

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. 2412.01, OMB No. 2070-NEW)

1 IDENTIFICATION OF THE INFORMATION COLLECTION

1.1 Title of the Information Collection

Information Collection Request (ICR) for the 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. EPA ICR No. 2412.01, OMB Control No. 2070-NEW

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 is developing a proposed 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 would enable, and eventually require manufacturers, importers, and processors of TSCA chemical substances to use the Internet, through EPA's Central Data Exchange (CDX), to submit the respective TSCA section reports to the Agency.

This ICR covers certain testing and reporting requirements related to submitting sections 4, 8(a) PAIR, and 8(d) information to EPA. This ICR incorporates proposed requirements for electronic reporting under TSCA. If the revisions are finalized, EPA estimates that approximately 353 respondents would incur paperwork-related burden in the first year of this ICR. EPA estimates a total reporting and recordkeeping burden for these respondents at approximately 6,560 hours in each year of this ICR.

This ICR also covers 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 would 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 Agency will be utilizing CDX to access the Chemical Information Submission System (CISS) web-based reporting tool to report data, reports and other documents to the Agency. EPA will require that all submissions be generated with the CISS reporting tool. Paper submissions will no longer be accepted, and submitters will be required to submit electronically via CDX using CISS and 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. 1139.08 *TSCA Section 4 Test Rules, Consent Orders, Test Rule Exemptions, and Voluntary Data Submission*, EPA ICR No. 0574 *Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances*, EPA ICR No. 0586.11, *TSCA 8(a) Preliminary Assessment Information Rule (PAIR)*, EPA ICR No. 0575.12 *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, 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 facilitates the submission of information by displaying certain basic data elements, permitting EPA more easily to identify, log, track, distribute, review and index submissions, and makes information publicly available to the mutual benefit of both industry and EPA. The specific reporting form used by this information collection is known as the TSCA Health & Safety Study Cover Sheet (EPA Form No. 7710-58), a copy of which, along with its associated instructions, appears below as an Attachment 7. This rule-related ICR incorporates the data elements captured in the voluntary form and addresses the incremental paperwork activities related to submitting the form electronically and describes the changes that will be incorporated into the existing ICR approved under OMB Control No. 2070-0156 (EPA ICR No. 1780.05 *Voluntary Cover Sheet for TSCA Submissions*).

2 NEED FOR AND USE OF THE COLLECTION

2.1 Need/Authority for the Collection

2.1.1 Section 4

TSCA section 2(b)(1) states that it is the policy of the United States that “adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture [which is defined by statute to include import] and those who process such chemical substances and mixtures.” To implement this policy, TSCA section 4(a) mandates that EPA require manufacturers and processors of chemical substances and mixtures to conduct testing if it finds that:

“(1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data [.]”

If EPA makes these findings for a chemical substance or mixture, the Agency must require that testing be conducted on that chemical substance or mixture. The purpose of the testing would be to develop data about the substance or mixture’s health and environmental effects where there is an insufficiency of data and experience in order to support a determination that the manufacture, distribution in commerce, processing, use or disposal of the substance or mixture, or any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

Once the Agency has made a finding under TSCA section 4(a)(1), EPA may require any type of health or environmental effects testing necessary to address unanswered questions about the effects of the chemical substance.

For section 4, respondents must submit the specified test data to the EPA, and respondents may also need to submit a letter of intent, study plans and progress reports, an exemption application, and the test data to EPA as described in the existing ICR No. 1139.08 and OMB Control No. 2070-0033. Under this rule-related ICR all information submitted under section 4 will be submitted electronically. The existing ICR No. 1139.08 and OMB Control No. 2070-0033, will reflect the incremental paperwork activities related to submitting section 4 documents electronically to EPA upon its renewal date.

2.1.2 Section 5 Notice of Commencement (NOC) and Supporting Documents

TSCA section 5(a)(1), 15 U.S.C. 2604, requires manufacturers and importers of new chemical substances to submit to the Administrator of EPA a premanufacture notice (PMN) of intent to manufacture or import a new chemical substance at least 90 days before manufacture or import begins. TSCA section 5(a)(1) also requires notification from any person who proposes to manufacture, import or process a chemical substance for a use that EPA has by rule determined to be a significant new use. The notice must include, insofar as known to or is reasonably ascertainable by the submitter, information described in TSCA section 8(a)(2) (e.g., chemical identity, use and exposure data), plus test data and descriptions of other data related to the effects on health and the environment of the manufacture, processing, use, distribution in commerce and disposal of the new chemical substance. EPA reviews the information to evaluate the health and environmental effects of the new chemical substance. On the basis of the review, EPA can take further regulatory action under TSCA sections 5(e) and 5(f), if warranted. If EPA takes no action at the end of 90 days, the submitter is free to manufacture or import the new chemical substance.

