August 31, 2015

1Supporting Statement for a Request for
OMB Review under the Paperwork Reduction Act

1 IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title and Number of the Information Collection

Title: Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies

EPA ICR No.: 0575.15 OMB Control No.: 2070-0004

1(b) Short Characterization

On September 2, 1982, EPA promulgated the final Toxic Substances Control Act (TSCA) (15 U.S.C. 2607(d); see Attachment 1 and http://www.epa.gov/lawsregs/laws/tsca.html) Section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716; see Attachment 2 and http://www.access.gpo.gov/nara/cfr/waisidx_03/40cfr716_03.html). The Model Rule was revised by amendments on September 15, 1986 (51 FR 32720) and April 1, 1998 (63 FR 15965). The Model Rule describes the requirements and procedures for submitting lists and copies of unpublished health and safety studies under section 8(d) of TSCA (40 CFR 716). It requires manufacturers and (if specified) processors to submit lists and copies of health and safety studies relating to the health and/or environmental effects of the chemical substances and mixtures listed in the TSCA section 8(d) rule. The listed chemical substances and mixtures include chemicals recommended for testing under section 4 by the Interagency Testing Committee (ITC) and other chemical substances that EPA (particularly the Office of Pollution Prevention and Toxics (OPPT)), or other federal agencies, wish to assess for health or environmental effects. EPA amends the TSCA section 8(d) rule periodically to add chemical substances and mixtures.

To comply with the reporting requirements of the rule, the respondents (manufacturers and processors) must search their files to identify any health and safety studies in their possession, copy and process the relevant studies, make lists of studies that are currently in progress, and review the studies for confidential business information.

All studies submitted to EPA will be verified and the contents of the submissions recorded and inspected for the inclusion of confidential business information. Copies of the documents will then be prepared and distributed, based on the associated chemical identity, to program offices at EPA and/or to other federal agencies for scientific analysis. A coding form will be completed to capture certain descriptive information such as identity, document control number, confidentiality indicator, document title, document date, receipt date and chemical identity. The document will be stored electronically for archival purposes. EPA will use the studies to support its investigation of the risks posed by listed chemicals and, in particular, to support its decisions on whether to require industry to test chemicals under section 4 of TSCA.

The total economic burden imposed by TSCA section 8(d) on the regulated community is estimated at 1,605 hours with an associated cost of $116,551 (119 respondents). The total estimated respondent burden is based on a rate of chemical additions of 70 chemicals per year.

2 NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

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.

2(b) Use/Users of the Data

Studies submitted pursuant to TSCA section 8(d) rules will be evaluated in conjunction with other available data. EPA and other federal agencies will use the data to construct a complete picture of the known effects of the chemical substance. From this picture, OPPT will be able to determine what kinds of testing, if any, are needed. The TSCA section 8(d) studies will ensure that OPPT bases its testing decisions on the most complete information available and does not require testing that may have already been done.

In addition, EPA will require that copies of health and safety studies be submitted on other chemicals that are under investigation either in the early stages of risk assessment or when action to control exposure is being considered by EPA or another federal agency. These chemicals may be ones for which persons have submitted substantial risk notification under TSCA section 8(e), or other chemicals for which data are needed to support a control measure under sections 5 and 6 of TSCA or under other EPA-administered statutes. If this information collection did not exist, 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 TSCA sections 5 and 6.

In the past, the following offices have also utilized submitted studies: the Office of Air and Radiation (OAR) for developing Tier II analyses; the Office of Research and Development (ORD) for developing extended risk assessments; the Consumer Product Safety Commission (CPSC) for assessing the hazards of known consumer exposure; the American Council for Government Industrial Hygienists (ACGIH); and the National Institute for Occupational Safety and Health (NIOSH) for developing recommended occupational exposure levels.

3 NON-DUPLICATION, CONSULTATIONS AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

In drafting a TSCA section 8(d) rule, EPA considers all available information, i.e., published and unpublished literature, databases, and all data available from EPA programs and offices and other federal entities. If existing data are sufficient for assessment or control purposes, EPA will not require TSCA section 8(d) reporting. However, if that information is not sufficient, or is obtained in a way that makes EPA doubt its validity, then the Agency must require the submission of non-published health and

safety studies.

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 Rule 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 respondents previously have submitted on a non-confidential basis to other EPA offices or programs need only be listed.

