SUPPORTING STATEMENT for an
INFORMATION COLLECTION REQUEST (ICR)
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.: 0575.16
OMB Control No.: 2070-0004
EPA Form Nos.: None.
Docket ID No.: EPA-HQ-OPPT-2017-0646

1(b) Short Characterization

This ICR covers the information collection activities that implement the statutory mandates in section 8(d) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2607(d). Specifically, TSCA section 8(d) authorizes EPA to promulgate rules requiring certain persons who manufacture, process or distribute in commerce (or propose to manufacture, process or distribute in commerce) chemical substances and mixtures, to submit to EPA lists and copies of health and safety studies in their possession with respect to such chemical substances and mixtures. These rules, which are codified in 40 CFR part 716, require the manufacturers and processors of the chemical substances and mixtures subject to a TSCA section 8(d) rulemaking to submit lists and copies of health and safety studies relating to the health and/or environmental effects of the chemical substances and mixtures. To comply, respondents must search their records to identify any health and safety studies in their possession, copy and process relevant studies, list studies that are currently in progress, and submit this information to EPA.

The collection schedule under this ICR is chemical-specific in nature and occurs once in an established timeframe 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. Studies previously submitted to EPA are exempt.

EPA uses this information to construct a complete picture of the known effects of the chemical substance in question, leading to determinations by EPA of whether additional testing of the chemical substance should be required. The information enables EPA to base its testing decisions on the most complete information available and to avoid requiring testing that may be duplicative. EPA will use information obtained via this collection to support its investigation of the risks posed by the chemical substance and, in particular, to support its decisions on whether to require additional test data be submitted under TSCA section 4.

Responses to the collection of information are mandatory (see 40 CFR part 716). Respondents may claim all or part of a response confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

EPA amends the list of subject chemicals in 40 CFR part 716 periodically to add chemical

substances and mixtures. The listed chemical substances and mixtures include chemicals recommended for testing under TSCA 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, choose to assess for health or environmental effects.

All studies submitted to EPA will be verified and the contents of the submissions recorded and inspected for the inclusion of confidential business information (CBI). 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. In addition, EPA will make non-confidential versions of the health and safety studies available via its ChemView database (https://chemview.epa.gov/chemview). 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 paperwork burden imposed by TSCA section 8(d) on the regulated community is estimated at 302 hours. The total estimated respondent burden is based on a conservatively estimated rate of 13 chemical additions 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), authorizes EPA to promulgate rules requiring certain persons who manufacture, process or distribute in commerce, or propose to manufacture, process or distribute in commerce chemical substances and mixtures, to submit to EPA lists and copies of health and safety studies in their possession with respect to such chemical substances and mixtures (Attachment 1). EPA regulations implementing the statute are codified at 40 CFR Part 716 (Attachment 2). TSCA as amended by the Lautenberg Chemical Safety for the 21st Century Act requires EPA to develop a pipeline of chemicals for prioritization and risk evaluation. Information from section 8(d) health and safety studies could help to inform the Agency's prioritization and risk evaluation work, as well as determine whether additional information on hazard, health or environmental effects, or exposure of the listed chemicals exist is necessary to assess risks; and for considering control actions. Collection of unpublished health and safety studies can reduce the need for testing. Additionally, 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 as EPA assesses risks of existing chemicals. 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 information gaps, if any, exist and whether testing may be 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 unnecessary or duplicative testing, which is consistent with the requirements of TSCA section 4(h).

In addition, EPA may require that copies of unpublished health and safety studies be submitted

on chemicals that are being considered for prioritization under section 6 of TSCA or 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 a 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 available information on a chemical and evaluate the need for testing or data development under section 4 of TSCA or controlling chemical substances under TSCA sections 5 and 6.

In the past, EPA's Office of Air and Radiation (OAR) has used the submitted studies for developing Tier II analyses and the EPA's Office of Research and Development (ORD) has used the information for developing extended risk assessments. In addition, other organizations have utilized the submitted studies: 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 unpublished 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 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 September 24, 2018 (83 FR 35271, July 25, 2018) (FRL-9980-27). EPA received one comment during the comment period; from Brett Howard, Director of Chemical Management, American Chemistry Council. Copies of the public comment and of EPA's response to the public comment appear in Attachment 3.