NOC reports under TSCA section 5 are submitted when “any person who commences the manufacture or import of a new chemical substance for a nonexempt commercial purpose for which that person previously submitted a section 5(a) notice.”

With the exceptions of the new minor revisions to the PMN form that were incorporated into the e-PMN software, that is, the required User Fee Payment Identity Number, optional E-mail address for Principal Contacts, and software-generated format for Biotech notices (EPA Form 6300-07, *TSCA Biotechnology Notice for Online Submissions*), the data items presently approved under OMB Control Numbers 2070-0012 and 2070-0038 are otherwise unchanged. In addition to these data items, respondents will also be required to register with CDX and complete the electronic signature agreement. The existing ICR No. 0574.15 and OMB Control No. 2070-0012, will reflect the incremental paperwork activities related to submitting NOCs electronically to EPA upon its renewal date.

2.1.3 Section 8(a) PAIR

TSCA section 8(a) gives EPA the authority to promulgate rules under which manufacturers (which by statute includes importers) and processors of chemical substances must maintain records and/or report such data as EPA may reasonably require to carry out the TSCA mandates. Examples of information that can be required to be reported under TSCA section 8(a) include:

- Chemical or mixture identity;

- Categories of use;
- Quantity manufactured or processed;
- By-product description;
- Health and environmental effects information;
- Number of individuals exposed; and
- Method(s) of disposal.

Under PAIR, producers and importers of a listed chemical are required to report the following site-specific information on a two page form:

- Quantity of chemical produced and/or imported;
- Amount of chemical lost to the environment during production or importation;
- Quantity of enclosed, controlled and open releases of the chemical; and
- Per release, the number of workers exposed and the number of hours exposed.

As described under EPA ICR No. 0586.11 and OMB Control No. 2070-0054, PAIR requires manufacturers or importers of the listed chemical substances, mixtures or categories to report to EPA information such as the substances' chemical identification, quantity produced or imported, chemical processes, employee exposure, environmental releases, uses and products.

Respondents are only required to report information that is known or reasonably ascertainable by them. As described in the previous section, extensive files searches are not required. The PAIR reporting requirements are included in the PAIR form and instructions (EPA Form 7710-35). The existing ICR No. 0586.11 and OMB Control No. 2070-0054, will reflect the incremental paperwork activities related to submitting the PAIR Form electronically to EPA upon its renewal date.

2.1.4 Section 8(d)

TSCA section 8(d), 15 U.S.C. 2607(d), requires EPA to promulgate rules requiring persons who manufacture, process or distribute, or propose to manufacture, process or distribute chemical substances and mixtures, to submit to EPA lists and copies of health and safety studies in their possession. OPPT reviews these studies to determine the kinds of testing needed to fill the information gaps in known effects of the listed chemicals, to make decisions during the risk assessment process, and for considering control actions. Other federal agencies use the studies when they are assessing a listed chemical substance for health or environmental effects.

As described under EPA ICR No. 0575.12 and OMB Control No. 2070-0004, persons who manufacture (including import) chemical substances and mixtures, or propose to do so, and processors of such substances and mixtures (if specifically identified in a particular rule) must submit copies of the unpublished health and safety studies in their possession for the listed substances or mixtures. They must also submit lists of reportable studies that they initiate or, about which they know, for each of the listed substance or listed mixtures. The existing ICR No. 0575.12 and OMB Control No. 2070-0004, will reflect the incremental paperwork activities related to submitting 8(d) documents electronically to EPA upon its renewal date.

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)

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 would 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 is a widely-used 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. See NIST Special Publication 800-52, *Guidelines for the Selection and Use of Transport Layer Security (TLS) Implementations*, <http://csrc.nist.gov/publications/nistpubs/800-52/SP800-52.pdf>.

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. Details about AES can be found on the NIST website at <http://csrc.nist.gov/publications/fips/fips197/fips-197.pdf>, 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.

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

Each of these data elements are already incorporated into a voluntary instrument for certain TSCA submissions and approved under OMB Control No. 2070-0156 (*Voluntary Cover Sheet for TSCA Submissions*). As explained in that ICR, the voluntary 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. ACC developed the voluntary “TSCA Health and Safety Study Cover Sheet,” and its data elements, 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, would 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 needs to mandate 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 would 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
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • improved internal company cataloguing • more efficient preparation and submission • standardized keywords • improved data quality • quicker decisions • 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 Section 4

Prior to proposing a test rule or issuing a consent order, EPA searches the scientific literature, holds public information gathering meetings if deemed appropriate, and has discussions with industry representatives in order to determine what types of data have already been obtained about the chemical under consideration. The Agency proposes a test rule or issues a consent order only after it has determined that necessary tests have not yet been conducted.