3(b) Public Notice Required Prior to ICR Submission to OMB

11 In proposing to renew this ICR, EPA provided a 60-day public notice and comment period that ended on May 29, 2015 (80 FR 16672, March 30, 2015). EPA received no comments during the comment period.

3(c) Consultations

Under 5 CFR 1320.8(d)(1), OMB requires agencies to consult with potential ICR respondents and data users about specific aspects of ICRs before submitting an ICR to OMB for review and approval. In accordance with this regulation, EPA submitted questions to nine parties via e-mail. The individuals contacted were:

Scott Jensen
American Chemistry Council
Scott_Jensen@AmericanChemistry.com

Jenny Gaines
Specialty Chemical Manufacturing Association
gainesj@socma.com

Dan Turner
E. I. du Pont de Nemours and Company
Daniel.a.Turner@dupont.com

Eric Wohlschlegel
American Petroleum Institute
wohlschlegele@api.org

Melissa Scanlan
Environmental Law Center, Vermont Law School
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Stacy Cooks
Asthma & Allergy Foundation of America
stacy@aafa.org

Sharyn Stein
Environmental Defense Fund

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Ken Cook
Environmental Working Group
ken@ewg.org

David Goldston
Natural Resources Defense Council
eheyd@nrdc.org

EPA received no responses to its solicitation for consultations. A copy of EPA's consultation e-mail to the above potential respondents is included in Attachment 3.

3(d) Effects of Less Frequent Collection

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(e) General Guidelines

This information collection activity is necessary to implement the statutory requirements of section 8(d) of TSCA and is consistent with the requirements of the PRA, OMB implementing regulations (5 CFR 1320.6), and OMB Guidance.

3(f) Confidentiality

Under the TSCA section 8(d) rule, a person submitting a health and safety study may claim certain parts of the study confidential. EPA has implemented procedures to protect confidential, trade secret and proprietary information from disclosure. These procedures comply with EPA's confidentiality regulation, 40 CFR Part 2, Subpart B.

3(g) Sensitive Questions

This section is not applicable. The information requested is not sensitive in nature.

4 THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

4(a) Agency Activities

The activities routinely conducted by EPA related to the rule development, processing, analysis and storage of the information collected under this rule include the following:

1. Review and select chemicals;
2. Develop and issue an amendment to the TSCA section 8(d) rule to add the substances or mixtures;
3. Answer respondents' questions;
4. Process and analyze rule submissions, including requests for confidentiality; and
5. Maintain and distribute the data.

4(b) Collection Methodology and Management

EPA's current collection methodology and information management system is based on the current requirements in 40 CFR 716.30 and 716.35 for the submission of electronic copies, which was implemented by a rule published in the Federal Register on December 4, 2013 (78 FR 72818).

To aid persons subject to this information collection, OPPT has set up a TSCA Hotline that provides information regarding TSCA section 8(d) reporting as well as other regulatory information. When Hotline staff are unable to answer questions regarding TSCA section 8(d), the questions are referred to OPPT staff for appropriate resolution.

All Non-Confidential Business Information submitted under TSCA section 8(d) is placed in the OPPT public docket, indexed and available for public inspection. A vast majority of TSCA section 8(d) submissions to date are reflected in the TSCA Test Submissions (TSCATS) database, a publicly available and searchable database.

4(c) Small Entity Flexibility

The TSCA section 8(d) rule applies to all manufacturers and processors of chemicals and others in possession of studies, regardless of size. However, EPA does not anticipate that many small businesses possess health and safety studies because they are unlikely to have the financial resources to perform the studies on chemicals subject to the rule. Therefore, the burden on such companies should be minimal.

4(d) Collection Schedule

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 ITC's 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 THE RESPONDENTS AND THE INFORMATION REQUESTED

5(a) Respondents/NAICS Codes

Respondents affected by this collection activity are identified mainly by North American Industry Classification System (NAICS) codes 325 (chemical manufacturing and allied products) and 32411 (petroleum refiners).

5(b) Information Requested

(i) Data Items

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 substances or listed mixtures.

All submitted studies must be accompanied by a cover letter that contains the following data (40 CFR 716.30):

- Name,
- Job title,
- Address, and
- Telephone numbers of the submitting official.
- Name and address of the manufacturing or processing establishment on whose behalf the submission was made
- Identify any impurity or additive known to have been present in the substance or listed mixtures as studied, unless so noted in the study.
- Identify that the study is being submitted under Part 716.