3(c) Consultations

Additionally, 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 several interested parties via e-mail. The individuals contacted were:

Mike Walls, Vice President
Regulatory and Technical Affairs
American Chemistry Council Inc.
700 2nd Street N.E.
Washington, D.C. 20002

Matthew Moedritzer, Manager
Legal and Governmental Relations
Society of Chemical Manufacturers and Affiliates (SOCMA)
1400 Crystal Drive, Suite 630
Arlington, VA 22202

Steve Bennet, Vice President
Scientific Affairs
Household and Commercial Products Association
1667 K Street N.W., Suite 300
Washington, D.C. 20006

Derek Swick, Senior Policy Advisor
Regulatory and Scientific Affairs
American Petroleum Institute
1220 L Street N.W.
Washington, D.C. 20005-4070

Melissa Scanlan
Co-Founder and Director, New Economy Law Center
Professor of Law
Environmental Law Center, Vermont Law School
164 Chelsea St, PO Box 96
South Royalton, VT 05068

Stacy Cooks
Data Specialist
Asthma & Allergy Foundation of America
8201 Corporate Dr.
Landover, MD 20785

Sharyn Stein
Environmental Defense Fund
Media contact
1875 Connecticut Ave, NW
Washington, DC 20009

Ken Cook
President and Co-Founder
Environmental Working Group

500 Washington, St.
San Francisco, CA 94111

David Goldston
Director, Government Affairs
Natural Resources Defense Council
1152 15th Street, NW
Washington, DC 20005

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 4.

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 only once, the reporting frequency cannot be reduced. If the information requirement were less frequent, EPA would not be able to obtain the necessary information for evaluating the need for additional information under section 4 of TSCA or evaluating and 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

Submitters may designate information as confidential, trade secret, or proprietary. EPA has implemented procedures to protect any confidential, trade secret or proprietary information from disclosure. These procedures comply with TSCA section 14 and 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;
5. Maintain and distribute the data; and
6. Analyze submissions for confidentiality and analyze the information provided to substantiate the confidentiality claim.

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. TSCA section 8(d) submissions are also being made available through the ChemView database (see https://chemview.epa.gov/chemview), a publicly available and searchable database.

4(c) Small Entity Flexibility

The TSCA section 8(d) rule applies to all manufacturers and, when specified, 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 is expected to 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. Studies previously submitted to OPPT are exempt.

Amendments adding substances can be 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 can be 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 (which includes 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. 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 respondents; (2) studies respondents 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 or prepare electronic versions of the studies;
6. Voluntarily prepare robust summaries of the studies;
7. Review the responses for possible confidential business information and prepare information to substantiate a claim of confidentiality; and
8. Submit the studies to EPA electronically, and, 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 four times since 1996 yielding a historical average of 13 chemicals per year for the years between 1996 and the present. As such, EPA uses a basis of 13 chemical additions per year for the 2018-2021 ICR period.

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

Year	1996	1997-2003	2004	2005	2006*	2007	2008**	2009-2017	Average/Year
Number	47	0	15	0	208	0	12	0	13

of Chemicals									

* 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. (**) The TSCA Interagency Testing Committee added Lead and Lead Compounds to the Priority List as part of its 60th ITC Report. Based on this addition, EPA issued a final rule on January 20, 2008 (73 FR 5190) which added 12 Lead and Lead compounds to 40 CFR 716.120.

Moreover, to characterize the reporting implications per chemical addition associated with Section 8(d) reporting, this analysis uses TSCA Inventory Update Rule data from the 1998, 2002, and 2006 reporting cycles, and Chemical Data Reporting Rule data from the 2012 reporting cycle.[1] Table 2 summarizes the models and bases, as applied to the 2018-2021 ICR renewal.