Industry sponsors of chemicals in the Program also search publicly-available databases as well as unpublished sources for the screening-level hazard and fate test data that are the subject of the Program. Consequently, any new test data that are developed and/or submitted as a result of the Program are unlikely to be duplicative.

3.1.2 Section 5 NOC and Supporting Documents

EPA is the only federal agency that regularly collects information on new chemical substances used for purely industrial applications. (In instances where chemical substances with industrial applications also have drug or cosmetic uses, the Food and Drug Administration has concurrent jurisdiction.) Therefore, the information submitters provide in a PMN cannot be obtained elsewhere. However, data previously submitted to EPA need not be resubmitted if the following conditions are met: the data were submitted with no claims of confidentiality and the PMN (or other TSCA section 5 notice) identifies the office or person to whom the data were submitted and the date of the submission.

3.1.3 Section 8(a) PAIR

It is unlikely that the information to be reported is duplicative because (1) EPA estimates that each rule will generate only a few reports, (2) the information required by the PAIR is unique to the manufacturer or importer, and (3) efforts are made to ensure that the information requested is not currently in the possession of EPA or easily obtained by EPA from other public sources. The databases such as the Chemical Screening Branch's Existing Chemical Assessment Tracking System (CECATS), the Toxic Substances Control Act Test Submissions (TSCATS) database, the Toxicology Data Network (TOXNET), and other sources are checked for each list of chemical substances, mixtures or categories added to the PAIR.

3.1.4 Section 8(d)

The health and safety studies to be submitted under the TSCA section 8(d) rule are not available from any other source. The TSCA section 8(d) rule requires the listing and submission of studies that are conducted in-house by industry or by industry contractors and not published in the

scientific literature. Under the revisions to the Model Rule¹ promulgated in September 1986, respondents do not have to list or submit any studies that have been published in the scientific literature, or submitted previously to OPPT on a non-confidential basis. Studies that have previously been submitted on a non-confidential basis to other EPA offices or programs need only be listed.

3.1.5 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.

3.1.6 CDX Registrations

EPA has determined that approximately 80 percent of the same companies that would engage in electronic reporting under rule would 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 (eCDRweb), 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 to avoid multiple CDX registrations for what may be the same authorized company officials (and/or their designees). TSCA sections 4, 5, and 8 will be available under the new Chemical Information Submission System (CISS) reporting tool.

3.2 Public Notice Required Prior to ICR Submission to OMB

The proposed rulemaking serves as the public notice for this ICR. Interested parties should submit comments referencing Docket ID No. EPA-HQ-OPPT-2011-0519 to the address listed at the end of this document. Responses will be taken into account in developing the final rulemaking.

3.3 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 (approved under OMB control number 2070-0156) that was developed by industry (and sponsored by EPA) 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 proposed 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 would ultimately exceed the transition costs.

¹ The Model Rule describes the requirements and procedures for submitting lists and copies of unpublished health and safety studies under section 8(d) of TSCA (40 CFR 716).

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>. An “Industry Day” will be scheduled to allow users to become familiar with the CISS tool reporting tool in a collaborative setting. There will also be a week-long familiarization opportunity to allow users to become accustomed with the reporting tool on their own and to provide comments to the Agency on its functionality.

3.4 Effects of Less Frequent Collection

3.4.1 Section 4

Test rules and consent orders require the test sponsor to submit a letter notifying EPA who will be conducting the testing, study plans before beginning testing, and a final report of the study results. Each exemption applicant is required to submit an exemption application. Less frequent information collection would jeopardize EPA’s ability to ensure that testing is being conducted in accordance with the rules and consent orders, and to grant exemptions from test rules.

3.4.2 Section 5 NOC and Supporting Documents

The frequency of the submission of information under TSCA section 5 is not under the Agency’s control. Manufacturers of new chemical substances typically submit a PMN, Significant New Use Notice (SNUR), or Microbial Commercial Activity Notice (MCAN) at least 90 days prior to anticipated manufacturing or distribution of the substance for non-exempt commercial use. Submission of information thus is on an as-needed, on-occasion basis, initiated by respondents. Subsequent reporting would only be required if EPA determined that a specific use of a substance constituted a significant new use. Less frequent collection would mean respondents not being required to submit data at all. However, without such data, EPA would be unable to administer the new chemical review requirements found in TSCA and would be unable to carry out its mandate to protect the public from unreasonable risks to health and the environment.