Respondents may voluntarily choose to develop and submit robust summaries of the full toxicological study reports in conjunction with the submitted full study reports. The robust summaries should contain technical information to adequately describe the study and results, and should be written such that the information provided is sufficient to allow a technically qualified person to evaluate study results without needing to review an entire study report. Typically, a robust summary would include a description of the test substance, methods, results, conclusions, data quality description, and references associated with the full study.

List of studies shall include (40 CFR 716.35): (1) ongoing health and safety studies conducted by or initiated by them; (2) studies they know about but do not have copies of; and, (3) studies that have been sent to another federal agency with no claims of confidentiality.

For ongoing health and safety studies conducted by or initiated for the respondent, the list should include the following data:

- Beginning date of the study
- Purpose of the study

- Types of data to be collected
- Anticipated date of completion
- Name and address of the laboratory conducting the study

For studies known to the respondent but for which they do not possess copies, the list should include the following data:

- Name and address of a person known to them that possess a copy of the study.

For studies previously sent to a federal agency with no claims of confidentiality, the list should include the following data:

- Title of the study
- Name and address of the person to whom the study was sent
- Month and year in which the study was submitted

(ii) Respondent Activities

A representative respondent would engage in the following activities in order to produce the lists of studies and required data listed in section 5(b)(i) of this supporting statement:

1. Determine whether the firm may be required to report. If so, review the rule in more detail;
2. Conduct a corporate review to identify which firm sites must be searched to locate the appropriate health and safety studies;
3. Search the files at appropriate sites to locate relevant studies;
4. Compile and transcribe lists of studies being submitted, ongoing studies, newly initiated studies, studies known to exist but not known to be in the respondent's possession, and studies previously submitted to other federal agencies without confidentiality claims;
5. Photocopy the studies;
6. Voluntarily prepare robust summaries of the studies;
7. Review the responses for possible confidential business information; and
8. After initial study submissions, notify EPA when other studies are initiated; submit studies completed after the reporting period.

6 ESTIMATING THE COST AND BURDEN OF THE COLLECTION

The methodology used for estimating the burden and costs to industry resulting from the addition of chemicals to the TSCA section 8(d) rule over the next three years is derived from the previous information collection request (ICR). EPA has added chemicals to the TSCA section 8(d) list on an episodic basis. As shown in Table 1, chemicals have been added to the list three times since 1996, yielding an average of 15 chemicals per year for the years between 1996 and the present. EPA uses a basis of 70 chemicals per year for the 2015-2018 ICR period, using information from the 2006

rulemaking, which added 208 new chemicals (averaging 69 chemicals per year during the 2006-2009 ICR period).

Table 1. Number of Chemicals Added to the TSCA Section 8(d) Reporting List.

Year	1996	1997-2003	2004	2005	2006*	2007-2014	Average/ Year
Number of Chemicals	47	0	15	0	208	0	15

* EPA issued a TSCA section 8(d) rule (71 FR 47130) on August 16, 2006 for 243 HPV chemicals that were not sponsored in the voluntary portion of the HPV Challenge Program. EPA later withdrew 33 of these chemicals in a final rule issued on September 29, 2006 (71 FR 57439). In a subsequent direct final rule issued on April 30, 2007, EPA removed two additional chemicals (72 FR 21119), resulting in a total of 208 chemicals subject to Section 8(d) reporting.

Moreover, to characterize the reporting implications per chemical addition associated with Section 8(d) reporting (including information from the 10-year period prior to the 2006 TSCA section 8(d) rule), this analysis uses TSCA IUR data from the 1998, 2002, and 2006 reporting cycles.[1] Table 2 summarizes the models and bases, as applied to the 2015-2018 ICR Renewal.