Table 2: Reporting Implications per Chemical Added

Generic Model	ICR 2015-18 Model Sources	ICR 2015-2018 Detailed Model	ICR 2018-21 Model Sources	ICR 2018-2021 Detailed Model	BASIS ICR 2018-2021
Number of firms potentially impacted per chemical	TSCA IUR data, all manufacturers 1998, 2002, 2006: 344 firms associated with 208 chemicals	344 firms / 208 chemicals = 1.7	TSCA IUR/CDR data, all manufacturers 1998, 2002, 2006, 2012: 348 firms associated with 220 chemicals	348 firms / 220 chemicals	1.6
Sites per firm	TSCA IUR data, all manufacturers 1998, 2002, 2006: 344 firms associated with 208 chemicals; Sites per firm	Sites / firm = 1.5	TSCA IUR/CDR data, all manufacturers 1998, 2002, 2006, 2012: 348 firms associated with 220 chemicals; Sites per firm	Sites / firm = 1.5	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	59 firms submitting reports / 344 firms = 0.17	TSCA IUR/CDR data, all manufacturers 1998, 2002, 2006, 2012: 63 firms submitted 541 studies associated with 220 chemicals	63 firms submitting reports / 348 firms = 0.18	0.18
Number of studies per firm	TSCA IUR data, all manufacturers 1998, 2002, 2006: 59 firms submitted 527 studies associated with 208 chemicals	527 studies / 59 firms = 9	TSCA IUR/CDR data, all manufacturers 1998, 2002, 2006, 2012: 63 firms submitted 541 studies associated with 220 chemicals	542 studies / 63 firms = 9	9
Average length of study, pages	TSCA IUR data, all manufacturers 1998, 2002, 2006: 59 firms submitted 527 studies associated with 208 chemicals	20	TSCA IUR/CDR data, all manufacturers 1998, 2002, 2006, 2012: 63 firms submitted 541 studies associated with 220 chemicals	same	20
Percent studies with robust summaries; number of firms affected	10% of total studies	10% of reports	10% of total studies	10% of reports	1 Robust Summary per Firm

[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 CDR 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.

Percent of affected firms submitting second responses	5% of affected firms	5%	5% affected	5% affected	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 (including import) 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 section 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. 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. 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 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 21 firms is submitting an average of 9 studies, CBI review results in an estimated average of 9 hours of managerial time per firm.

CBI Legal Review and Confidential Business Substantiation. Firms will need to gather and prepare information to substantiate a claim for confidentiality. This will also involve approximately 1.5 hours of managerial and attorney time.

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. CBI Legal Review and CBI Substantiation	0.168	0.75	Managerial
	0.168	0.75	Attorney
7. 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: 18% 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 for many years. EPA has added a total of 282 chemicals to the list since 1996 (47 in 1996, 15 in 2004, 208 in 2006, and 12 in 2008), which is an overall program historical average of approximately 13 chemicals per year. For estimates in this ICR, EPA assumes that the historical average of 13 chemicals per year will be added to the section 8(d) list from 2018 to 2021, for a total of 39

chemicals over the three-year ICR period. Assuming that each chemical that is added to the list impacts 1.6 firms, then EPA expects 21 chemical manufacturing firms to be affected per year by this ICR.

Based on the reporting bases stated on Table 2, EPA assumes that 18% percent of the potentially affected manufacturers will submit studies each year, yielding 4 firms submitting studies (0.18 * 21 manufacturers). Each submitting firm is expected to submit a total of 9 studies, yielding an estimated total of 36 studies annually (4 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 approximately 1 firm (5% of 4 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 and 2008 section 8(d) rules and their reporting implications, along with the condition of 13 chemical additions per year, are assumed.

Table 4: Number of Firms Affected per Year, by Activity (13 Chemicals Added Per Year)

Collection Activity	No. of Firms
Review of Rule	21
Site Identification	21
Site File Search	21
Robust Summaries	4
CBI Review	1
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 2016. 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 attorney labor at $116.15, managerial labor at $83.15/hour; for technical labor at $78.08/hour; and for clerical labor at $34.29/hour.

Table 5: Loaded Hourly Wage Rates by Labor Category in 2016$

Labor Category	Wage	Fringe Benefits	Fringes as % of Wage	Overhead % of Wage[3]	Fringe + Overhead Factor	Loaded Wages
	(a)	(b)	(c) = (b)/(a)	(d)	(e)=(1)+(c)+(d)	(f) = (a) x (e)
Attorney[1]	$69.97	$34.40	49.17%	17%	1.66	**$116.15**
Managerial[2]	$50.09	$24.63	49.17%	17%	1.66	**$83.15**
Technical[2]	$45.66	$24.98	54.70%	17%	1.71	**$78.08**
Clerical[2]	$20.29	$10.52	51.848%	17%	1.69	**$34.29**

Sources: [1] BLS Occupational Employment Statistics (OES) May 2016 National Industry-Specific Occupational Employment and Wage Estimates (BLS, 2016b) [2]Employer Costs for Employee Compensation Supplementary Tables: December 2006-December 2016, US Bureau of Labor Statistics (BLS, 2016a)
[3]An overhead rate of 17 percent was estimated based on industry data gathered for the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002a) and *Wage Rates for Economic Analyses of the Toxics Release Inventory Program*. (EPA, 2002b)