3.4.3 Section 8(a) PAIR

Under PAIR, persons are required to report only once for a chemical listed in the PAIR. However, if information received from the initial report indicates human health and environmental risks, then the Agency may require that additional information be submitted at some future date to monitor any changes pertaining to that chemical. As such, the reporting frequency for PAIR cannot be reduced without effectively suspending the information collection requirement.

3.4.4 Section 8(d)

In most instances, respondents will be required to make only initial submissions under the TSCA section 8(d) rule. However, after the initial submission of lists and studies, respondents are required to notify EPA when certain health and safety studies are initiated by submitting a list of newly initiated studies. Because the reporting frequency for the TSCA section 8(d) rule is generally once, the reporting frequency cannot be reduced without suspending the information requirement. If this were to happen, EPA would not be able to obtain the necessary information for evaluating the need for testing under section 4 of TSCA or controlling chemical substances under sections 5 and 6 of TSCA.

3.5 General Guidelines

For TSCA sections 5 NOC, 8(a) PAIR, and 8(d), 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.

3.5.1 Section 4

The data retention requirements for test rules and consent orders exceed one of the Paperwork Reduction Act guidelines contained in 5 CFR 1320.6. Documentation records, raw data, and specimens pertaining to a test rule or consent order study are required to be retained for ten years from the effective date of the applicable test rule or publication date of the consent order. This requirement is necessary to permit sufficient time to review results, perform appropriate risk assessments and, when necessary, to institute appropriate regulatory control responses. Long-term studies may take five years from the effective date of the final test rule or consent order to perform and submit to the Agency; assessment of study results may require an additional one to two years of internal and external peer review; institution of regulatory controls and legal challenges may require an additional two to three years before final resolution of issues. All studies, both short and long-term, are relevant to assessing the potential risk of the chemical and therefore must be retained during the ten year period. In those regulatory cases where the Agency's action may be challenged, it is imperative that all records, raw data, and specimens be available to support the Agency's decision.

3.6 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 would allow the submitter to indicate if a study plan contains information claimed as CBI by checking the appropriate box. Then, the submitter would be prompted to submit the study plan document in an electronic format. The submitter would 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 would 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 would 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 would prompt the submitter to certify that the Confidentiality 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 would allow the submitter to indicate if the document contains CBI by checking the appropriate box. Then, the submitter would be prompted to submit the document in an electronic format. In submitting a document that contains CBI, the CISS reporting tool would 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 would need to have all confidential information deleted. Once CBI is claimed, the CISS reporting tool would 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.

3.7 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:

- 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. <i>Submission Type</i>	<i>Identifies the submission, including the type of submission and whether it is the initial submission, a follow-up or a final report.</i>
2. <i>Summary of Attachment</i>	<i>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.</i>
3. <i>Chemical Identification</i>	<i>Identifies the chemical(s) addressed in the submission.</i>
4. <i>Title of Attachment</i>	<i>Identifies the title of the attached study or report.</i>
5. <i>Indexing Terms</i>	<i>Allows the respondent to identify the proper terms to use for indexing purposes, which facilitates the search and retrieval of the information.</i>
6. <i>Study/Report Information</i>	<i>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.</i>
7. <i>Submitter Information</i>	<i>Identifies the submitter and/or technical contact, including name, title, company, mailing address, phone and e-mail address.</i>
8. <i>Comments</i>	<i>Allows the submitter to provide any additional comments, so as to avoid the need for or use of a separate cover letter.</i>

Each of these data elements are already incorporated into a voluntary instrument for certain TSCA submissions and approved under OMB Control No. 2070-0156 (*Voluntary Cover Sheet for TSCA Submissions*) and will be required for all electronic submissions.

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)

Register with EPA's CDX and Using CISS Reporting Tool

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 would 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 would 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

Register with EPA’s CDX and Complete Electronic Signature Agreement

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

There is a third form generated by CDX that the AO needs to fill out if the AO wants to authorize other persons to submit support documents on his or her behalf, including a paid employee of the company, an outside consultant for the company, or an authorized representative agent for the company. This form is entitled, “Authorization and Verification for section 5 Notice Support Submitter by Company Authorizing Official.” On this form, the AO designates various persons to submit support documents on his or her behalf, and attests to the completeness and accuracy of the submitted information. Persons designated by the AO to submit on his or her behalf must also sign this form along with the Electronic Signature Agreement form, in order to be “linked” to the AO by EPA; and therefore, be able to submit support documents via CDX on the AO’s behalf.