Table 2: Reporting Implications per Chemical Added

Generic Model	ICR 2009-12 Model Sources*	ICR 2009-2012 Detailed Model	ICR 2012-15 Model Sources	BASIS ICR 2015-2018
Number of firms potentially impacted per chemical	TSCA IUR data, all manufacturers 1998, 2002, 2006: 344 firms associated with 208 chemicals	$\frac{344\ firms}{208\ chemicals} = 1.7$	same	1.7
Sites per firm	TSCA IUR data, all manufacturers 1998, 2002, 2006: 344 firms associated with 208 chemicals; Sites per firm	$\frac{sites}{firm} = 1.5$	same	1.5
Fraction of firms potentially affected who submit reports of studies	TSCA IUR data, all manufacturers 1998, 2002, 2006: 59 firms submitted 527 studies associated with 208 chemicals	$\frac{59\ firms\ submitting\ reports}{344\ firms} = .17$	same	0.17

[1] According to 40 CFR 716.5, persons are required to report under a TSCA section 8(d) rule if, during the 10 years preceding the effective date of the rule, they manufactured (including imported) or planned to manufacture (including import) a listed chemical. The IUR data for this analysis is not limited to reporting from chemical manufacturers and petroleum refiners. This scope does not affect the accuracy of the results, given that only firms regulated under TSCA 8(d) submit reports.

Number of studies per firm	TSCA IUR data, all manufacturers 1998, 2002, 2006: 59 firms submitted 527 studies associated with 208 chemicals	$\frac{527\ studies}{59\ firms} = 9$	same	9
Average length of study, pages	TSCA IUR data, all manufacturers 1998, 2002, 2006: 59 firms submitted 527 studies associated with 208 chemicals	20	same	20
Percent studies with robust summaries; number of firms affected	10% of total studies	10% of reports	same	1 Robust Summary per Firm
Percent of affected firms submitting second responses	5% of affected firms	5%	same	5%

6(a) Estimating Respondent Burden

Firms will undertake a number of actions in response to a TSCA section 8(d) listing and the unit burden associated with each of these tasks is discussed in detail below.

Review the Rule. Firms in the relevant industries that may have unpublished health and safety studies will have to determine whether they manufacture a listed chemical and may thus be required to report. If so, they will have to review the rule in detail to understand its requirements, such as the types of health and safety studies EPA is asking for, the grade or purity of the test material, and the timeframe of the reporting period.

Note that, unless EPA specifies otherwise, the coverage of 8(d) rules is limited to chemical manufacturers and petroleum refineries. Most firms in these industries will not manufacture a listed chemical, and many will spend a de minimis amount of time making that determination. Those firms that manufacture a listed chemical must review the rule to understand its specific requirements. This is estimated to take an average of 2 hours of managerial time for each firm manufacturing a listed chemical.

Conduct Corporate Review for Site Identification. Firms that manufacture a listed chemical will need to conduct a corporate review to identify which of the firm's sites must be searched for appropriate health and safety studies. This corporate review is estimated to require an average of 3 managerial hours per firm.

Conduct Site File Search. Firms that manufacture a listed chemical must search the files at appropriate sites to look for studies that are responsive to the TSCA section 8(d) rule. It is estimated that the search will take an average of 3 hours of technical time per site. EPA estimates that each firm will have an average of 1.5 sites manufacturing a listed chemical. This yields an average burden of 4.5 technical hours per firm for site file searching (3 hours per site * 1.5 sites per firm).

Provide Study Title Lists. Respondents are required to submit lists containing the titles of any studies being submitted, titles of studies that are initiated or ongoing during the reporting period but that have not yet been completed, titles of any unpublished studies that the respondent knows to exist but does not have in its possession, and titles of studies previously submitted to other federal agencies without confidentiality claims. Prior to electronic reporting, an average of 1 hour of clerical time per firm was estimated to be dedicated to transcribing the list of study titles. EPA expects that the major burden of compiling this list was incurred during the file search and would already be available in electronic format; therefore, there is no additional burden associated with this activity.

Prepare Robust Summaries. Respondents may choose to develop and submit robust summaries of the full toxicological study reports. The robust summaries should contain technical information to adequately describe the study and results, and should be written in such a way that the information provided is sufficient to allow a technically qualified person to evaluate study results without needing to review an entire study report. Typically, a robust summary would include a description of the test substance, methods, results, conclusions, data quality description, and references associated with the full study. It is estimated that 8 to 16 hours of technical time are needed to develop and review a robust summary, depending on the type of study conducted. This ICR assumes an average of 12 hours of technical time to prepare a robust summary. Because submission of robust summaries is voluntary, EPA does not expect that many companies will undertake this activity. EPA estimates that each firm will submit an average of 9 studies, with 10% of those studies including a robust summary; therefore, EPA expects to receive an average of 0.9 robust summaries per firm submitting studies, which we round up to 1 robust summary per firm submitting studies. The estimated average burden per robust summary is 12 hours of technical time.

