**

The estimated changes in the industry burden per submission for each section are presented in Table C- 9 below.

Table C- 9 Estimated Burden Comparison Per Submission			
TSCA Section	**Current Inventory Burden Per Submission (hours)**	**New Burden Estimate Per Submission (hours)**	**Electronic Reporting Burden Reduction Per Submission (hours)**
Section 4	265	204.1	-60.9
Section 5 NOC	1	0.7	-0.3
Section 8(a) PAIR	28.9	27.5	-1.5
Section 8(d)	32.6	31.6	-1.0
TOTAL	**327.5**	**263.9**	**-63.7**