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

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

In all cases, respondents will use the e-PMN software to:

- **generate** the submission materials for TSCA section 5 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 identifyin reason for sbumision 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

In addition, the Agency activities described in the ICR approved under OMB Control No. 2070-0156 are mostly unchanged, although the identification of the type of submission or the type of information contained in a submission would now be done by the submitter when providing standardized submission meta-data.

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 proposed 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 proposed rule would result in burden reduction for the affected companies because the time required to enter, review, edit, and submit their reports using CDX would be reduced compared to the existing paper-based process.

In addition to the quantifiable cost savings, EPA believes that this rule would result in other benefits. For example, electronic reporting would allow for faster review and transmission of submissions to EPA. For studies containing CBI, electronic reporting would also improve security and transmission of CBI data to EPA. Additionally, all information submitted electronically could be linked in an improved tracking system, which would facilitate document management efforts. This would 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 proposed rule would 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 would reduce the burden of the TSCA section submissions for industry, including small businesses.

As estimated in the Economic Analysis for the proposed rule², all small parent entities potentially affected by this proposed rule would 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).

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.

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 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 proposed rule that would require electronic submission for TSCA section 4, section 5 NOC (not previously submitted online), 8(a) PAIR, and 8(d) reports. EPA estimated that the proposed rule would affect 353 respondents each year. Although respondents would experience some additional

burden (e.g., CDX registration and signature) as a result of the electronic reporting rule, EPA estimates that report submitters would experience overall burden reduction and cost savings associated with the proposed rule.

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

- 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.

Additionally, submitters under each section would be required to familiarize themselves with the new electronic reporting rule, register for and submit reports using the CDX reporting system, as well as submit a CDX electronic signature.

6.1 Estimating Total Respondent Burden

Respondents subject to this proposed rule would still be required to fulfill all reporting and testing requirements for each TSCA section. Section 4 respondents would be required to submit results from any type of health effects, ecological effects and environmental fate testing necessary to address unanswered questions about the effects of a chemical substance, as well as maintaining certain records related to testing, submitting a letter of intent, study plans, and progress reports, or an exemption application. Section 5 NOC respondents would be required to submit a NOC when manufacture or importation of a substance or microorganism begins after a company has already submitted a PMN or MCAN. Section 8(a) PAIR respondents would be required to submit information (substances' chemical identification, quantity produced or imported, chemical processes, employee exposure, environmental releases, uses and products) that is known or readily ascertainable on any PAIR listed chemical substance. Section 8(d) respondents would be required to submit copies of unpublished health and safety studies for any section 8(d) listed substances or mixtures as well as submit lists of reportable studies are initiated or known about for each listed substance or mixture. As a result of the new electronic reporting

requirements, respondents for all sections subject to this rule must use the CDX electronic reporting system to submit information to EPA.

The methodology used in estimating the total burden and costs to respondents of the electronic reporting rule over the next three years is based on the previous ICRs for each respective section and assumptions used in the e-PMN rule published in April 2010⁴. Estimates from previous ICRs were revised to reflect the current reporting universe, the burden reduction associated with electronic reporting, as well as the one-time cost incurred due to CDX activities.

This section discusses the total potential paperwork-related burden to respondents of the proposed electronic reporting rule. While some of the reporting and recordkeeping requirements would stay the same after the electronic reporting rule is implemented, other requirements would change as a result of this rule. Therefore, this section discusses the estimated burden for activities affected and unaffected by the proposed rule separately.

6.1.1 Reporting and Recordkeeping Burden Affected by the Proposed Rule

As a result of the proposed electronic reporting rule, EPA estimates that respondents would incur minimal additional burden and costs in carrying out the additional paperwork activities that would be imposed by the proposed 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 analysis. Besides this one-time burden, EPA expects that respondents would experience overall burden reduction as a result of the electronic reporting rule.

EPA estimates that section 4, section 5 NOC (not previously submitted online), 8(a) PAIR, and 8(d) submitters would 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 experience these burden reductions due to the efficiencies and reduced time associated with submitting these reports via CDX. Respondents are expected to realize burden savings each time a respective TSCA section report subject to this rule is submitted.

EPA estimated that the proposed electronic reporting rule would result in burden reduction and cost savings associated with electronic submission of each TSCA section 4, 5 NOC (not previously submitted online), 8(a) PAIR, and 8(d). These burden reduction and cost savings would result from reduced time spent on reporting (by clerical/administrative staff) and recordkeeping tasks. Elimination of paper submissions would also result in cost savings associated with paper use and postage.

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.

EPA estimated that companies submitting TSCA sections 4, 5 NOC (not previously submitted online), 8(a) PAIR, and 8(d) reports would 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 clerical/administrative 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.

Reporting and Recordkeeping Burden Reduction

EPA estimated the reporting and recordkeeping burden reduction for each section.