Review Responses for Confidential Business Information (CBI). Firms will need to review responses for possible CBI and delete any material that is considered by the firm to be CBI from one copy of the study. A separate copy of the study must be submitted without deletions of CBI. CBI review is estimated to take an average of 1 hour of managerial time for each study. Since each of the 20 firms is submitting an average of 9 studies, CBI review results in an estimated average of 9 hours of managerial time per firm.

Post-Reporting Period: Submit Ongoing or Newly-Initiated Studies. Firms that have an ongoing or newly-initiated study during the reporting period are required to provide EPA with a copy of the study once it is completed. CBI review and submission of ongoing or newly-initiated studies are estimated to require an average of 1 hour of managerial time.

Table 3. Unit Burden for TSCA Section 8(d) Reporting

Collection Activity	Affected Respondents (Weight)*	Average Burden per Firm (Hours)	Labor Category
1. Review of Rule	1.000	2	Managerial
2. Site Identification	1.000	3	Managerial
3. Site File Search**	1.000	4.5	Technical
4. Robust Summaries	0.008	12	Technical
5. CBI Review	0.168	9	Managerial

6. Post-Reporting Period Submission	0.008	1	Managerial
*Not all respondents perform all activities. This weight reflects that for every firm that has to check for reports: 17% will submit reports, of which 1 firm (about 5%) will provide robust summaries and 5% (about 1 firm) will provide a second response. ** Basis of 1.5 sites per firm			

These unit burden estimates are average values. Large multi-divisional, multi-departmental firms may require more than the average time to comply. However, there are smaller firms that are less complicated, and these firms may have a simpler process that requires less time.

6(b) Estimating the Respondent Universe

The number of chemicals added to the section 8(d) list has varied significantly from year to year and has been zero in many years. EPA has added a total of 270 chemicals to the list since 1996 (47 in 1996, 15 in 2004, and 208 in 2006), which is an overall program historical average of approximately 15 chemicals per year. For estimates in this ICR, EPA assumes that an average of 70 chemicals per year will be added to the section 8(d) list from 2015 to 2018, for a total of 210 chemicals over the three-year ICR period. Assuming that each chemical that is added to the list impacts 1.7 firms, then EPA expects 119 chemical manufacturing firms to be affected per year by this ICR.

Based on the reporting bases stated on Table 2, EPA assumes that 17% percent of the potentially affected manufacturers will submit studies each year, yielding 20 firms submitting studies (0.17 * 119 manufacturers). Each submitting firm is expected to submit a total of 9 studies, yielding an estimated total of 180 studies annually (20 firms * 9 studies per firm). A total of 10% of the studies are expected to contain robust summaries, yielding a total of 1 robust summary per firm (9 studies * 0.10, and rounding up to 1); and 1 firm (5% of 20 firms) is estimated to submit a second response (for a newly initiated or ongoing study) after the reporting period ends.

The number of firms estimated to engage in the various reporting activities is summarized in Table 4. Note that not all respondents incur every aspect of reporting burden. For this analysis, the conditions of the 2006 rule and its reporting implications, along with the condition of 70 chemical additions per year, are assumed.

Table 4: Number of Firms Affected per Year, by Activity (70 Chemicals Added Per Year)

Collection Activity	No. of Firms
Review of Rule	119
Site Identification	119
Site File Search	119
Robust Summaries	20
CBI Review	20
Post-Reporting Period Submission	1

The number of firms or studies described above is combined with the estimated average unit

burden hours and wages from Tables 3 and 5 to estimate the total burden hours and cost per year based on three types of response activities: searching files, submitting studies during the reporting period, and submitting studies after the reporting period. The results are shown in Table 6.

6(c) Estimating Respondent Cost

Unit labor costs are calculated by adding fringe benefits and overhead to the wage or salary to derive a fully loaded labor cost. Costs are calculated for managerial, professional/ technical, and clerical workers. Wages and fringe benefits for managerial, professional/ technical, and clerical labor are taken from the Bureau of Labor Statistics (BLS) *Employer Costs for Employee Compensation* (ECEC) manufacturing industry data from 2013. The cost of fringe benefits such as paid leave and insurance are taken from the same ECEC series for each labor category. Fringe benefits as a percent of wages are calculated separately for each labor category. Table 5 presents these results with fully loaded rates for managerial labor at $77.77/hour; for technical labor at $67.59/hour; and for clerical labor at $30.35/hour.