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	2	Managerial ($83.5)	$769	21	200	$16,149
	Site Identification	3	Managerial ($83.5)				
	Site File Search	4.5	Technical ($78.08)				
Submission of health and safety studies during the reporting period and CBI Substantiation	Robust summaries	12	Technical ($78.08)	$1,838	4	90	$7,352
	CBI Review	9	Management ($83.5)				
	CBI Legal Review and CBI Substantiation	0.75	Managerial ($83.5)				
		0.75	Attorney ($116.15)				
Notification and submission of health and safety studies initiated and/or completed after the reporting period	Post-reporting period submission	1.0	Managerial	$83.5	1	1	$83.5
Total					**26**	**291**	**$23,584**

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, CBI substantiation, and possibly submit a robust summary and/or a post-reporting period submission. Assuming that 13 chemicals per year are added to the TSCA section 8(d) list and that reporting is similar to the 2006 and 2008 section 8(d) reporting experiences, but considering that the CBI substantiation has been added, the average annual burden and cost per response is 11 hours and $907, respectively.

6(e) CDX Registration Activities to Enable Electronic Reporting

EPA estimates that respondents will incur a small amount of cost 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-TSCA web 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 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	4	1	0.93	$83.15	1.73	$78.08	11	$851

Non-labor costs include a $0.49- stamp and a $0.03 standard business envelope for each of five required electronic signature agreements. The total non-labor cost for electronic signature agreements equals $2.60. This amounts to $10.40 in non-labor costs per year.

Conservatively assuming that all 4 firms submitting studies will need to register with CDX, the average burden and cost per CDX registration is 2.75 hours and $212.75, 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 2017 hourly wage rate for this level of employee in the Washington, D.C. locality is $51.48 per hour. Adding 60% for benefits and overhead yields a loaded annual wage rate of $82.36 per hour.[2]

The estimated annual cost to the federal government for TSCA section 8(d) data collection totals $4,813.94 for 58.45 hours, as presented in Table 8.

Table 8. Agency Annual Cost Estimates

Collection Activity	FTEs	Hours	Annual Cost
Data processing and system support	0.025	41.75	$3,438.53
Storage and distribution	0.010	16.70	$1,375.41
TOTALS	**0.035**	**58.45**	**$4,813.94**
Source: OPM 2017 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 13 chemicals per year to the TSCA section 8(d) list during the time period covered by this ICR, burden associated with section 8(d) review and reporting will be incurred by 4 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 hours and $907, respectively, with overall estimated annual totals of 291 burden hours and $23,584. 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 2.75 hours and $212.75, respectively. This yields an estimated annual burden and cost per response for CDX-related activities of 11 hours and $851.

As noted earlier, basing the future burden estimates on the reporting from the 2006 and 2008 section 8(d) rules 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 chemicals that were added in 2006 and 2008.

The total annual respondent burden and cost for this collection (sum of Tables 6 and 7) is 302

[2] The EPA wage rate is calculated based on the GS-13 Step 5 wage rate for calendar 2017, 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).

hours and $24,435 respectively.

6(h) Reasons for Changes in Burden

Although CBI substantiation has added 31.5 burden hours per year to the total estimated burden, there is an overall net decrease of 1,303 hours (from 1,605 to 302) in the total estimated respondent burden compared with that currently in the OMB inventory. This net decrease in burden is due to the following:

- This ICR assumes that a historical average (from 1996 to present) of 13 chemicals will be added to the section 8(d) list over the next three years.
- The previous ICR based the average number of chemicals to be added to the section 8(d) list on the period from 2006 – 2015. In 2006, 208 chemicals were added to the list, the largest addition since 1996.
- The final section 8(d) rule issued on January 20, 2008 (73 FR 5190) added 12 Lead and Lead Compounds to 40 CFR 716 120 was included in this ICR.
- The number of chemicals added to the section 8(d) list has been zero since early 2008.
- The methodology used in the previous ICR overestimated the burden resulting from the addition of chemicals to the TSCA section 8(d) rule.

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 11 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-2017-0646 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-2017-0646 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-2017-0646** 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: **Response to Comments Memo.**

Attachment 4: **Consultations Correspondence.**