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 two types of studies submitted resulted in a burden of 26 hours, based on the annual number of studies from the ICR (35 short-term studies and 15 long-term studies each year). The weighted average was used 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 would 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 would be reduced by 50 percent,⁵ resulting in an overall recordkeeping burden for section 4 reporting of 0.5 hours.

Section 5 NOC and Supporting Document

Since this proposed rule evaluates the reporting burden (for clerical/administrative staff) and recordkeeping burden for 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 determine the industry burden. According to the ICR, companies incur a reporting burden (for clerical/administrative staff) of 0.25 hours. 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 would be eliminated with electronic reporting.

⁵ Based on EPA's best professional judgment from the Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule (July 13, 2009).

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. EPA assumed that the recordkeeping burden associated with maintaining records of section 5 NOC forms submitted would be reduced by 50 percent,³ 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 (for clerical/administrative staff) associated with submitting a section 8(a) PAIR form of 0.5 hours. 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 would 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 would be reduced by 50 percent,³ 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 (clerical/administrative staff) associated with photocopying a submission would be eliminated with electronic reporting.

There is no recordkeeping burden for section 8(d). Since according to the latest ICR, there is no recordkeeping burden for section 8(d), there would be no burden reduction associated with recordkeeping.

Material Burden Savings

EPA assumed that electronic reporting would eliminate the need for postage and paper for reports, required for submitting hard copies.

One-time CDX Burden

EPA estimated that management, technical and clerical staff at companies submitting sections 4, 5 NOC (not previously submitted online), 8(a) PAIR, and 8(d) would incur the following one-time burden under the proposed electronic reporting rule. EPA used a simplifying assumption that submitters from each of the affected companies would need to register with CDX.

However, some submitters from companies that had already registered with CDX through other rules such as e-PMN, e-CDR, or TRI-ME web will not need to register again. Determining how many new users from companies previously registered with CDX would need to register as a result of this rule proved difficult for the following reasons: 1) different individuals within a company need to register with CDX separately with their own username and password; 2) while some users within a company who are already registered with CDX for some rules will not need to re-register as a result of this rule, there are other individuals within the same company who will need to register to CDX as a result of this rule and it is impossible to predict what the number of new users will be. Therefore, the Agency used the most conservative assumption that all affected submitters would register with CDX and, thus, incur an associated cost. This assumption would result in overestimating the costs associated with the proposed rule.

The one-time CDX burden includes the following:

- *CDX Registration* – Based on the CROMERR *Cost Benefit Analysis*, EPA assumed that companies would spend eleven minutes per employee to register with CDX (EPA, 2004). Furthermore, EPA assumed that an average of four technical staff members and one manager would need to register for each company, resulting in 55 minutes of burden per company.
- *CDX electronic signature (labor burden)* – Based on the CROMERR *Cost Benefit Analysis*, EPA assumed that companies would 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 would incur this burden, totaling 75 minutes of burden per company. In addition, EPA used its best professional judgment to estimate that a manager would 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 would 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 would 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 would spend 33 minutes and one technical staff member would 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			
Burden Category	Managerial (hours)	Technical (hours)	Clerical (hours)
CDX Registration	0.18	0.73	0.00
CDX Electronic Signature	0.75	1.00	0.00
Rule Familiarization	0.55	0.27	0.00
Total	1.48	2.00	0.00

Recurring CDX Burden

In addition to the one-time CDX registration and familiarization cost, a company would incur recurring burden associated with the time it takes to submit reports via CDX. However, EPA assumed that this burden would be less than the reporting cost currently incurred by industry for submitting hard-copy reports.

EPA estimated the time it would take to prepare and submit a report electronically 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.⁶ Each participant was given detailed instructions of how to navigate the simulation document in order to mimic the actual electronic reporting process.⁷ 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.⁸ 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. The average estimate for the electronic submitting burden for each section was multiplied by the loaded hourly wage for clerical workers to determine the recurring cost associated with submitting a report via CDX. This recurring cost per submission was used when estimating the total cost of this ICR and is presented below in

⁶ EPA assumed that five individuals would be a large enough sample size to generate an estimate for the average time required to submit an electronic report.

⁷ 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.

⁸ 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.

Table 2.

Table 2

As mentioned previously, The Voluntary TSCA Cover Sheet is expected to be discontinued since EPA has incorporated data elements captured in the voluntary form for sections 4 and 8(d) reporting in this ICR and 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 2.

Table 2 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 submission 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 would occur with electronic reporting.⁹ 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) would be included in the recurring CDX burden presented in Table 2.