Table 5: Loaded Industry Wage Rates (December 2013)

EPAB Labor Category	Data Sources [d]	Date	Wage	Fringe Benefit	Fringes as % wage	Overhead % wage [b]	Fringe + overhead factor [c]	Loaded Wages [a]
			(A)	(B)	(C) = (B) / (A)	(D)	(E) = (C)+(D) +1	(F) = (A)*(E)
Managerial	BLS *ECEC,* **Private Manufacturing Industries,** "Mgmt., Business and Financial"	Dec. 2013	$46.21	$23.70	51.29%	17%	1.68	$77.77
Professional/ Technical	BLS *ECEC,* **Private Manufacturing Industries,** "Professional and Related"	Dec. 2013	$39.70	$21.14	53.25%	17%	1.70	$67.59
Clerical	BLS *ECEC,* **Private Manufacturing Industries,** "Office and Administrative Support"	Dec. 2013	$18.05	$9.23	51.14%	17%	1.68	$30.35

Notes:
[a] Wage data were rounded to the closest cent in this table; however in calculations using these numbers for this report, unrounded values were used.
[b] An overhead rate of 17% was used based on assumptions in *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* (Rice, 2002) and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPAB, 2002)
[c] An inflation factor of "1" means wage data were not escalated to reflect inflation.
[d] Source: *Employer Costs for Employee Compensation Supplementary Tables: December 2006-March 2014,* U.S. Bureau of Labor Statistics, September 10, 2014 (pp 31, 33, 37) (http://bls.gov/ncs/ect/sp/ecsuphst.pdf, accessed October 23, 2014)

6(d) Estimating Reporting Burden and Costs

Table 6. Annual Respondent Cost and Burden Hour Estimates

Information Collections	Response Activities	Burden per Response (Hours)	Labor Category	Cost per Response	Number of Responses	Total Burden (Hours)	Total Cost
Compliance determination and data search	Rule review, site identification and site file search	9.5	Managerial/ Technical	$693	119	1,131	$82,468
Submission of health and safety studies during the reporting period	Robust summaries and CBI review	21.0	Managerial/ Technical	$1,511	20	420	$30,220
Notification and submission of health and safety studies initiated and/or completed after the reporting period	Post-reporting period submission	1.0	Managerial	$78	1	1	$78
Total					**140**	**1,552**	**$112,766**

A typical firm submitting a response is conservatively estimated to engage in review of the rule, site identification, site file search, preparing study title lists, CBI review, and possibly submit a robust summary and/or a post-reporting period submission. Assuming that 70 chemicals per year are added to the TSCA section 8(d) list and that reporting is similar to the 2006 experience, the average annual burden and cost per response is 31.5 hours and $2,282, respectively.

Additionally, in late 2012, EPA promulgated a direct final rule requiring the submission of unpublished health and safety data by manufacturers and importers of cadmium and cadmium compounds. As a result, the number of responses (1,384 responses) and burden hours (7,019 hours) for this rule were included in the OMB action notice for the most recent renewal of this information collection. Likewise, the respondent and burden hour totals were included in the OMB inventory for this information collection. However, subsequent to the publication of the direct final rule, and subsequent to OMB's most recent approval of the TSCA sec. 8(d) information collection, EPA withdrew the cadmium reporting rule. Consequently, EPA has eliminated from the current request for OMB approval of this information collection a total of 1,384 responses and 7,019 burden hours to reflect the withdrawal of the cadmium reporting rule. These values do not otherwise appear in any of the tables included in this section.

6(e) CDX Registration Activities to Enable Electronic Reporting

EPA estimates that respondents will incur a small amount of additional burden and costs in carrying out the additional paperwork activities that were imposed by the *Electronic Reporting under the Substances Control Act (TSCA) Final Rule*. This includes the burden associated with activities that facilitate submission of an electronic report: CDX registration and CDX electronic signature. These activities occur only once for each submitter. Some submitters may already have registered to use the e-TSCAweb reporting tool in CDX (and obtained an accompanying electronic signature) in order to comply with the mandatory electronic reporting requirements of EPA's e-PMN rule and/or IUR/CDR

rule. Those submitters will not need to repeat the CDX registration and e-signature process in order to file their health and safety studies. While there may be some overlap in the specific individuals already that have already completed CDX activities, EPA is using a conservative assumption that all submitters who will file electronically will need to register with CDX and, thus, incur associated burdens. This assumption may overestimate the burdens and costs actually experienced by respondents.