TSCA Section	Recurring Burden per Submission (hours)	Recurring Cost per Submission (2010\$)
Section 4	0.06	\$1.75
Section 5 NOC	0.05	\$1.33
Section 8(a) PAIR	0.05	\$1.33
Section 8(d)	0.06	\$1.78

TSCA Section	Year 1	Year 2	Year 3	Annual Average
Section 4	1.16	0.06	0.06	0.43
Section 5 NOC	3.48	0.05	0.05	1.19
Section 8(a) PAIR	1.74	0.05	0.05	0.95
Section 8(d)	0.87	0.06	0.06	0.33

IC Classifications - New CDX Activities by Submission Type	Annual Number of Respondents	Responses per Respondent*	Annual Number of Responses	Burden per Response	Annual Burden Hours*
Section 4	24	3	67	.43	29

⁹ OMB Control No. 2070-0156 (EPA ICR No. 1780.5 *Voluntary Cover Sheet for TSCA Submissions*)

Section 5 “Legacy” NOCs	305	1	364	1.19	434
Section 8(a) PAIR	15	2	33	.95	31
Section 8(d)	9	4	33	.33	11
TOTALS	0	--	0	--	0
*Figures rounded to the nearest integer.					

6.1.2 Reporting and Recordkeeping Burden Not Affected by the Proposed Rule

Respondents would still be required to fulfill all reporting and testing requirements under the respective TSCA sections. Some of the reporting and testing burden figures would 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 not affected by the proposed rule for respondents submitting reports under section 4 are listed in Table 5 below.

Table 5: 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 would be affected by the electronic reporting rule. The only respondent burden that would 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 would 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 .

Table 6: 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 would not be affected by the electronic reporting rule are presented below in Table 7.

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 period	Post reporting period submissions	0.0	0.0	1.0	1.0	1	1
TOTAL							441

6.2 Estimating Respondent Costs

EPA estimated the respondent cost for the electronic reporting rule by multiplying the unit burden hour estimates for each respective section by fully loaded hourly rates for workers of appropriate labor categories.

For each labor category, the respondent cost was estimated by:

1. Multiplying the amount of time staff from each labor category spends on an activity by the loaded hourly wage rate for each labor category;
2. Multiplying the labor cost derived in Step 1 by the number of employees that incur this burden;
3. Adding any non-labor costs associated with the activity.

The hourly wage rates by labor category are presented in the table below.

Wage Component	Clerical	Technical	Managerial
Hourly Wage Rate	\$17.36	\$36.93	\$42.82
Benefit Costs	\$8.67	\$18.50	\$19.64
Fringe and Overhead Factor	1.67	1.67	1.63
Total Hourly Cost	\$28.98	\$61.71	\$69.74

6.3 Total Respondent Burden and Costs

EPA calculated the total industry burden and cost for respondents by multiplying the per-company burden (respondent burden affected by the electronic reporting rule and respondent

burden not affected by the electronic reporting burden) and cost by the total number of reports received for each respective section subject to the rule each year.

The total industry burden and cost associated with total requirements of each section is presented in Table below.

TSCA Section	Annual Industry Burden (hours)	Annual Industry Cost (2010\$)
Section 4	4,961.52	\$308,649
Section 5 NOC	249.34	\$11,864
Section 8(a) PAIR	907.01	\$58,128
Section 8(d)	440.86	\$28,763
Total	6,558.73	\$407,404

6.4 Estimating Agency Burden and Cost

The conversion to an electronic reporting system as well as the adoption of CDX to facilitate form submission and processing are expected to create long term burden reductions and increased efficiencies for EPA. 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 would 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.¹⁰ In addition, annual costs would be associated with the operation and maintenance (O&M) of CDX for the data flow. EPA developed an estimate of CDX O&M costs attributable to chemical reporting program by apportioning the overall CDX maintenance cost estimated in the CROMERR *Cost Benefit Analysis, Final* (EPA, 2004) to individual programs. This approach yields an estimate of \$57,353 per year per program. Note that although the data flow for this rule would be smaller than the data flows included in the CROMERR analysis, the CROMERR analysis does not include costs associated with operations and, therefore, the \$57,353 might be considered a lower bound estimate of total O&M.

Agency burden savings are expected due to the elimination of the need to process paper forms, reduced quality assurance/quality control (QA/QC) and O&M costs for the existing system. Potential Agency burden savings associated with the 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 saving 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 would handle each type of report. Agency salaries for the GS and Step level responsible for handling each section report are presented in Appendix A.

¹⁰ US EPA, 2004. Cross-Media Electronic Reporting Rule (CROMERR) Cost Benefit Analysis. Final. November 17, 2004.