The *one-time* CDX burden includes the following:

CDX Registration – Based on the CROMERR Cost Benefit Analysis, EPA assumed that companies would spend 11 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 firm.

CDX electronic signature (labor burden) – Based on the CROMERR Cost Benefit Analysis, EPA assumed that firms 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 firm would incur this burden, totaling 75 minutes of burden per company. In addition, EPA estimates 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 firms 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.

Table 7. Estimated Burden Associated with New CDX Registration Activities

Information Collection	Estimated Number of Annual Respondents	Number of Responses/ Respondent	Estimated Burden Hours and Cost per Response				Estimated Burden Hours /Year	Estimated Labor Cost /Year
			Managerial		Technical			
			Hours	Wage Rate	Hours	Wage Rate		
CDX Registration & E-signature	20	1	0.93	$77.77	1.73	$67.59	*53.2*	$3,785

Non-labor costs include a $0.44 stamp and a $0.02 standard business envelope for each of five required electronic signature agreements. The total non-labor cost for electronic signature agreements equals $2.30. This amounts to $46 in non-labor costs per year.

Conservatively assuming that all 20 firms submitting studies will need to register with CDX, the average burden and cost per CDX registration is 2.66 hours and $189.25, respectively.

6(f) Estimating Agency Cost

The activities routinely conducted by EPA related to processing and storage of the information collected under this rule include processing and analyzing the materials submitted under the rule, including requests for confidentiality; and maintaining and distributing data.

The activities associated with Agency responses to TSCA section 8(d) listings are assumed to be accomplished by a GS 13, Step 5 federal employee. The 2014 hourly wage rate for this level of employee in the Washington, D.C. locality is $48.83 per hour. Adding 60% for benefits and overhead

yields a loaded annual wage rate of $78.13 per hour.[2]

As a result of the *Electronic Reporting under the Substances Control Act (TSCA) Final Rule*, EPA expects that the Agency will have a burden savings due to the elimination of the need to process paper forms, and reduced quality assurance/quality control (QA/QC) and O&M costs for the existing system. Potential Agency burden savings associated with electronic reporting of TSCA section 8(d) health and safety studies were characterized based on information in the *CDX Business Case Analysis* regarding the estimated monetary benefit from using CDX. Of the six Program Data Flows studied in the CDX Business Case Analysis, monetary benefits from using CDX as compared to a paper submission baseline were quantified for two flows: TRI (Toxic Release Inventory) and e-NOI (electronic Notice of Intent under the National Pollution Discharge Elimination System). Benefits ranged from eleven percent savings (e-NOI) to 22 percent savings (TRI) compared to the cost of the baseline process. For this ICR, EPA assumed an average annual burden savings of 16.5 percent. This percentage savings results in a total annual burden of 3,542 hours for electronic submissions.

The estimated annual cost to the federal government for TSCA section 8(d) data collection totals $4,566.70, for 58.45 hours, as presented in Table 10.

Table 8. Agency Annual Cost Estimates

Collection Activity	FTEs	Hours	Annual Cost
Data processing and system support	0.025	41.75	$3,261.93
Storage and distribution	0.010	16.70	$1,304.77
TOTALS	**0.035**	**58.45**	**$4,566.70**

Source: OPM 2014 hourly rate table for the Washington-Baltimore-Northern Virginia Locality Pay Area, with 60% for benefits and overhead added.

6(g) Bottom Line Burden Hours and Cost

As shown in Table 6, if EPA adds 70 chemicals per year to the TSCA section 8(d) list during the time period covered by this ICR, burden associated with 8(d) review and reporting will be incurred by 119 firms. Note that not all these firms incur every aspect of reporting burden. Those firms that do ultimately submit studies incur a small amount of additional burden and cost associated with registering with CDX in order to comply with new electronic reporting requirements. The burden activities associated with CDX registration occur only once, during the first year of the ICR period.

The average annual reporting burden and cost per response is estimated at 11.1 hours and $805.47, respectively, with overall estimated annual totals of 1,552 burden hours and $112,766. Conservatively assuming that all firms submitting studies will need to complete a *one-time* CDX registration, the average annual burden and cost per CDX registration is 2.66 hours and $189.25, respectively. This yields an estimated annual burden and cost per response for CDX-related activities of

[2] The EPA wage rate is calculated based on the GS-13 Step 5 wage rate for calendar 2014, from the Office of Personnel Management salary and wage tables for Washington-Baltimore-Northern Virginia. The 60% fringes-and-overhead rate is from *ICR Handbook: EPA's Guide to Writing Information Collection Requests under the Paperwork Reduction Act of 1995.* (EPA Office of Environmental Information, 2005).

53.2 hours and $3,785.

As noted earlier, basing the future burden estimates on the reporting from the 2006 rule may overestimate reporting burden and cost if number and characteristics of the chemicals that are added to the TSCA section 8(d) list during the next three years are less burdensome than the 208 HPV chemicals that were added in 2006. Moreover, this ICR conservatively estimates that all submitters are new CDX registrants and will, therefore, need to incur the additional burden associated with registering with CDX and submitting an electronic signature agreement. EPA recognizes that some respondents may have already registered for CDX in order to comply with the mandatory electronic reporting requirements of other TSCA collection activities; those respondents would not need to register again and would avoid the associated burden and cost altogether.

The total annual respondent burden and cost for this collection (sum of Tables 6 and 7) is 1,605 hours and $116,551 respectively.

6(h) Reasons for Changes in Burden

There is a net decrease of 6,778 hours (from 8,383 to 1,605) in the total estimated respondent burden compared with that currently in the OMB inventory. This net decrease in burden is due to the following:

- The previous ICR incorrectly used a total of 1 robust summary per year as the total number of annual robust summary responses, yielding a total of 12 hours of annual burden. This ICR corrects this burden estimate by using a total of 20 robust summary responses per year, yielding a total annual reporting burden of 240 hours – an increase of 228 hours per year.

- This ICR renewal incorporates changes made to Health and Safety Data reporting under TSCA section 8(d) that mandate the use of electronic reporting in lieu of traditional paper-based reporting. The new electronic reporting requirements eliminated the clerical burden associated with transcribing study title lists and photocopying studies for paper-based submissions. This change resulted in a decrease of 40 hours to the average annual reporting burden. While electronic reporting serves to streamline and reduce the administrative/clerical costs and burdens associated with submitting paper-based health and safety studies, the burden savings were not sufficient to offset the new burden associated with CDX registration activities. However, it should be noted that these activities occur only once for each submitter and, since some respondents while most likely have already registered with CDX, this analysis conservatively overestimates the burden and costs actually experienced by respondents.

- The new electronic reporting mandate requires that submitters of health and safety data under TSCA section 8(d) register with CDX in order to submit studies electronically. The new annual burden associated with CDX registration activities is 53 hours.

- Finally, EPA has reduced the burden estimate by 7,019 hours to reflect the 2012 withdrawal of the cadmium reporting rule as noted above in section 6(d).

6(i) Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0004, is estimated to average about 10.0 hours per response. Burden is defined in 5

CFR 1320.3(b). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection appears above. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPPT-2014-0734, which is available for online viewing at www.regulations.gov, or in-person viewing at the Pollution Prevention and Toxics Docket in the EPA Docket Center (EPA/DC). The EPA/DC Public Reading Room is located in the West William Jefferson Clinton Bldg., Room 3334, 1301 Constitution Ave., N.W., Washington, DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280.

You may submit comments regarding the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden, including the use of automated collection techniques. Submit your comments, referencing Docket ID No. EPA-HQ-OPPT-2014-0734 and OMB Control No. 2070-0004, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: Pollution Prevention and Toxics Docket, Environmental Protection Agency Docket Center (EPA/DC), Mailcode: 28221T, 1200 Pennsylvania Ave., N.W., Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, N.W., Washington, DC 20503.

ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number **EPA-HQ-OPPT-2014-0734**. These attachments are available for online viewing at www.regulations.gov or otherwise accessed as described in section 6(f) of the supporting statement.

Attachment 1: **15 U.S.C. 2607(d) - Section 8(d) of the Toxic Substances Control Act.** Also available online at the U.S. House of Representatives' U.S. Code website

Attachment 2: **40 C.F.R. part 716 - Health and Safety Data Reporting**. Also available online at the National Archives and Records Administration's Electronic CFR website

Attachment 3: **Copy of Consultations Message Sent by EPA to Potential Respondents**