Final annual Agency burden and costs are presented in Table . Since the Agency would 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 10: Total 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
All Sections: One-Time CDX Conversion Cost	--	\$200,000
All Sections: Recurring O&M CDX Cost	--	\$57,353
Total Cost (Year 1)	3,212	\$466,758
Total Cost (Subsequent Years)	3,212	\$266,758

6.5 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.

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 submission statistics from the Office of Pollution, Prevention and Toxics (OPPT). The total number of submissions recorded for each section was divided by the number of reporting years to estimate the average number of submissions each year.¹¹

Average Number of Pages Submitted

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

- **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

¹¹ The average number of submissions for section 4, section 8(a), and section 8(d) was calculated using the total number of submissions from 2006 to 2010, a five-year reporting period. The average number of NOCs submitted each year was calculated using the number of NOC submissions from 2008-2010 for PMNs received prior to April 2010.

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 form, 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 ICR (EPA, 2007c).

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 for each type of TSCA report divided by the number of reporting years.¹² The average annual number of submitters under each TSCA section is presented in Table 1.

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 1.

Table 1 presents the submission statistics for each TSCA section covered in this analysis.

TSCA Section	Average Number of Annual Submissions¹	Average Number of Pages Submitted	Average Number of Submitters	Average Number of Submissions per Submitter²
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 would 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 anymore. EPA estimated the total outstanding NOC submissions from PMNs submitted before April 2010 at 10,027 at the start date of this rule (May 2012). Therefore, EPA only expects to receive the average number of annual NOC submissions (364) for approximately 28 more years (10,027 total submissions divided by 364 annual submissions roughly equals 28 years).

² The average number of submissions per submitter is rounded to the nearest integer.

¹² The average number of submitters for section 4, section 8(a), and section 8(d) was calculated using the total number of submitters from 2006 to 2010, a five-year reporting period. The average number of NOC submitters was not available for the same time period; therefore, EPA used the average number of section 5 notice submitters from 2003 to 2007, based on the e-PMN rule (EPA, 2009).

6.6 Reasons for Change in Burden

This proposed rule ICR consolidates four existing ICRs: sections 4, 5, 8(a) PAIR, and 8(d). Therefore, EPA could not evaluate the change in burden for this electronic reporting rule. However, the Agency estimated a change in burden for each respective TSCA section. The estimated burden hours have decreased compared to previous ICRs. The estimated changes in annual industry burden for each section are presented in the table below.

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 the table below.

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

The estimated changes in burden from the previous ICRs are attributed to both adjustments and program changes. Adjustments capture updates to the number of respondents, wages, and costs in the absence of the proposed rule. Program changes reflect the proposed revisions to the reporting requirements. Changes in the paperwork burden attributed to the electronic reporting rule are 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 analysis. Besides this additional one-time burden, the electronic reporting rule results in overall burden reduction.

An estimated decrease in burden for all sections combined is 30,142 hours. The decrease of approximately 29,271 hours for section 4 is primarily due to the inclusion of the HPV Challenge Program in the previous section 4 ICR. This electronic reporting ICR has a much smaller reporting universe for section 4 because it did not include the HPV Challenge Program. Other reasons for burden changes include difference in the approaches, e.g., the previous ICRs did not include estimates for material burden (paper, postage, etc.).

Burden estimates for all other sections decreased primarily due to a smaller reporting universe and a lower reporting burden as a result of the electronic reporting. The reporting universe is based on the number of chemicals EPA adds annually to the reporting list for each section. The decrease in reporting burden is due to the development of electronic reporting, which eliminates the clerical/administrative reporting burden hours as well as decreases the recordkeeping burden.

This ICR also uses the most recent industry and agency wages from 2010, which tend to be higher compared to wages used in the previous ICRs. However, due to an overall burden reduction, the cost estimates for each section are lower compared to the previous ICRs.

6.7 Burden Statement

The annual public burden for the new collection of information related to one-time and recurring CDX activities under the Electronic Reporting Under the Toxic Substance Control Act rule is estimated to average about 505 hours per year.

According to the Paperwork Reduction Act, “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to review instructions; develop, acquire, install and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection appears above. The OMB control numbers for EPA’s regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

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 EPA West Building, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280. 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

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EPA Docket ID No. EPA-HQ-OPPT-2011-0519 and OMB control number 2070-NEW in any correspondence.

Appendix A

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 1: 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-14 Step 5 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, <i>Instructions for Preparing ICRs</i> (EPA, 1992).								

Exhibit 2: 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-14 Step 5 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, <i>Instructions for Preparing ICRs</i> (EPA, 1992).								

Exhibit 3: 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	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-14 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, <i>Instructions for ICRs</i> (EPA, 1992).								